21st Annual Indy Hematology Review™

Saturday, February 24th 2024

JOURNAL OF INDY HEMATOLOGY REVIEW 2024

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Photography

Photos of attendees will be taken throughout the Symposium. These photos are for Indy Hematology Review and Indy Hematology Education, Inc.'s use only and may appear on the IHR website, in promotional brochures, or other future promotional material. By virtue of your attendance, you agree to the usage of your photograph in such media, unless we are notified in writing along with a clear photo to identify yourself.

Presentation Slides

Faculty Presentation slides (as permitted by each faculty member) are available at www.indyhematologyreview.com/2024-presentations

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CHAIRMAN'S LETTER

THE MEANING OF LIFE: What is our purpose?

The meaning of life and the questions of human purpose are as ancient as the Great Pyramids, and perhaps they are even as old as when we lived in caves and found happiness hunting and gathering. Yet, finding this purpose is central to our being.

Are we meant to find success through great educational and professional accomplishments? Gather and produce great wealth, not wanting for anything? Be respected and celebrated for our publications, attainments, and standing in the community of men and women with beautiful garlands worn around our vestments with unending pride?

Perhaps having a beautiful spouse desired by many, attired in the most fashionable clothing labeled and sealed by celebrated designers, inebriated with the finest of beverages with our loosened tongues and spirits and accompanied with similarly desirable, impeccably engineered automobiles. Would all this produce a sense of purpose in life?

Alas, do we achieve happiness, and is our life most fulfilled when all our wants and desires are satisfied? Yes, this must be the meaning of life. But no, it cannot be just that. This merely describes contentment, which is defined by the Oxford American English dictionary as "a state of happiness and satisfaction."

For the physicians amongst us, what is our purpose? We all willingly swore to the Hippocratic oath while attired in our first white vestments and proudly stating, "I will remember that I remain a member of society, with special obligations to all my fellow human beings, those sound of mind and body as well as the infirm."

The Abrahamic religions do provide additional context on our purpose with the commandment "love your neighbor as thy self" which is also central to eastern religious teachings.

African religious teachings and proverbs are partly based on the communal normative philosophy, known as communalism. Simply put, communalism focuses on engaging harmoniously with others and achieving one's purpose through this. Thus, the Ubuntu mantra "… A person is a person through other persons…"

> **Our meaning and purpose can be achieved when our lives are centered on uplifting our community, ensuring that we are our neighbors' keepers and purposefully equipping ourselves to provide for the betterment of our fellow human beings.**

Our meaning and purpose can be achieved when our lives are centered on uplifting our community, ensuring that we are our neighbors' keepers and purposefully equipping ourselves to provide for the betterment of our fellow human beings.

Accordingly, as health care providers addressing social determinants of health ensures that our treatments are aimed with the intention to heal and promote health with dignity for all persons in our care. Social

determinants of health (SDOH) are defined by the United States Department of Health and Human Services (DHHS) as the conditions in the environments where people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks.

SDOH can be grouped into five domains:

- Economic Stability
- Education Access and Quality
- Health Care Access and Quality
- Neighborhood and Built Environment
- Social and Community Context

In recognition of this goal, DHHS created Healthy People 2030. Addressing the elements of SDOH in our patients ensures that we are promoting healthy communities and keeping with the stated goals of the Healthy People 2030 program (https://health.gov/healthypeople). This program has five overarching goals specifically related to SDOH: “Create social, physical, and economic environments that promote attaining the full potential for health and well-being for all.” The goals of this program are to set data-driven national objectives to improve health and well-being over the next decade. Achieving these objectives as a community is our purpose.
We as servants of our communities and our patients and should work together with DHHS to achieve these goals, aiming to create and promote health for everyone in our communities.
Yes, our purpose is ethereal and beyond ourselves. It is based on the universal principles of agape, promoting love of our communities and ensuring we are because we all are. Promoting health and ensuring that our skills are for the purpose of humankind. Providing care beyond medication administration, surgical interventions, but addressing SDOH is our calling and ensures that our common humanity is central to our meaning.
We can, as keepers of our brothers and sisters, find fulfillment, meaning, and purpose in our lives by being communal in the care of our patients.
We train and excel for ourselves and most importantly for the betterment of our communities. We have a responsibility to promote health and to ensure that our neighbors are safe and secure in their health.

> **Our life’s purpose is in the service of our patients and our community.**

Our life’s purpose is in the service of our patients and our community. We are because you are!
Learn, train, and educate to achieve tomorrow’s outcomes through education today.
Enjoy our 2024, 21st Annual Indy Hematology Review!

Thank you.
Ruemu E. Birhiray, MD
Chair, Indy Hematology Review

D.R.I.V.E. INITIATIVE AGENDA

FRIDAY, FEBRUARY 23, 2024

Capitol 2 (1st Floor)

6:45 AM – 7:15 AM	Registration/Continental Breakfast
7:15 AM – 7:45 AM	Welcome and Promoting Clinical Research Diversity: DRIVEing BEYOND The Indianapolis Black Paper | **Ruemu E. Birhiray, MD**
7:45 AM – 8:15 AM	Promoting DEIA in Oncology Clinical Oncology Research: The Role of Major Medical Societies | **Sanford Jeames, DHA**
8:15 AM – 8:45 AM	FDORA - How to Wear a FDORA: Implications for Today's Clinical Researchers and the Pharmaceutical Industry | **Nicole Gormley, MD**
8:45 AM – 9:15 AM	A Clinical Investigator's Approach to Promoting DEIA in Oncology Clinical Research | **Karen Winkfield, MD, PhD**
9:15 AM – 9:25 AM	BREAK
9:25 AM - 9:30 AM	Five Simple Steps | **Kathi Ridley-Merriweather, PhD**
9:30 AM – 10:00 AM	How We do It: BEYOND TALK: Improving Accrual of Minorities to Clinical Trials **Kenneth Anderson, MD**, Dana-Farber Cancer Institute, Jerome Lipper, Multiple Myeloma Center, (Boston, MA) | **Ayalew Tefferi, MD,** Mayo Clinic, (Rochester, MN) | **Matthew Lunning, DO, FACP**, University of Nebraska Medical Center
10:00 AM – 10:15 AM	Advocating Alongside and Not Just About: Community Outreach and Engagement | **Audrey Davis,** CSC's Health Equity Director
10:15 AM - 10:30 AM	Educating Minority Populations: The Alliance of Community Organizations and Medicine | **Rev. Brian Shobe**
10:30 AM – 10:45 AM	Bringing a Drug to Market: The Ethics of Drug Development from the Perspective of the Pharmaceutical Industry | **Tyrone Brewer**
10:45 AM – 11:00 AM	DRIVEing the Next Generation of Medical Researchers **Maya N. Birhiray, BS, MS**, Indy Hematology Education, Inc. **Sam Ranger, BS, MS**, Indy Hematology Education, Inc.
11:00 AM – 11:35 AM	DRIVE KEYNOTE CONVERSATION: Leave No Patient Behind: Our Collective Responsibility in Clinical Data Generation and Application | **Robin Zon, MD, FASCO**, 2023 President-Elect American Society of Clinical Oncology
11:35 AM – 12:50 PM	Lunch: DRIVE Break-Out Sessions CHAIRPERSON: **Muzaffar Qazilbash, MD** - Diversity Officer **Yogesh Jetheva, MD, FACP** – Ranking **Richard Stone, MD, IO** – Individual **Rafat Abonour, MD** – Verification **Coleman Obasaju, MD** – Elevate
12:50 PM – 1:05 PM	CONSENSUS | **Andrew Hantel, MD**
1:05 PM – 1:10 PM	Closing Remarks | **Ruemu E. Birhiray, MD**
7:30 PM	Plan to attend the Dinner Product Theater presented by Seagen | Cameral (1st Floor)

SYMPOSIUM AGENDA

SATURDAY, FEBRUARY 24, 2024

All sessions are in Grand Ballroom 4-5 (2nd Floor) unless otherwise noted.

6:00 AM – 10:00 AM	**Registration** | Grand Ballroom Foyer
6:45 AM – 7:25 AM	**Breakfast and Product Theater** | House (2nd Floor)
6:45 AM – 4:55 PM	**Exhibit Hall and Coffee Bar** | Grand Ballroom 1-3
7:30 AM – 7:55 AM	State of the Art: 2024: Emerging Therapies in Hematologic Malignancies | **Ruemu Birhiray, MD | Pablo Bedano, MD**, Introduction
7:55 AM - 8:15 AM	Treatment of Acute Myeloid Leukemias: Managing the AML Patient When Transplant is Not an Option | **Harry Erba, MD, PhD**
8:15 AM – 8:35 AM	Current, Emerging and Targeted Therapies for the Treatment of Relapsed and Refractory AML | **Rami Komrokji, MD**
8:35 AM – 9:00 AM	Removing Bad Humor and Targeting Aberrant Signaling: Treatment Strategies of Myelodysplastic Syndromes and Acute Lymphoblastic Leukemia | **Richard Stone, MD, IO**
9:00 AM – 9:10 AM	Myeloid Leukemias PANEL DISCUSSION | **Harry Erba, MD, PhD** | **Rami Komrokji, MD** | **Richard Stone, MD, IO**
9:10 AM – 9:30 AM	Controversies in the Management of Chronic Myeloid Leukemia: How I Approach Patients in 2024 | **Richard Larson, MD**
9:30 AM – 9:45 AM	**Coffee Break – Exhibit Hall** | Grand Ballroom 1-3
9:45 AM – 10:10 AM	Emerging and Current Treatment of Multiple Myeloma | **Kenneth Anderson, MD**
10:10 AM – 10:35 AM	Waldenstrom's Macroglobulinemia: Approaching the Newly Diagnosed and Relapsed Patient | **Steven Treon, MD, MA, PhD, FACP, FRCP**
10:35 AM – 10:55 AM	Managing Amyloidosis: How We Diagnose and Treat | **Morie Gertz, MD, MACP**
10:55 AM – 11:05 AM	Plasma Cell Disorders PANEL DISCUSSION | **Kenneth Anderson, MD** | **Steven Treon, MD, MA, PhD, FACP, FRCP** | **Morie Gertz, MD, MACP**
11:05 AM – 11:15 AM	**Coffee Break – Exhibit Hall** | Grand Ballroom 1-3
11:15 AM – 11:40 AM	BEYOND PAIN: Improving the Outcomes of Sickle Cell Disease with Therapeutics and Cellular Therapy in 2024 | **Arun Shet, MD, PhD**
11:40 AM – 12:10 PM	Classical Hematology: Managing Disorders of Bleeding and Clotting | **Craig Kessler, MD, MACP**
12:10 PM – 12:35 PM	Evaluation, Diagnosis and Prognostication and Emerging Therapies for Myeloproliferative Neoplasms | **Ayalew Tefferi, MD**
12:35 PM – 1:00 PM	Myelofibrosis, Philadelphia Chromosome Negative Myeloproliferative Neoplasms and Systemic Mastocytosis | **Raajit Rampal, MD, PhD**
1:00 PM – 1:10 PM	Classical and Malignant Hematology PANEL DISCUSSION | **Richard Larson, MD** | **Craig Kessler, MD, MACP** | **Ayalew Tefferi, MD** | **Raajit Rampal, MD, PhD** | **Peter Hillmen, MB, ChB, PhD**
1:10 PM – 1:55 PM	**Lunch and Product Theaters** | Cameral, Cabinet, Capitol 1, Caucus (1st Floor), House (2nd Floor)
1:55 PM – 2:10 PM	**Coffee Break – Exhibit Hall** | Grand Ballroom 1-3

SESSION CHAIR: **Michael Wiemann, MD, FACP**

2:10 PM – 2:15 PM	2024 IHE Named Sponsor "Community" Recognition and Presentation of T. Howard Lee Lectureship and Trophy, **Michael Wiemann, MD, FACP** | **Ruemu E. Birhiray, MD** | **Sumeet Bhatia, MD**

SYMPOSIUM AGENDA

SATURDAY, FEBRUARY 24, 2024

All sessions are in Grand Ballroom 4-5 (2nd Floor) unless otherwise noted.

2:15 PM – 3:00 PM	T. Howard Lee Keynote Lecture: The Emerging Story of Complementopathies: Treatment of Paroxysmal Nocturnal Hemoglobinuria and Aplastic Anemia | **Robert Brodsky, MD**
3:00 PM – 3:05 PM	**Questions and Answers**
3:05 PM- 3:30 PM	Immune Effector Cell Therapy for Lymphoid Malignancies: What to Do and Know in Community Oncology Practice | **Tycel Phillips, MD**
3:30 PM – 3:35 PM	Introduction, Presentation and Sponsorship Acknowledgement of Steven Coutre Lecture Medal by the Board of Directors of Indy Hematology Education, **Donna Birhiray, OTR, MBA** | **Jennifer Terry, JD** | **Thalia Hammond**
3:35 PM – 4:05 PM	Annual Steven Coutre Chronic Lymphocytic Leukemia Memorial Lecture: Targeted Therapies in Hematologic Disorders Treatment Considerations for Initial Therapy of Chronic Lymphocytic Leukemia | **Peter Hillmen, MB, ChB, PhD**
4:05 PM – 4:35 PM	Chronic Lymphocytic Leukemia: Evaluating and Therapeutic Approaches for the Management of the Relapsed/Refractory Patient | **Jennifer Woyach, MD**
4:35 PM – 4:40 PM	**Questions and Answers**
4:40 PM – 4:55 PM	**Coffee Break – Exhibit Hall** | Grand Ballroom 1-3
4:55 PM – 5:20 PM	When Not to Watch and Wait: Emerging Strategies in the Treatment of Indolent Lymphoma and Mantle Cell Lymphoma | **Michael Williams, MD, ScM, FACP**
5:20 PM – 5:45 PM	Current Advances in the treatment of Aggressive B and T Cell Lymphomas | **Sonali Smith, MD, FASCO**
5:45 PM – 6:10 PM	Emerging and Current Treatment for Hodgkin Lymphoma | **Stephen Ansell, MD, PhD**
6:10 PM – 6:35 PM	Immune Effector Cell Therapy for Multiple Myeloma: What to Do and Know in Community Oncology Practice | **Saad Usmani, MD, MBA, FACP, FRCP**
6:35 PM – 7:00 PM	Hematopoietic Transplantation and Cellular Therapies: When to Refer and Managing Complications | **Richard Childs, MD**
7:00 PM – 7:15 PM	Lymphoid Malignancies and Cellular Therapies PANEL DISCUSSION, **Ruemu Birhiray, MD**, Chair and Moderator **Tycel Phillips, MD** | **Peter Hillmen, MB, ChB, PhD** | **Jennifer Woyach, MD** | **Michael Williams, MD, ScM, FACP** | **Sonali Smith, MD, FASCO** | **Stephen Ansell, MD, PhD** | **Saad Usmani, MD, MBA, FACP** | **Richard Childs, MD**
7:15 PM – 7:30 PM	**Hors D'oeuvres** | Grand Ballroom Foyer
7:30 PM – 8:30 PM	Hematologic Malignancies Town Hall **Ruemu E. Birhiray, MD** – Chair and Moderator **Pablo Bedano, MD** - Introduction **Michael Wiemann, MD, FACP** – Co-Chair **Richards Childs, MD** - Hematopoietic Stem Cell Transplantation **Morie Gertz, MD, MACP** – Plasma Cell Disorders and Amyloidosis **Rami Komrokji, MD** - Acute Leukemias and Myelodysplastic Syndromes **Matthew Lunning, DO, FACP** - Lymphomas **Tycel Phillips, MD** - Lymphomas **Ayalew Teferri, MD** – Myeloproliferative Neoplasms **Saad Usmani, MD, MBA, FACP, FRCP** – Multiple Myeloma **Jennifer Woyach, MD** - Chronic Lymphocytic Leukemia

NURSING/ALLIED PROVIDERS AGENDA

SATURDAY, FEBRUARY 24, 2024

All sessions are scheduled in Capitol Ballroom 2 (1st Floor) unless otherwise noted.
Moderators: Donna M. Birhiray, OTR, MBA | Thalia Hammond

6:00 AM – 10:00 AM	**Registration** | Grand Ballroom Foyer
6:45 AM – 7:25 AM	**Breakfast and Product Theater** | House (2nd Floor)
6:45 AM – 4:55 PM	**Exhibit Hall and Coffee Bar** | Grand Ballroom 1-3
7:30 AM – 7:55 AM	State of the Art: 2024: Emerging Therapies in Hematologic Malignancies | **Ruemu Birhiray, MD |** Grand Ballroom 4-5
8:10 AM – 8:35 AM	Emerging and Current Treatment of Waldenstrom's Macroglobulinemia | **Steven Treon, MD, MA, PhD, FACP, FRCP**
8:35 AM – 9:00 AM	Current Approaches in the Treatment of Myeloproliferative Neoplasms | **Ayalew Teferri, MD**
9:00 AM – 9:30 AM	Managing Disorders of the Benign Hematology | **Craig Kessler, MD, MACP**
9:30 AM – 9:45 AM	**Coffee Break – Exhibit Hall** | Grand Ballroom 1-3
9:45 AM –10:15 AM	Understanding the Diagnosis and Treatment of Plasma Cell Disorders and Amyloidosis | **Saad Usmani, MD, MBA, FACP, FRCP**
10:15 AM – 10:45 AM	Understanding and Managing Immune Effector Toxicities in Hematologic Toxicities | **David Reeves, PharmD, BCOP**
10:45 AM – 11:15 AM	Management of Long-Term Survivors of Hematologic Malignancies | **Sandra Garofalo, MS, APRN, AOCNP**
11:15 AM – 11:30 AM	**Coffee Break – Exhibit Hall** | Grand Ballroom 1-3
11:30 AM – 11:55 AM	Recognizing Toxicities of Oral Oncolytics in the Management of Hematologic Malignancies | **Kristi Orbaugh, RN, MSN, RNP, AOCNP**
11:55 AM – 12:25 PM	Current and Emerging Therapies for Acute Myeloid Leukemias and Myelodysplastic Syndromes | **Rami Komrokji, MD**
12:25 PM – 12:55 PM	How I treat Chronic Myeloid Leukemia: Understanding and Addressing | **Richard Larson, MD**
12:55 PM – 1:00 PM	**Question and Answers**
1:10 PM – 1:55 PM	**Lunch and Product Theaters** | Cameral, Cabinet, Capitol 1, Caucus (1st Floor), House (2nd Floor)
1:55 PM – 2:10 PM	**Coffee Break – Exhibit Hall** | Grand Ballroom 1-3
2:10 PM – 8:30 PM	**All join the Main Symposium** | Grand Ballroom 4-5

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Meet Hyginus Opara, MD: This Year's Scholarship Recipient

Written by Nicola Donelan

Dr. Hyginus Opara is the recipient of the scholarship award to attend the 21st Annual Indy Hematology Review on February 24, 2024, in Indianapolis, USA. He is a practicing pediatrician at the Federal Medical Center in Asaba, Nigeria. The following article was developed from a recent interview with Dr. Opara that highlights his interesting career journey, his daily challenges, and his desire to provide better care for his patients by improving his knowledge and practice.
Opara is 56 years old, married and father of four children, his eldest daughter is also a doctor. He graduated in 1991 from medical school at the University of Nigeria, Nsukka, and worked as medical officer at the Central Hospital Asaba, before doing his residency in pediatrics in 2000 at the Nnamdi Azikiwe University Teaching Hospital, Nnewi. In 2010, he qualified as a specialist pediatrician and presently works at the Federal Medical Center in Asaba which is located in the Delta State, in midwestern Nigeria.

The Federal Medical Centre (FMC), Asaba employs about 260 doctors, 65 of whom are specialist consultants. FMC, Asaba has the following clinical departments – Pediatrics, Internal Medicine, General Surgery, Obstetrics and Gynecology, Dentistry, Ophthalmology, Family Medicine, Orthopedic Surgery, Public Health and ENT. There is also a Radiology department (with X-rays and Ultrasound services, but no CT, MRI nor radiotherapy services), a Physiotherapy Unit and a Laboratory department (mostly non-automated). In the Department of Pediatrics, there are 15 consultants and about 25 residents, apart from those on internship. The department attends to an average of 60 patients daily while the Hematology-Oncology unit records about 10 to15 patients during the weekly clinics, with an average of 5 patients on admission at any point in time.

During medical school, Opara admitted that he did not enjoy pediatrics and that he always wanted to become a surgeon. However, his opinion started to change when he worked as a medical officer. During this time, he did a 6-month rotation in the pediatric department and many of his work colleagues stated that he seemed most at home in that department and asked him to stay on while the other medical officers handled the other departments. From this point on he was called a pediatrician even though he did not yet have any formal certification in that area. Afterwards when he realized that this was his calling, he started on the path to getting certified as a pediatrician. His mentors played an important role in directing his career as well. He was encouraged by Professor Angela Okolo to do pediatrics, as well as his former medical director Dr. Leo Erhunmwunsee who was also a pediatrician. Another mentor was Professor Ifeoma Egbuonu, (a former president of West African College of Physicians) at the Nnamdi Azikiwe University Teaching Hospital where Opara did his residency. While on his residency program, Opara took a break to work as a Research Clinician at the Medical Research Council, in The Gambia, between 2014 and 2015, working on the Pediatrics arm of a multi-center study of a potential antimalarial drug.

According to the latest statistics from WHO, Nigeria's population is just over 208 million. The country continues to grow while the resources available are limited. Particularly noticeable is the paucity in providing adequate healthcare to its citizens. Dr. Opara pointed out that in his rural region about 80% of the population live below the poverty line. He

explained that there is poor access to diagnostic facilities, with only rudimentary tests being used, no access to MRI, doctors must send patients out of town to get CT scans, and when tests are done the results take a long time to receive. Added to these challenges is the fact that Nigeria has a rudimentary health insurance scheme with very limited coverage, so patients must pay out of pocket. As a result, patients present themselves to the doctors at a late stage of their disease, resulting in poorer prognosis because of this delay.

Additionally, there is the challenge of limited support services. There is no formal blood bank in Asaba, therefore when patients need blood transfusions, they must look for donors themselves from relatives or friends which most often causes further delays in care. Another problem is that the drug supply in Nigeria is highly undependable. "The market is riddled with fake drugs and there is no way of knowing if patients may be getting placebo in place of chemotherapy," said Dr. Opara. People in Asaba and other rural areas have no access to most recent drugs as they are unaffordable. "There may be clinical trials happening in the bigger centers like Lagos and in the capital of Abuja, but none happen where I am where it is more provincial," explained Opara.

The opportunity to attend the Indy Hematology Review meeting this year means a lot to Dr. Opara. When asked how he came to apply for the scholarship he explained that his brother-in-law is a practicing physician in Detroit, Michigan and shared the information about this scholarship opportunity with him, knowing that he was interested in this field of medicine. He is very excited about learning new treatment modalities for sickle cell anemia and leukemia and adapting them for use in Nigeria, as these two conditions are the most prevalent among his patients. "I intend to share a summary of the total experience in the departmental seminar, then do smaller more focused seminars with those under me, on any skill or new treatment modality that I have acquired," he said. Opara intends to adapt the information received so that it can be applied in Nigeria. "I would raise awareness of existence of these types of opportunities, so other persons in Nigeria can benefit from attending such meetings as well," stated Opara.

An Interview with Nicole Gormley, MD

Written by Nicola Donelan

Dr. Nicole Gormley joined the Food and Drug Administration (FDA) in 2011 and is the division director for the Division of Hematologic Malignancies II. She did her fellowship training in hematology and critical care at the National Institutes of Health (NIH) and admitted that she did not have any clue when she started that she would end up being a regulator at the FDA. At the NIH, Dr. Gormley had a lot of exposure to clinical trials and research, and this really interested her. She then had an opportunity to do a rotation at the FDA, where she found that there was an entirely different level of discussion about clinical trials and a multidisciplinary approach was used. This experience inspired her to become a regulator. Soon after completing her training at the NIH, she joined the FDA and is very happy there. She described the FDA as a very family friendly environment, and as a mother of four she has a lot of personal experience in this area. According to Gormley, the FDA allows women to establish a healthy work life balance while affording them opportunities for career advancement.

EMBRACE CHANGE TO FIND A REWARDING CAREER

When Dr. Gormley was asked what advice she would give to women in the hematology oncology field on balancing work and family obligations, and working towards leadership positions she placed emphasis on the power of change. ***"Find out what works for you and pursue that, and if it's not working, then change," advised Dr. Gormley.*** There is an inherent hesitancy to change that we all have, but according to Gormley if you find yourself in a situation where you're not feeling that support, then the options are to be aggressive and seek that support from other sources or change your situation completely.

AIMING FOR DIVERSITY IN CLINICAL TRIALS

"If we don't have information on diverse populations from the clinical trials, then we won't know how those products perform in patients that are ultimately going to be receiving the therapy," stated Dr. Gormley.

In December 2022, a law was passed by Congress with the purpose of taking the necessary steps towards improving clinical trial diversity. It is now required by law that sponsors of most drug and device clinical studies submit a Diversity Action Plan when they submit key trial documents to the FDA. This requirement, enacted under section 3601 of Food and Drug Omnibus Reform Act (FDORA) defines the recommendations for sponsors to develop Diversity Action Plans to improve the enrollment of racial and ethnic populations in clinical trials. Now, FDORA makes these plans mandatory for most drug and device studies.

Even some of the best plans do not come to fruition due to external circumstances that are beyond anyone's control. ***"If despite the sponsors best efforts, we don't have adequate representation in a clinical trial the FDA may try to obtain that information either as a post marketing requirement or post marketing commitment," explained Gormley.*** In an ideal situation data on diverse populations should be collected at the early stages and throughout drug development. However, according to Dr. Gormley if the FDA does not have that information at the time of approval, they will still try to seek it after approval. Reaching a diverse population, especially minorities in underserved areas, requires an effort to make sure that participation in clinical trials is not burdensome to patients. ***"It is going to require a broad community effort to try to prioritize this diversity issue to ensure that all trials are available to all patients," said Dr. Gormley.***

The division that Dr. Gormley is responsible for overseeing reviews of products for multiple myeloma and lymphomas and she described that in the past year there have been many approvals of new products. These include several bispecifics, various CART products, and gene therapies. ***"It is a very exciting time in this field, with advancements that will contribute to improved patient outcomes," said Dr. Gormley.*** She stressed that the community needs to come together to ensure that there is access to these therapies for all patients. ***"All patients need access to clinical trials because, in general, that is where the best care is received," she emphasized.***

2024 FACULTY AND ABSTRACTS

Ruemu E. Birhiray, MD
Partner, Hematology Oncology of Indiana, a Division of American Oncology Network and President and CEO, Indy Hematology Education Inc. Clinical Professor, Marian University College of Osteopathic Medicine (Indianapolis, Indiana)

Dr. Birhiray is an attending physician in medical oncology, hematology, and hematopoietic stem cell transplantation at Hematology-Oncology of Indiana, and at St. Vincent Hospital in Indianapolis, IN. After completing his internal medicine residency at Columbus Hospital in Chicago where he also served as Chief Medical Resident in 1994, he was a postgraduate fellow in bone marrow transplant at Johns Hopkins University in Baltimore and in medical oncology at the National Cancer Institute, National Institutes of Health in Bethesda, Maryland.

Abstract unavailable at the time of publication

Kenneth Anderson, MD
Kraft Family Professor of Medicine, Harvard Medical School, Director of the Jerome Lipper Multiple Myeloma Center at Dana-Farber Cancer Institute (Boston, MA)

Dr. Anderson trained in internal medicine at Johns Hopkins Hospital, and then completed hematology, medical oncology, and tumor immunology training at the Dana-Farber Cancer Institute. He is a Doris Duke Distinguished Clinical Research Scientist and American Cancer Society Clinical Research Professor. Over the last four decades, he has developed laboratory and animal models of myeloma in its microenvironment which have allowed for both identification of novel targets and validation of novel targeted therapies. He has then rapidly translated these studies to clinical trials culminating in FDA approval of novel targeted therapies, which have markedly improved patient outcomes.

Emerging and Current Treatments for Multiple Myeloma
Currently, there are 16 classes of agents comprising 32 FDA approved treatments for multiple myeloma (MM). Minimal residual disease (MRD) negativity is achieved at high frequency in newly diagnosed and relapsed refractory MM. Mass spectroscopy detects monoclonal protein and single cell sequencing genetically profiles MM at unprecedented sensitivity. In newly diagnosed MM, four drug combinations of lenalidomide, proteasome inhibitors (bortezomib or carfilzomib), dexamethasone, and anti-CD38 monoclonal antibodies (MoAbs; daratumumab or isatuximab) as induction pre- and consolidation after transplant achieves MRD negativity, even in high-risk disease. Triplet therapies incorporating second generation protease inhibitor (carfilzomib) and immunomodulatory drug (pomalidomie), with MoAbs (daratumumab, isatuximab, elotuzumab), achieve high rates of durable responses in relapsed MM. CAR T cells targeting B-cell maturation antigen (BCMA) achieve high rates of durable MRD negative responses in patients who have received four or more prior therapies, and showed promise when used to treat earlier relapses. GPRC5D directed CAR T therapies are active even in relapsed MM post BCMA therapies. Bispecific T cell engagers (BiTEs) targeting BCMA and/or GPRC5D achieve high extent and frequency of response in patients who have received four or more prior therapies. Response to these therapies is associated with target expression and cytolytic T cell response, whereas resistance/infection is associated with downregulation/mutation of target antigens and/or exhausted T cells. In the future, targeted and immune therapies including CART/BiTEs will be incorporated into initial treatment of MM to achieve durable MRD negative responses and restore memory anti-MM immunity, allowing patients to be disease free and off all therapy.

Stephen M. Ansell, MD, PhD
Dorotha W. and Grant L. Sundquist Professor in Hematologic Malignancies Research Mayo Clinic (Rochester, MN)

Dr. Ansell is a consultant in the Division of Hematology, Department of Internal Medicine at Mayo Clinic in Minnesota. He currently serves as chair of the Division of Hematology and the Enterprise Deputy Director of the Mayo Clinic Cancer Center. He joined the staff of Mayo Clinic in 1999 and holds the academic rank of Professor of Medicine, Mayo Clinic College of Medicine and Science. He earned his MB, ChB, and PhD degrees at University of Pretoria in Pretoria, South Africa, where he also completed an internship in internal medicine and surgery, a residency in internal

medicine, and a fellowship in medical oncology.

Hodgkin lymphoma (HL) is a relatively uncommon B-cell lymphoid malignancy affecting approximately 8,500 new patients per year and representing approximately 10% of all lymphomas in the United States. It is composed of two distinct disease entities, namely classical HL, and nodular lymphocyte predominant HL. Nodular sclerosis, mixed cellularity, lymphocyte depletion, and lymphocyte-rich HL are subgroups of classical HL. To appropriately select therapy, an accurate assessment of the stage of disease is critical. Based on the disease stage, prognostic models that identify patients at low or high risk for recurrence are used to optimize therapy. Response to therapy as determined by PET scan is predictive of patient outcome and is also used to optimize treatment. Initial therapy for HL patients is based on the abovementioned factors, particularly the histology of the disease, the anatomical stage, and the presence of poor prognostic features. Patients with early-stage disease are typically treated with combined modality strategies utilizing abbreviated courses of combination chemotherapy followed by involved-field radiation therapy, while those with advanced stage disease receive a longer course of chemotherapy often without radiation therapy. Newer agents including brentuximab vedotin and anti-PD-1 antibodies are now being incorporated into frontline therapy and have redefined the frontline therapy of choice. The standard of care for most patients who relapse following initial therapy is high-dose chemotherapy followed by an autologous stem cell transplant. For patients who subsequently relapse, participation in a clinical trial testing novel agents or combinations should be considered.

Robert A. Brodsky, MD
Johns Hopkins Family Professor of Medicine and Oncology, Director of the Division of Hematology Johns Hopkins University School of Medicine (Baltimore, MD)

Dr. Brodsky is the Johns Hopkins Family Professor of Medicine and Oncology, and a member of the Johns Hopkins Kimmel Cancer Center. He also serves as the Director of the Division of Hematology and the T32 Training Program. He received his medical degree from Hahnemann University and completed his residency in Internal Medicine at Vanderbilt University School of Medicine and his fellowship training in hematology at the National Institutes of Health and in oncology at Johns Hopkins University. His clinical and academic interests relate to bone marrow failure disorders, hemolytic anemias, and complement. He is on the editorial board for Blood, is a Section Editor for UpToDate. He is on the Executive Committee of the American Society of Hematology (ASH) and serves as Past-President for ASH.

Abstract unavailable at the time of publication

Richard Childs, MD
Clinical Director and Acting Scientific Director, National Heart, Lung, and Blood Institute (NHLBI) at the National Institutes of Health (NIH) (Bethesda, MD)

Dr. Childs oversees one of the NIH's largest clinical and translational science programs, directing an office that oversees the research efforts of more than 900 staff members including with more than 350 clinical researchers conducting over 250 investigator-initiated clinical trials in heart, lung, and blood diseases.

Abstract unavailable at the time of publication

Harry P. Erba, MD, PhD
Professor of Medicine, Division of Hematologic Malignancies and Cellular Therapy Director, Duke Leukemia Program, Chair, SWOG Leukemia Committee, Duke University (Durham, NC)

Dr Erba is a professor of medicine in the Division of Hematologic Malignancies and Cellular Therapy

at Duke University. He serves as the Director of the Leukemia Program. Dr Erba graduated from Yale University with a Bachelor of Science degree in Biology. He earned his medical degree and Doctor of Philosophy degree in Biophysics from Stanford University School of Medicine in California. He completed his internship, residency and fellowship at Brigham and Women's Hospital. He has served as the Chair of the SWOG Leukemia Committee since 2012.

Abstract unavailable at the time of publication

Sandra G. Garofalo MS, APRN, AOCNP
Nurse practitioner, Hematology Oncology of Indiana, a Division of American Oncology Network (Indianapolis, IN)

She has over 18 years of experience in the field of oncology. She completed her Bachelor of Science in nursing as well as her Master of Science at The Ohio State University. She started her nursing career in hematopoietic stem cell transplant at The Medical University of South Carolina. Since that time, she has had extensive experience in hematological and solid tumor malignancies as well as benign hematology at The James Cancer Center at The Ohio State University. She currently works as a nurse practitioner at Hematology Oncology of Indiana and St. Vincent's Hospital in Indianapolis.

Abstract unavailable at the time of publication

Morie Gertz, MD, MACP
Roland Seidler Jr. Professor, Art of Medicine, Chair Emeritus, Department of Internal Medicine, Mayo Clinic (Rochester, MN)

Dr. Gertz is a Master of the American College of Physicians. His undergraduate degree was awarded with highest distinction from Northwestern University graduating Phi Beta Kappa.

Abstract unavailable at the time of publication

Peter Hillman, MB, ChB, PhD
Emeritus Professor of Hematology at the University of Leeds and since May 2022 has been employed by Apellis Pharmaceuticals.

He qualified in Medicine at Leeds University Medical School in 1985 and completed his general medical training in Leeds in 1988. He then spent 5 years specializing in hematology at the Hammersmith Hospital including completing a PhD on the pathophysiology of paroxysmal nocturnal hemoglobinuria (PNH) under the supervision of Professor Lucio Luzzatto. He returned to Leeds in 1994 and was appointed Professor of Hematology at the University of Leeds in 2013. Professor Hillmen's research interests include both paroxysmal nocturnal hemoglobinuria (PNH) and chronic lymphocytic leukemia (CLL).

Abstract unavailable at the time of publication

Craig Kessler, MD, MACP
Professor of Medicine and Pathology and attending physician in the Division of Hematology-Oncology at Georgetown University Medical Center (Washington, DC)

Dr. Kessler serves as the Director of the Division of Coagulation in the Department of Laboratory Medicine and is the Director of the Therapeutic and Cellular Apheresis Unit. With a distinguished career beginning in 1973, Dr Kessler earned his medical degree from Tulane University School of Medicine in New Orleans, Louisiana. He remained in New Orleans to complete his medical internship and residency before moving to Baltimore, Maryland, in 1976 to assume a Fellowship in Special Hematology at Johns Hopkins Hospital.

Abstract unavailable at the time of publication

Rami Komrokji, MD
Vice Chair of the Malignant Hematology Department and the Head of the Leukemia and MDS Section, Moffitt Cancer Center (Tampa, FL)

Dr. Komrokji is a senior Member of the Malignant Hematology and Experimental Therapeutics Program at the Moffitt Cancer Center, and Professor in Medicine & Oncologic Sciences at the College of Medicine, at the University of South Florida in Tampa, FL After earning a medical degree in 1996 from the Jordan University School of Medicine, he completed an internship and residency at Case Western University, St. Vincent Program. He then completed a fellowship at Strong Memorial Hospital, University of Rochester, in Hematology/Oncology and Hematopoietic Stem Cell Transplantation.
Abstract unavailable at the time of publication

Richard Larson, MD
Professor of Medicine in Hematology/Oncology, Director of Hematologic Malignancies Clinical Research Program, the University of Chicago Comprehensive Cancer Center (Chicago, IL)

He received his medical degree from the Stanford University School of Medicine in 1977, and completed his postdoctoral training in Internal Medicine, Hematology, and Medical Oncology at the University of Chicago. He has been a member of the faculty in the Section of Hematology/ Oncology and the Comprehensive Cancer Center at the University of Chicago since 1983.

How I manage chronic myeloid leukemia in 2024
The survival of patients with newly diagnosed chronic phase CML is >90% at 10 years with first or second-generation tyrosine kinase inhibitors (TKIs). Patients presenting with features of accelerated phase (AP) disease have less favorable outcomes with ~70% survival at 5 years. However, those with low or intermediate ELTS (European Long-Term Survival) scores have considerably better outcomes. The International Consensus Classification continues to define AP as 10-19% blasts in the blood or marrow, or >20% basophils, or the presence of additional chromosomal abnormalities (such as +8, +Ph, i(17), +19, or a complex karyotype) in Ph+ cells. When AP evolves in a patient undergoing therapy, the outcome is similar to that of patients presenting with blast phase CML (median survival <2-3 years). Important tools for helping patients achieve their goals of increased survival, quality of life, and/or treatment-free remission (TFR) include risk assessment (ELTS score), mileposts such as the ELN (European LeukemiaNet) recommendations, molecular monitoring, and when necessary, mutation detection. Successful TFR reduces chronic side-effects, late complications, and costs. After 5 years of frontline TKI therapy, ~35-50% of patients are eligible to discontinue after stable MR4 or MR4.5 responses for >2-3 years; about half are successful and remain in TFR. Lineage-specific detection of CML DNA predicts for successful discontinuation. Most patients with detectable BCR::ABL1 in granulocytes or T-cells experience molecular relapse. Asciminib is the most recently approved TKI. It binds to the myristoyl site and inactivates the BCR::ABL1 enzyme. The frontline randomized ASC4FIRST trial compares asciminib to each of the other TKIs and has completed accrual; we await the results.

Matthew Lunning DO, FACP
Associate Professor, Division of Hematology/Oncology, University of Nebraska Medical Center, Associate Vice Chair of Research for the Department of Internal Medicine, Medical Director of the Clinical Research Center (CRC), and Medical Director of Cellular Therapies. (Omaha, NE)

He received his medical degree from Des Moines University in 2006. Dr. Lunning completed his internal medicine residency at UNMC where he served as Chief Medical Resident. He completed his Hematology/ Oncology fellowship and served as the Hematology Chief Fellow at Memorial Sloan-Kettering Cancer Center. Dr. Lunning returned to UNMC in 2013 and has been active in clinic research, research mentoring, education, and patient care. Dr. Lunning was the recipient of the Distinguish Scientist Award in 2019.

Abstract unavailable at the time of publication

Kristi Orbaugh, RN, MSN, RNP, AOCNP
Kristi's entire career has been in the oncology field. She received her undergraduate degree from Purdue University and her master's degree from Indiana University Purdue University of Indianapolis. She works at Community Hospital Cancer Center North which is an affiliate of MD Anderson as a nurse practitioner. She has published several oncology related articles. She has presented locally, regionally, nationally, and internationally. Kristi is passionate about oncology and enjoys presenting and providing oncology education on regional, national, and international level. (Indianapolis, IN)

Combination chemotherapy regimens have added to the complexity of cancer treatment.
When oral oncolytic drugs are used, they add another layer of difficulty due to their potential toxicities and the need for patient adherence. Oral chemotherapy drugs have the ability to cause toxicities that will need to be assessed regularly. The focus of this presentation will be on discussing some of the most common

toxicities that are seen with regimens that are frequently used to treat hematologic malignancies. It is vital that oncology nurses recognize and continually assess potential toxicities caused by oral chemotherapy. Differentiating between drug toxicity and disease-related symptoms will need to be evaluated as well. Nurses will also need to educate patients on potential side effects and have a plan for managing any toxicities. Education is imperative in helping patients understand the proper way to take their medication, and the importance of adhering to the medication regimens. Finally, the issue of financial toxicity will be discussed briefly.

Tycel Phillips, MD
Associate Professor, Division of Lymphoma, Department of Hematology and Hematopoietic Cell Transplantation, City of Hope Comprehensive Cancer Center (Duarte, CA)

Dr. Phillips earned his medical degree from Rush University, followed by a residency in internal medicine at the John H. Stroger Jr. Hospital of Cook County in Chicago. His fellowship training in oncology/hematology took place at University Hospitals in Cleveland. Before joining City of Hope, he was a clinical associate professor at the University of Michigan, where he was appointed the Maria Reinhardt DeCesare Research Professor of Blood Cancers and Bone Marrow Transplantation.

Abstract unavailable at the time of publication

Raajit K. Rampal, MD, PhD
Associate Attending Physician and Director of the MPN and Rare Hematologic Malignancies Program at Memorial Sloan-Kettering Cancer.

He received his undergraduate degree in Biochemistry from the University of Rochester. He subsequently went on to train in the Medical Scientist Training Program (MSTP) at Stony Brook University. This was followed by an internship and residency at the University of Chicago and fellowship in hematology and medical oncology at Memorial Sloan-Kettering Cancer Center.

Abstract unavailable at the time of publication

David Reeves, PharmD, BCOP
Associate Professor of Pharmacy Practice, College of Pharmacy and Health Sciences, Butler University, Clinical Pharmacy Specialist in Hematology/Oncology, Franciscan Physician Network Oncology/Hematology Specialist (Indianapolis, IN)

David Reeves, PharmD, BCOP is a professor of pharmacy practice for the College of Pharmacy and Health Sciences at Butler University and clinical pharmacy specialist in hematology/oncology at Franciscan Physician Network Oncology/Hematology Specialists in Indianapolis, IN.

Understanding and Managing Immune Effector Cell Toxicities in Hematologic Malignancies in 2024
The therapeutic use of immune system manipulation to treat hematologic malignancies continues to expand with the use of chimeric antigen receptor (CAR) T-cell therapies and bispecific T-cell engagers (BTCE). In addition to the immune related destruction of malignant cells, immune effector cells can produce significant toxicity, namelycytokine release syndrome (CRS) and neurotoxicity. Upwards of 90% of patients experience immune effector toxicity with CAR T-cell therapies. Additionally, multiple BTCE therapies have come to the market recently and the rate of immune effector cell toxicity is approximately 50 - 75% with these agents. Established therapy to reverse the hyperinflammatory state and decrease effects of cytokines include use of an IL-6 receptor antibody (tocilizumab), steroids, and an interleukin 1 receptor antagonist (anakinra). While most patients respond to therapy, there remians work to be done to optimize management of these potentially fatal toxicities. Strategies, including prophylactic tocilizumab, anakinra, JAK 1/2 inhibition, and use of simvastatin have been recently investigated to help manage or prevent these toxicities. Given the efficacy of prophylactic strategies, outpatient administration of BTCE is being trialed due to the relatively mild CRS observed and efficacy of management strategies. Though immune effector cell toxicities of CAR T-cell therapies may be more difficult to manage, outpatient CAR T-cell management via use of remote monitoring technology has also been described. To support the expansion of therapies with a risk for immune effector

cell toxicities and the increasing number of patients receiving these therapies, guideline driven management along with novel therapeutic and prophylactic approaches are necessary to decrease the impact of toxicity.

Arun Shet, MD
Senior Research Physician and Assistant Clinical Investigator in the Cellular and Molecular Therapeutics Branch at the National Heart Lung and Blood Institute.

Dr Shet heads the Laboratory of Sickle Thrombosis and Vascular Biology where he studies the crosstalk between sickled red cells, vascular endothelial cells, and leucocytes that mediates inflammation and thrombosis and leads to the vascular pathobiology characteristic of Sickle Cell Disease.

Abstract unavailable at the time of publication

Sonali M. Smith, MD, FASCO
Elwood V. Jensen Professor of Medicine, Section Chief of Hematology/Oncology, Co-Leader of the Cancer Service Line, and Co-Director of the Lymphoma Program at the University of Chicago in the Department of Medicine (Chicago, IL)

She is a clinical investigator in lymphoma and a clinical expert in Hodgkin and non-Hodgkin lymphomas. As faculty member at the University of Chicago since 2001, she has over 200 publications in peer-reviewed journals and has written over 25 review articles on lymphoid malignancies. She is particularly interested in targeted agents and pathway inhibitors and has first and senior author publications through cooperative group trials and investigator-initiated trials.

Abstract unavailable at the time of publication

Richard Stone, MD, IO
Lunder Family Chair in Leukemia and Chief of Staff at Dana-Farber Cancer Institute, Director of Translational Research for the Adult Leukemia Program, at DFCI, and Professor of Medicine at Harvard Medical School (Boston, MA)

Dr. Stone is nationally recognized for translational and clinical research in blood and bone marrow malignancies including acute leukemia, myeloproliferative disorders, and myelodysplastic syndrome (MDS). He has had a significant leadership role in the development of at least five recently approved agents for the treatment of acute myeloid leukemia (AML). Dr. Stone is a Vice Chair of the National Comprehensive Cancer Network (NCCN) MDS panel and a member of the NCCN AML panel. He previously served as the Chair of the Alliance Leukemia Committee, Chair of the Medical Advisory Board of the Aplastic Anemia and MDS International Foundation, and the Chair of the ABIM Oncology Board.
Using two similar, but disparate systems used for disease designation (W.H.O and I.C.C.), myelodysplastic syndrome (MDS) patients are often divided into "higher risk" (largely excess blasts) who might benefit from chemotherapy and/or stem cell transplant vs those with "lower risk" disease whose care is primarily supportive. The most "accurate" prognostic system is the IPSS-M, which requires knowledge of the patient's blood counts, marrow findings, karyotype, and molecular studies. The recently published COMMANDS trial suggested that luspatercept might supplant ESA (Erythropoiesis-Stimulating Agent) as the first line agent in lower risk disease, although the greatest benefit is in those with SF3B1 mutations. Other trials suggest that the telomerse inhibitor, imetelstat or low dose hypomethylating agents may have utility. For higher risk MDS, DNA hypomethylating agents are the mainstay as is allogeneic stem cell transplant in younger fit patients. Treatment choice in acute lymphoblastic leukemia (ALL) is based on patient age and chromosome analysis (questions the absence of Philadelphia positivity). The successful application of blinatumomab, the antibody conjugate inotuzumab, and CAR T cells in the relapse

setting has promoted the use of these agents in earlier stage disease. In Philadelphia-positive ALL, the tyrosine kinase inhibitors have markedly improved the prognosis; chemotherapy/stem cell transplant may be obviated if used in conjunction with a minimal residual disease eradicator such as the anti-CD19-CD3 bispecific antibody blinatumomab. The use of pediatric-inspired therapies (emphasizing non-myelosuppressive agents) has been successful in younger adults.

Ayalew Tefferi, MD
Barbara Woodward Lips II Professor of Medicine at the Mayo Clinic (Rochester, MN)

Dr. Tefferi's research interest is primarily focused on myeloid neoplasms including acute myeloid leukemia and chronic myeloid neoplasms. His web of science core collection publications, as of 6/3/2021, number over 1500 with an H-index of 120. He has participated in hundreds of invited lectureships including service as core faculty for GW, MDACC and Harvard annual board review courses.

Abstract unavailable at the time of publication

Steven P. Treon, MD, MA, PhD, FRCP, FACP
Director, Bing Center for Waldenstrom's Macroglobulinemia (WM) at the Dana Farber Cancer Institute (DFCI), Professor of Medicine at Harvard Medical School, Chair of the WM Clinical Trials Group (Boston, MA)
Using whole-genome sequencing, Dr. Treon's laboratory was the first to clarify the genetic basis of WM by identifying MYD88 (L265P) as a highly recurring somatic mutation in 95% of WM patients. This finding has permitted differentiation of WM from other B-cell malignancies that share overlapping characteristics, and was adopted in WHO and NCCN guidelines as a supportive diagnostic marker for WM. His lab also identified the CXCR4 mutation found in 40% of WM patients. Professor Treon's lab has focused on the development of novel agents to target both mutated MYD88 and CXCR4. His lab was the first to report that Bruton's tyrosine kinase (BTK) was a downstream target of MYD88 L265P mutation, in a study that enabled a clinical trial that led to the investigation, adoption and approval of BTK-inhibitors for WM.

Mutations in MYD88 (95-97%) and CXCR4 (30-40%) are common in Waldenstrom macroglobulinemia (WM). TP53 is also altered in 20-30% of WM patients, particularly those previously treated. Mutated MYD88 upregulates and activates HCK that drives BTK pro-survival signaling. Both nonsense and frameshift CXCR4 mutations occur in WM. Nonsense variants such as CXCR4S338X show greater resistance to BTK-inhibitors. Covalent BTK-inhibitors (cBTK-i) produce major responses in 70-80% of WM patients. MYD88 and CXCR4 mutation status can impact time to major response, depth of response and/or progression-free survival (PFS) in WM patients treated with cBTK-i. The cBTK-i zanubrutinib shows greater response activity and/or improved PFS in wild-type MYD88, mutated CXCR4, or altered TP53 patients. Marked differences in the occurrence of adverse events have been observed between BTK-inhibitors in WM patients, including atrial fibrillation, bleeding diathesis and neutropenia. Intolerance is also common with c-BTKi, and dose reduction or switchover to another c-BTKi can be considered. For patients with acquired resistance to c-BTKi, newer options include the non-covalent BTK-inhibitor, pirtobrutinib or the BCL2 antagonist, venetoclax. Combinations of BTK-inhibitors with chemoimmunotherapy, CXCR4 and BCL2 antagonists have advanced and are discussed. Algorithms for positioning BTK-inhibitors in treatment-naïve and previously treated WM patients based on genomics, disease characteristics, and co-morbidities are presented.

Saad Z. Usmani, MD, MBA, FACP, FRCP
Chief Attending and Member, Myeloma Service Member, Memorial Sloan Kettering Cancer Center, New York, NY. Professor of Clinical Medicine, Weill Cornell Medical College – Cornell University (New York, NY)

Dr. Usmani received his medical education at Allama Iqbal Medical College in Lahore, Pakistan. He completed a residency in internal medicine at Sinai-Grace Hospital/ Wayne State University in Detroit, Michigan and a fellowship in hematology and oncology at the University of Connecticut Health Center in Farmington, Connecticut. He then joined the Myeloma Institute for Research & Therapy, University of Arkansas for Medical Sciences in Little Rock,

AR in 2010 as the Director of Developmental Therapeutics and Assistant Professor of Medicine. He was recruited to the Levine Cancer Institute/Atrium Health in 2013 as the inaugural Division Chief of Plasma Cell Disorders and Director of Clinical Research for Hematologic Malignancies where he built an internationally renowned myeloma program and was then recruited in 2021 as the Chief of Myeloma Service at MSKCC.

Abstract unavailable at the time of publication

Michael Wiemann, MD, FACP
Vice President, Indy Hematology Education, Inc., Regional President & CEO, Ascension Michigan, Metro West Region, President, Ascension Medical Group (MI) Clinical Professor of Medicine at Michigan State University, College of Human Medicine. (Warren, MI)
Dr. Wiemann is the President of the Ascension Medical Group, Michigan, and Clinical Professor of Medicine at Michigan State University College of Human Medicine. Dr. Wiemann is a medical oncologist and Co-Founder of the Indy Hematology Review. While in Indianapolis, he held several leadership positions at St. Vincent Hospital and Health Center, including Medical Director of Oncology, Chief Medical Officer, and Interim President.

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Meaghan Wiggins, MA, LMHCA, OPN-CG
Clinical Hospital Coordinator, Cancer Support Community, Art Therapist (Carmel, IN)
Works exclusively with those who have been touched by cancer since 2017. She works with those touched by cancer at Cancer Support Community as a clinical hospital coordinator, and a mental health therapist specializing in art therapy. She has a passion for helping others and creating art.

Michael E. Williams, MD, ScM, FACP
Byrd S. Leavell Professor of Medicine and Professor of Pathology, Physician Lead, Oncology Service Line, UVA Health, Associate Director for Clinical Affairs, UVA Comprehensive Cancer Center, University of Virginia School of Medicine (Charlottesville, VA)

Dr. Williams received his MD from the University of Cincinnati College of Medicine and Master of Science from the Harvard School of Public Health. Following residency and fellowship at UVA he joined the Department of Medicine and the NCI-designated Cancer Center. His patient care and research interests include clinical trials and translational science for mantle cell lymphoma, other non-Hodgkin lymphomas and CLL, with a focus on targeted agents and immuno-therapeutics.

Abstract unavailable at the time of publication

Jennifer Woyack, MD
Professor, Division of Hematology, Section Chair of Chronic Lymphocytic Leukemia (CLL), and a Physician Scientist, Ohio State University. (Columbus, OH)

Dr. Woyach is focused on translational research in CLL at The Ohio State University. Her laboratory interests include experimental therapeutics in CLL with a focus on signaling pathways and kinase inhibition. She has extensive experience studying BTK inhibitors, resistance mechanisms associated with irreversible BTK inhibitors, and strategies to overcome resistance.

Relapsed/Refractory Chronic Lymphocytic Leukemia
Currently, the treatment of relapsed CLL mirrors frontline treatment, and is highly dependent on initial therapy. For those who were initially treated with chemotherapy, the choices for second line treatment include Bruton tyrosine kinase inhibitors (BTKis) and venetoclax in combination with antibody therapy, with similar considerations to frontline treatment. The CLL13 study, investigating frontline treatment of CLL, demonstrated that obinutuzumab was the optimal antibody to combine with venetoclax, 1 although this combination only has approval in the frontline setting. When choosing among BTKis, data from

ELEVATE-RR demonstrated non-inferiority of acalabrutinib to ibrutinib in terms of efficacy, and superiority in terms of safety. 2 The ALPINE study demonstrated superiority of zanubrutinib to ibrutinib in both safety and efficacy. 3 It is difficult to infer any comparison of acalabrutinib and zanubrutinib beyond the potential for some differential side effects. For patients who progress on initial treatment with a continuous BTKi, venetoclax +/- antibody is the only approved standard therapy. 4 5 Current studies may show if there is a role for pirtobrutinib in this setting as well. For those patients initially treated with venetoclax plus obinutuzumab, accumulating data suggest retreatment is an option for many patients, although remission durations are unknown with this approach. Covalent BTKi therapy is another standard option for these patients.

Pirtobrutinib was recently approved for patients previously treated with both covalent BTKi and venetoclax, and is the only effective standard therapy for these patients. 6 Current trials of immune based therapies and novel single agents and combinations will hopefully lead to additional options for this group of patients.

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An Interview with Peter Hillmen, MB, ChB, PhD

Written by Nicola Donelan

Professor Hillmen is giving this year's annual Steven Coutre Chronic Lymphocytic Leukemia (CLL) Memorial Lecture. Since 1995 Professor Hillmen has been involved in researching and understanding the pathophysiology of CLL, and in developing novel therapies for this disease. He was the chairman of the National Cancer Research Institute (NCRI) CLL sub-group responsible for conducting CLL clinical trials in the UK from 2002 to 2018.

"Steve was a good friend and a very compassionate hematologist, I knew him very well for many decades so it will be my pleasure to do this lecture in his honor," said Hillmen.

Professor Hillmen attended Leeds Medical School and completed his general medical training in in 1988. He was a Hematology Registrar in Hammersmith Hospital, London between 1989 and 1990. Then from 1991 to 1993 he was a Welcome Training Fellow based at the Royal Postgraduate Medical School in London where he received his PhD working on paroxysmal nocturnal hemoglobinuria (PNH) under the supervision of Professor Lucio Luzzatto. He then moved back to Leeds as a Senior Registrar in Hematology in 1994 and stayed on there in various capacities. In 2013, he was appointed as Professor of Experimental Hematology at the University of Leeds. Peter Hillmen led the Experimental Hematology section in Leeds Institute of Medical Research (LIMR), and the Translational Hematology Research group. Until his move to Apellis Pharmaceuticals in May 2022 he was the Professor of Experimental Hematology and Honorary Consultant Hematologist at Leeds Teaching Hospitals NHS Trust. He now works as the Head of Rare Disease at Apellis Pharmaceuticals focusing on complement therapies and has an Emeritus Professorship at the University of Leeds where he continues his interest in CLL.

"My practice was always patient focused searching for the best therapy for each individual patient. My interest in both PNH and CLL originated from single patients who I treated and the desire to understand their disease and searching for the best therapies. It is critical to understand the disease process and use this to decide upon the best treatments for patients," said Professor Hillmen.

While in academia as a hematology professor at the University of Leeds, Professor Hillmen focused on paroxysmal nocturnal hemoglobinuria (PNH) and chronic lymphocytic leukemia (CLL). He has published over 250 peer-reviewed papers in journals including The Lancet, New England Journal of Medicine, and Blood. After decades in academia a new venture awaited, and in May 2022 Professor Hillmen joined Apellis Pharmaceuticals, as head of hematology engagement. At Apellis his focus is on PNH therapies, in particular targeting complement, and leveraging his expertise and providing counsel on various initiatives across the organization.

We discussed some key differences between academia and biotech industry gleaned from his experience. According to Professor Hillmen, academia is more focused on the disease and training PhD students, while in the biotech industry the focus is more on developing and understanding new therapies and investigating various drugs.

"Biotech is also more fast paced, and I am no longer training people to become scientists and physicians," said Professor Hillmen.

Teams in biotech tend to be bigger explained Hillmen. At Leeds there were 150-200 people in the hematology department, whereas at Apellis the teams are upwards of 700 people globally which includes all the lab people, the regulatory people, sales, and marketing teams. Even with all his new responsibilities, Professor Hillmen continues to be involved in overseeing CLL trials at Leeds.

"There were several of my students at Leeds who were ready to take over the reins and they are doing really well and it's great to see that they have flourished since I left," said Professor Hillmen proudly.

When asked for advice, Professor Hillmen recommended that medical and doctorate students try different specialties and see what suits them best. Additionally, he believed that gaining a deep understanding of the disease, its biology and patients is important.

"Go to the best center for the area that you are interested in, get good mentors, if possible, do scientific research, being able to understand what you are doing makes it more enjoyable and this is something you are going to do for 30-40 years," he emphasized.

"Treatments for CLL have developed rapidly over the last decades from when there was only a single drug that didn't work that well and increased chances of survival marginally by about one year. Now there are several treatments that work extremely well to the point where I believe CLL is largely curable and patients with this disease will not die from it," said Professor Hillmen.

Seeing the change in life expectancy of patients because of more effective and targeted therapies is very encouraging, and Professor Hillmen believes that combination therapy in frontline patients is the best treatment leading to cures in CLL. However, the development of new therapies is key as there are many patients that have already failed on one or more therapies that need alternatives.

"A cure for CLL is difficult to define, and we might have to wait 20 years to actually prove that." said Professor Hillmen.

His lecture at the 21st Indy Hematology Review meeting titled "Targeted Therapies in Hematologic Disorders: Treatment Considerations for Initial Therapy of Chronic Lymphocytic Leukemia," will focus on his group's recently published data in the New England Journal about treating CLL patients without chemotherapy. Data from this phase 3, multicenter, randomized, controlled, open-label platform trial compared ibrutinib–venetoclax and ibrutinib monotherapy with fludarabine-cyclophosphamide-rituximab (FCR) in patients with untreated CLL.

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T. HOWARD LEE AWARD RECIPIENTS

T. Howard Lee, MD, founder and President Emeritus, Hematology Oncology of Indiana, PC (Indianapolis, IN)

The following respected individuals have been presenters and recipients at the T. Howard Lee Keynote Lecture:

2003: Professor Bertrand Coiffier, MD
Bertrand Coiffier is Professor of Hematology at the Department of Hematology, Hospices Civils de Lyon and the University Claude Bernard, Lyon, France, Chairman, GELA

2004: Kanti Rai, MD
Past President of American Society of Hematology, ASH, Chief, Division of Hematology/Oncology, Long Island Jewish Medical Center, Professor of Medicine, Albert Einstein College of Medicine

2005: Claire Dearden, MBBS
Dr Claire Dearden is Consultant Hematologist and Head of the Chronic Lymphocytic Leukemia (CLL) Unit at The Royal Marsden and The Institute of Cancer Research, and Medical Director of the South West London Cancer Network.

2006: Sandra Horning, MD
Professor of Oncology, Sanford University, Past President of The American Society of Oncology, ASCO

2007: Lewis R. Silverman, MD
Director, Myelodysplastic Syndrome and Myeloproliferative Disease Program, Mount Sinai School of Medicine, New York, NY

2008: Neal Young, MD
Chief of the Hematology Branch of the National Heart, Lung and Blood Institute, National Institute of Health, Bethesda, MD

2009: Professor Michael Pfreundschuh, MD
Professor and Director of Medical Oncology, Department of Internal Medicine, Saarland University, and Chairman, German Lymphoma Group

2010: James Armitage, MD
Past President of ASCO, Joe Shapiro Professor of Medicine, and Past Dean, University of Nebraska Medical School, Omaha, NE

2011: Michael Keating, MBBS
Professor of Medicine and Internist, Department of Leukemia, Division of Cancer Medicine, The University of Texas MD Anderson Cancer Center, Houston, TX

2012: Kenneth Anderson, MD
Kraft Family Professor of Medicine, Department of Medicine, Harvard Medical School, Medical Director, Kraft Family Blood Center, Dana-Farber Cancer Institute, Boston, MA

2013: Susan O'Brien, MD
Ashbel Smith Professor and Chief of the Section of Acute Lymphocytic Leukemia, Department of Leukemia at the University of Texas MD Anderson Cancer Center

2014: Ross Levine, MD
Associate Attending Physician at Memorial Sloan-Kettering Cancer Center, Associate Professor of Medicine at Weill Cornell Medical College, New York, NY

2015: Stephen Ansell, MD, PhD
Professor of Medicine, Mayo Clinic Department of Hematology at the Mayo Clinic, MN

2016: David Porter, MD
Abramson Cancer Center, University of Pennsylvania Health System, Jodi Fisher Horowitz Professor of Leukemia Care Excellence Director, Blood and Marrow Transplantation, Philadelphia, PA

2017: Bruce Cheson, MD
Deputy Chief, Division of Hematology/Oncology in the Department of Medicine, Head of Hematology and Professor of Medicine, Lombardi Comprehensive Cancer Center, Georgetown University Hospital, Washington, DC

2018: Thomas Kipps, MD, PhD
Deputy Director of Research, Moores UCSD Cancer Center; Professor of Medicine UC San Diego, School of Medicine, San Diego, CA

2019: Pier Luigi Zinzani, MD, PhD
Professor of Hematology, Head of Lymphoma Group, Institute of Hematology, "L. e A. Seràgnoli", University of Bologna, Bologna, Italy

2020: Edward Stadtmauer, MD
Professor of Medicine and Section Chief of the Hematologic Malignancies in the Division of Hematology-Oncology at the Hospital of the University of Pennsylvania, Philadelphia, PA

2021: Ranjana Advani, MD
Saul A. Rosenberg Professor of Lymphoma at Stanford University School of Medicine and Physician Leader of the Lymphoma Clinical Care Program, Stanford, CA

2022: Sonali Smith, MD, FASCO
Elwood V. Jensen Professor of Medicine, Section Chief of Hematology/Oncology, Co-Leader of the Cancer Service Line, and Co-Director of the Lymphoma Program at the University of Chicago in the Department of Medicine, Chicago, IL

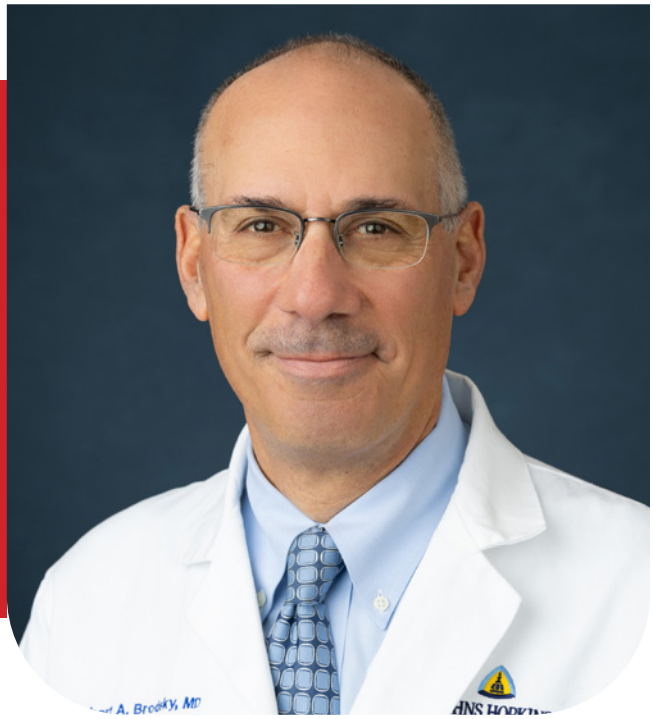
2023: Gilles Salles, MD, PhD
Chief of the Lymphoma Service at the Memorial Sloan Kettering Cancer Center, New York, NY

2024: Robert Brodsky, MD
Johns Hopkins Family Professor of Medicine and Oncology, Director, Division of Hematology Johns Hopkins University School of Medicine, Baltimore, MD

AN INTERVIEW WITH 2024 T. HOWARD LEE PRESENTER: ROBERT A. BRODSKY, MD

Forever Inspiring and Leading from the Front - Getting to Know Robert A. Brodsky, MD

Written by Nicola Donelan



Professor Robert A. Brodsky requires no introduction, he is after all a world-renowned hematologist who is no stranger to the Annual Indy Hematology Review, having attended it over the years at least 10 times. This year he will be there in person and giving the T. Howard Lee Keynote Lecture.
Brodsky is a professor of medicine and the director of the Division of Hematology at Johns Hopkins School of Medicine in Baltimore. He served as president of the American Society of Hematology (ASH) in 2023, where he has been a member for 30 years. Brodsky is also the director of the T32 Research Training Program in Hematology at Johns Hopkins that trains MDs, PhDs, and MD/PhDs in academic hematology.

MENTORSHIP

"If you want to go fast, go alone. If you want to go far, go together." – African Proverb

Robert's father, **Isadore Brodsky, MD**, was a well-known hematologist and his first mentor. They had a very close relationship on many levels, as father and son, student, and mentor and eventually as collaborators. At Vanderbilt University, Brodsky had two exceptional mentors, **Sanford Krantz, MD**, who was the head of hematology at the time, and John Oates, MD, the head of medicine. Both men encouraged him to pursue research in the laboratory, which led him to become a physician-scientist following in their footsteps. The experience of being in a lab enabled Brodsky to better understand the intricacies of hematology by providing him with a solid understanding of molecular biology and biochemistry. Brodsky enjoyed being in the lab and went on to spend three years at the National Institutes of Health (NIH) in the lab of **Arthur Nienhuis, MD**, who was a former president of ASH in 1994, and an editor of Blood. Dr. Niehuis ran a large lab and was a very busy man recalls Dr. Brodsky. Fortunately, there was no shortage of very knowledgeable people in the lab who were very generous with their time and taught him valuable skills. People like **David Bodine, PhD, Steve Jane, MD**, and **Elio Vanin, PhD** were really instrumental in teaching him molecular biology techniques taught such Western blots, Southern blots, and polymerase chain reactions. Richard Jones, MD was Brodsky's mentor at John Hopkins, and it was Dr. Jones (fondly known as Rick by Brodsky) who taught him the critical value of translational research.

Professor Brodsky was very fortunate to have had such a talented team of mentors that came into his life and he in return has been an invaluable mentor to many others. Closest to home, are his two sons, Max and Brett, who have both followed in his footsteps in to medicine. Then there is Dr. Ruemu Birhiray, who admires and is constantly inspired by Rob, as he refers to him fondly. Ruemu was a Hematopoietic Stem Cell Transplant (HSCT) fellow when he met Rob in 1998 at John Hopkins University in Baltimore. At that time Brodsky was an assistant professor working in the HSCT department and he was immediately welcoming and started mentoring Ruemu. Brodsky's research at the time focused on the use of cyclophosphamide

immunosuppressive therapy in patients with super severe aplastic anemia with the hope of avoiding allogeneic hematopoietic transplantation, an idea thought of at time as "crazy" recalled Dr. Birhiray.

"Rob taught me the principle of believing and trusting your own scientific instincts and using your deep insight to promote clinical knowledge and practice while using proven and new methods to improve science and discovery," said Ruemu.

ADVANCES IN TREATING PNH

Treating complement-mediated disorders has been and remains today the main focus area for Professor Brodsky. He remembers decades ago as a new physician when there were no treatments for paroxysmal nocturnal hemoglobinuria (PNH) and thrombosis was a common cause of death. There is a vast difference today, presently PNH patients have a normal life span with minimal symptoms due to the invention of complement inhibitors. Eculizumab (Soliris) was approved in 2007 and ravulizumab (Ultomiris) was approved in 2018 by the FDA, both drugs specifically target and block the C5 complement protein, which is a key player in the hemolysis process. Most recently a third drug, iptacopan, was approved in December 2023 based on the findings of the phase III APPLY-PNH trial. Iptacopan is a first-in-class, small molecule complement inhibitor that targets factor B. By doing so it inhibits the production of C5a, another molecule that is essential for the hemolysis process. Iptacopan (Fabhalta) is an oral drug unlike the previous anti-C5 therapies that require IV infusion, and this represents a major leap in the treatment of PNH. Professor Brodsky was the lead inventor of all three of these life changing therapies.

A few months ago, during a conversation between Dr. Birhiray and Professor Brodsky about the new oral therapy for PNH, Brodsky warned physicians to use caution when prescribing oral iptacopan. ***"Patients on ravulizumab are not at risk for thrombosis even if they come in a week late for treatment, but this is not the case for the oral therapies", said Brodsky***. If a patient misses one dose of iptacopan they would probably be fine, but missing two doses, according to Brodsky will lead to massive hemolysis, leading to massive thrombosis and that is what worries him. He advised that iptacopan should be used in patients who primarily have hemolytic PNH with no overt thrombosis, and in patients who have a good reputation of being compliant. Professor Brodsky will give the **T. Howard Lee Keynote Lecture: The Emerging Story of Complementopathies: Treatment of Paroxysmal Nocturnal Hemoglobinuria and Aplastic Anemia**

"Rob remains a great friend and mentor. Forever inspiring and leading from the front. A great supporter of our educational efforts in Indianapolis," said Dr. Birhiray.

Sources:

1. Pulling Back the Curtain: Robert A. Brodsky, MD https://ashpublications.org/ashclinicalnews/news/6659/Pulling-Back-the-Curtain-Robert-A-Brodsky-MD
2. Robert A. Brodsky, MD, Begins Term as 2023 ASH President https://www.hematology.org/newsroom/press-releases/2023/robert-brodsky-begins-term-as-2023-ash-president

EXHIBITOR LISTING

As of 2/8/2024

AbbVie
AcroTech BioPharma
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An Interview with Professor Steven P. Treon, MD, MA, PhD, FRCP, FACP
Every day is an opportunity to find a cure for Waldenstrom's Macroglobuliemia

Written by Nicola Donelan

Enthusiastic and interested in science from an early age, the young Steven Treon competed in science fairs during middle and high school. He found research related to medicine the most exciting, and this had a profound effect on Treon which led him to medical school, and the rest is history.

Professor Treon's journey to becoming an oncologist was forged in his third year of medical school while he was caring for a patient. The patient was a young and vibrant pilot who had one of the worst forms of circulating multiple myeloma. Treon recalls spending the night pressing down on the dressing on his bone marrow biopsy site so he would stop bleeding. Over the next few months this patient received chemotherapy and Treon got to know him quite well. ***"He became very sick because of the chemotherapy and his deteriorating disease and did not look anything like the 40-year-old vibrant individual that I first met," explained Treon. "His case inspired me to learn more about myeloma and ways to better treat this awful disease," said Treon***. When asked what his daily motivation is, Professor Treon stated that every day is an opportunity to find a cure for Waldenstrom's Macroglobuliemia (WM). ***"Despite improvements in the survival of patients with this disease, we still lack a cure," he said.*** However, over the past decades the progress that has been made in developing targeted therapies for WM is formidable. ***"Our research has opened up new chapters on understanding the pathogenesis of WM, and we have assembled an incredible team that is devoted to finding a cure," said Treon***.

The majority of WM patients (95-97%) have MYD88 mutations, and this discovery was made in Professor Treon's laboratory using whole-genome sequencing. Targeting MYD88 signaling is Treon's current research focus area. BTK as a key molecule in MYD88 signaling was discovered in his lab, where research led to the development of ibrutinib and zanubrutinib, both FDA approved BTK inhibitors.

In terms of treatment options that are currently or soon to be available, Professor Treon believes that both BTK and BCL2 inhibitors are highly active and well tolerated treatments for WM. Venetoclax is a BCL2 inhibitor that was recently tested in combination with ibrutinib in symptomatic treatment-naïve WM. By itself, venetoclax was very active in previously treated patients producing a major response in 81% of patients, it was well tolerated with neutropenia being the key concern. Given these findings, a phase II trial of venetoclax combined with ibrutinib was initiated by the team at Dana-Farber led by Dr. Jorge Castillo. The results were recently published in BLOOD and showed this combination to be highly effective with a VGPR rate of 42% and a 24-month PFS rate of 76%. Unfortunately, the trial was discontinued early due to occurrence of unexpected ventricular arrhythmia. A study presented at ASH 2023 by Treon's team studied the molecular impact of BCL-2 inhibition and showed that more robust eradication of mutated MYD88 occurred with BCL-2 versus BTK inhibitors. A study that Professor Treon and his team are now focused on is the development of sonrotoclax (BGB-11417), a second-generation

BCL2 inhibitor with a greater potency than that of venetoclax in biochemical assays. ***"Sonrotoclax has the potential to offer more convenient and possibly safer administration than first-generation BCL2 inhibitors," explained Treon***.

Professor Treon mentioned another ongoing trial with pirtobrutinib, a highly selective, non-covalent (reversible) BTK inhibitor. ***"The new non-covalent pirtobrutinib is an exciting option for managing patients with resistance to covalent BTK inhibitors like ibrutinib and zanubrutinib," said Treon***. A clinical trial combining pirtobrutinib and venetoclax is ongoing at Dana-Farber. The options for treating WM are increasing and Treon also expressed enthusiasm about the BTK degrader BGB-16673 which shows nice activity in patients who have seen covalent and non-covalent BTK inhibitors and not responded. Most recently his team has also been developing ways to target IRAK and HCK signaling molecules that are responsible for driving the survival of MYD88 mutated lymphomas. ***"While these drugs are early in their development, they are quite promising," said Treon***.

According to Treon, 25 years ago WM patients had a life expectancy of 3-5 years, now this has changed to decades due to the efficacy of new targeted therapies. Specializing in hematology affords medical and doctoral students the opportunity to do research that makes a difference now. ***"I can't think of any other field of medicine that has the potential to make profound and generational improvements in patient care," concluded Professor Treon***.

FDA Approvals - December 2022 – January 2024 for Hematology and Oncology/Hematologic Malignancies

Epiontersen for the treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults

On December 21, 2023, the FDA approved epiontersen (Wainua, AstraZeneca Pharmaceuticals LP) a transthyretin-directed antisense oligonucleotide indicated for the treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults.

Exagamglogene Autotemcel (exa-cel) for the treatment of sickle cell disease (SCD) in patients 12 years and older

On December 8, 2023, the FDA approved exa-cel (Casgevy,Vertex Pharmaceuticals Incorporated) an autologous genome edited hematopoietic stem cell-based gene therapy indicated for the treatment of sickle cell disease (SCD) in patients 12 years and older with recurrent vaso-occlusive crises (VOCs).

Lovotibeglogene autotemcel (lovo-cel) for sickle cell disease (SCD) in patients 12 years and older

On December 8, 2023, the FDA approved lovo-cel (Lyfgenia, Bluebird bio, Inc.) an autologous hematopoietic stem cell-based gene therapy indicated for the treatment of patients 12 years of age or older with sickle cell disease and a history of vaso-occlusive events.

Iptacopan for the treatment of adults with paroxysmal nocturnal hemoglobinuria (PNH)

On December 5, 2023, the FDA approved iptacopan (Fabhalta, Novartis) is a complement factor B inhibitor, indicated for the treatment of adults with PNH.

Pirtobrutinib for chronic lymphocytic leukemia or small lymphocytic lymphoma (CLL/SLL)

On December 1, 2023, the FDA approved pirtobrutinib (Jaypirca, Eli Lilly and Company) for adults with chronic lymphocytic leukemia or small lymphocytic lymphoma (CLL/SLL) who have received at least two prior lines of therapy, including a BTK inhibitor and a BCL-2 inhibitor.

Efbemalenograstim alfa-vuxw for treating neutropenia

On November 16, 2023, the FDA approved efbemalenograstim alfa-vuxw (Ryzneuta, Evive Biotechnology) a leukocyte growth factor indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in adult patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.

ADAMTS13, recombinant-krhn for treating congenital thrombotic thrombocytopenic purpura (cTTP)

On November 9, 2023, the FDA approved ADAMTS13, recombinant-krhn (Adzynma, Takeda) a human recombinant “A disintegrin and metalloproteinase with thrombospondin motifs 13” (rADAMTS13) indicated for prophylactic or on demand enzyme replacement therapy (ERT) in adult and pediatric patients with cTTP.

Ivosidenib for relapsed or refractory myelodysplastic syndromes (MDS)

On October 24, 2023, the FDA approved ivosidenib (Tibsovo, Servier Pharmaceuticals LLC) for adult patients with relapsed or refractory MDS with a susceptible isocitrate dehydrogenase-1 (IDH1) mutation, as detected by an FDA-approved test.

Bosutinib for the treatment of chronic myelogenous leukemia (CML)

On September 26, 2023, the FDA approved bosutinib (Bosulif, Pfizer) for pediatric patients 1 year of age and older with chronic phase (CP) Ph+ chronic myelogenous leukemia (CML) that is newly diagnosed (ND) or resistant or intolerant (R/I) to prior therapy. The FDA also approved a new capsule dosage form available in strengths of 50 mg and 100 mg.

Momelotinib for high-risk myelofibrosis in adults with anemia

On September 15, 2023, the FDA approved momelotinib (Ojjaara, GlaxoSmithKline), a kinase inhibitor indicated for the treatment of intermediate or high-risk myelofibrosis (MF), including primary MF or secondary MF [post- polycythemia vera (PV) and post-essential thrombocythemia (ET)], in adults with anemia.

Motixafortide for autologous transplantation in patients with multiple myeloma

On September 8, 2023, the FDA approved motixafortide (Aphexda, BioLineRx Ltd), a hematopoietic stem cell mobilizer that is indicated in combination with filgrastim (G-CSF) to mobilize hematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in patients with multiple myeloma.

Elranatamab-bcmm for adults with relapsed or refractory multiple myeloma

On August 14, 2023, the FDA approved elranatamab-bcmm (Elrexfio, Pfizer, Inc.), a bispecific B-cell maturation antigen (BCMA)-directed CD3 T-cell engager, for adults with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody.

Talquetamab-tgvs for adults with relapsed or refractory multiple myeloma

On August 9, 2023, the FDA approved talquetamab-tgvs (Talvey, Janssen Biotech, Inc.) for adults with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody.

Quizartinib for the treatment of adult patients with newly diagnosed acute myeloid leukemia (AML)

On July 20, 2023, the FDA approved quizartinib (Vanflyta, Daiichi Sankyo, Inc.) with standard cytarabine and anthracycline induction and cytarabine consolidation, and as maintenance monotherapy following consolidation chemotherapy, for the treatment of adult patients with newly diagnosed acute myeloid leukemia (AML) that is FLT3 internal tandem duplication (ITD)-positive, as detected by an FDA-approved test.

Glofitamab-gxbm for relapsed or refractory diffuse large B-cell lymphoma

On June 15, 2023, the FDA approved glofitamab-gxbm (Columvi, Genentech, Inc.) for relapsed or refractory diffuse large B-cell lymphoma, not otherwise specified (DLBCL, NOS) or large B-cell lymphoma (LBCL) arising from follicular lymphoma, after two or more lines of systemic therapy.

Epcoritamab-bysp for relapsed or refractory diffuse large B-cell lymphoma

On May 19, 2023, the FDA approved epcoritamab-bysp (Epkinly, Genmab US, Inc.) for the treatment of relapsed or refractory diffuse large B-cell lymphoma (DLBCL) not otherwise specified, including DLBCL arising from indolent lymphoma, and high-grade B-cell lymphoma after two or more lines of systemic therapy.

Polatuzumab vedotin-piiq for diffuse large B-cell lymphoma (DLBCL)

On April 19, 2023, the FDA approved polatuzumab vedotin-piiq (Polivy, Genentech, Inc.) with a rituximab product, cyclophosphamide, doxorubicin, and prednisone (R-CHP) for adult patients who have previously untreated DLBCL, not otherwise specified (NOS), or high-grade B-cell lymphoma (HGBL) and who have an International Prognostic Index (IPI) score of 2 or greater.

Omidubicel-onlv for use in umbilical cord blood transplantation following myeloablative conditioning

On April 17, 2023, the FDA approved omidubicel-onlv (Omisirge, Gamida Cell Ltd.) for use in adult and pediatric patients (12 years and older) with hematologic malignancies who are planned for umbilical cord blood transplantation following myeloablative conditioning to reduce the time to neutrophil recovery and the incidence of infection.

Daprodustat for the treatment of anemia due to chronic kidney disease

On February 1, 2023, the FDA approved daprodustat (Jesduvroq, GlaxoSmithKline), a hypoxia-inducible factor prolyl hydroxylase (HIF PH) inhibitor indicated for the treatment of anemia due to chronic kidney disease in adults who have been receiving dialysis for at least four months.

Pirtobrutinib for relapsed or refractory mantle cell lymphoma (MCL)

On January 27, 2023, the FDA granted accelerated approval for pirtobrutinib (Jaypirca, Eli Lilly and Company) to be used for treating relapsed or refractory MCL after at least two lines of systemic therapy, including a BTK inhibitor.

Zanubrutinib for chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL)

On January 19, 2023, the FDA approved zanubrutinib (Brukinsa, BeiGene USA, Inc.) for the treatment of chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL).

Mosunetuzumab-axgb for relapsed or refractory follicular lymphoma (FL)

On December 22, 2022, the FDA granted accelerated approval for mosunetuzumab-axgb (Lunsumio, Genentech, Inc.), a bispecific CD20-directed CD3 T-cell engager for adult patients with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy.

Olutasidenib for the treatment of relapsed or refractory acute myeloid leukemia (AML)

On December 1, 2022, the FDA approved olutasidenib (Rezlidhia, Rigel Pharmaceuticals, Inc) capsules for adult patients with relapsed or refractory acute myeloid leukemia (AML) with a susceptible IDH1 mutation as detected by an FDA-approved test.

INTRODUCING THE "NAME" SPONSOR: COMMUNITY HEALTH NETWORK MD ANDERSON CANCER CENTER

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Community MD Anderson is one of a select few partners with MD Anderson, a global leader in cancer care, and the only partner in Indiana. Based in Houston, Texas, MD Anderson has been named one of the nation's top two hospitals for cancer care by US News and World Report every year since the survey began in 1990.

Physicians with Community MD Anderson and MD Anderson in Houston are clinically and operationally integrated, simplifying access to MD Anderson specialists and researchers for consultations and second opinions.

An Interview with ASCO President Elect, Dr. Robin Zon

Written by Nicola Donelan

FROM CHEMIST TO ONCOLOGIST

Dr. Zon described her career journey as atypical. She graduated from college with a degree in Chemistry and started working at Dow Chemical as part of her college co-op program. She moved from working with oxides and intermediates, to the diagnostic divisions, and then post- graduate she continued with Dow in their pharmacologic division where she stayed for several years. Zon then moved on to Boehringer Mannheim and helped build up the research and development building in Indianapolis where she was one of the first five employees. After spending a couple years there managing a lab and transferring technology, she decided to start medical school.

According to Dr. Zon, there were a few pivotal experiences in her life that led her to follow a career path to becoming an oncologist. ***"I knew that I was destined to become a physician and work in cancer when I was in junior high school, the moment I heard President Nixon's declaration of the War on Cancer in 1971," she explained***. Hearing his speech at a very impressionable age, along with her interest in science had a great impact on her. Later, while working at Dow she lost her supervisor and friend to stage 4 breast cancer, subsequently with both personal and professional interests she was guided to the field of oncology.

MOTIVATION

"I often say that I have the best job in the world," stated Dr. Zon. She is constantly inspired by the incredible advances in cancer care both nationally and internationally, which at one time people just dreamed about. "Research and the willingness of patients to be part of the solution by participating in clinical trials is remarkably inspiring," she said.

Her motivation comes from being able to wake up each day to something new and exciting that will alter somebody's life somewhere in a positive manner. Dr. Zon realized that in addition to managing the clinical side of cancer care, she enjoys the "extras'". This includes empowering advocacy and working for patients to get the best care they can while working with the other stakeholders to help achieve maximum benefit. "***My mission is to apply the knowledge we have gained to conquer cancer. I enjoy embracing diverse communities and learning how people deliver care in different environments. But most importantly, what really motivates me is caring for patients and having that relationship with the patients and their families as they navigate their journey with cancer," said Dr. Zon***. She considers it an incredible privilege to be able to help patients get through their journeys and to be their beacon of hope and a generous collaborator, regardless of what the outcome is, while promoting what they wish, and living the ***"together we are stronger than cancer"*** mantra.

PRECISE TREATMENTS AND NEW TECHNOLOGIES ARE KEY TO PROGRESS IN CANCER CARE

According to Dr. Zon, due to advancing research and discovery, cancer care is becoming more precise. She listed several tools that are propelling cancer care to be more deliberate and exact by matching treatment to patients including: - precision medicine, immunotherapy, genomic and genetic driven cancer care. She strongly believes that this is where oncology care is currently and will continue to evolve and improve from here on. "The promise lies in the continuation of developing therapies that have less toxicity and maximum benefit and are more precisely tailored to the patient's particular cancer characteristics, while supporting their wishes and goals," said Dr. Zon.

The pertinent point of discussion that Dr. Zon brought up next was how she thinks technology will change the face of how we practice medicine and potentially reduce disparities and maximize benefit. She believes that liquid biopsies and artificial intelligence are two such technologies that will have a significant impact in this arena.

"Liquid biopsies are being used in both clinical trials as well as in clinical practice daily and have really come of age in the last few years," said Dr. Zon. A liquid biopsy is defined by the National Cancer Institute as a test done on a sample of blood to look for cancer cells from a tumor that are circulating in the blood or for pieces of DNA from tumor cells that are in the blood. Dr. Zon would like the medical community to define the criteria and standards needed to be fulfilled in order for physicians to reliably use this technology in an impactful and safe manner. She believes that monitoring disease by measuring circulating tumor DNA (ctDNA) can have several advantages over traditional biopsies that include improved patient comfort. Patients would much sooner have a blood draw versus a biopsy which comes with inherent complications and sometimes inadequate sampling. ***"Liquid biopsy is also an option to relieve the bottleneck we are currently experiencing in trying to get traditional biopsies ordered and scheduled," explained Dr. Zon***. Another critical advantage of using liquid biopsy technology Dr. Zon pointed out, is the potential it has to help address some of the disparate care by making it easier to get diagnoses and treatment plans without costly time consuming and distance prohibitive biopsies.

Artificial intelligence (AI) is the second technology that Dr. Zon believes will have a huge impact on improving cancer care. Research from many teams has demonstrated how radiology and pathology have been able to be improved with regards to diagnostic accuracy with utilization of AI. "Now there is potential to use AI in many ways for cancer care, including pairing patients with clinical trial opportunities, better linking precision medicine therapeutic options with patient characteristics, and even using AI to help with supportive care, and in the future, to support the entire cancer care spectrum," said Dr. Zon. AI's capacity is constantly evolving, it is even being utilized to help with reducing administrative burden for the physicians and cancer care teams. Although it may sound ironic, Zon believes that AI will help lead the process of returning humanity to the practice of medicine.

BECOMING BETTER VERSIONS OF OURSELVES

When asked what she would advise a medical student considering oncology hematology as their specialty Dr. Zon enthusiastically said that working in the field of oncology and hematology is one of the most incredible opportunities that anybody can ever have in a lifetime. ***"If you have a calling to be involved in oncology or hematology or research, accept this as a gift- as not only will your work benefit others but it will provide personal fulfillment beyond expectations," said Dr. Zon***. She describes the field as overflowing with a wealth of new knowledge being gained, the potential for new knowledge yet to be developed, new and better research questions to be answered. The opportunity to help patients and their families to realize the benefit of advances in medicine, outside influencers in terms of technology is key as according to Zon it will not only translate to better patient care, but also improve our ability to spend more time caring for patients and doing more effective and efficient care and research.

"At the end of the day, because of these opportunities, we get to be better versions of ourselves every day," said Zon.

Indy Hematology Education, Inc.
Achieving tomorrow's outcomes through education today™

Indy Hematology Education, Inc, is a 501(c), non-profit corporation, incorporated on February 15, 2010, in the State of Indiana, with the following purposes:

(a) Raise awareness and provide education regarding hematology and oncology diseases and disorders
(b) To encourage youth to pursue careers in hematology and oncology, and
(c) To connect individuals suffering from or affected by hematology and oncology diseases and disorders to organizations, programs, and service providers.

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Partner, Hematology Oncology of Indiana, a Division of American Oncology Network
Clinical Professor, Marian University College of Osteopathic Medicine

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Meeting Services Unlimited Inc.
Director of Conventions

EMERGING THERAPIES

WHAT DOES IT ALL MEAN? My thoughts

The Indy hematology review 2024 meeting has resulted in the presentation of amazing clinical data that would certainly continue to alter the outcomes of our patients and thus, using education today would ultimately result in improved clinical results in the future. Below are my thoughts on the data presented at the 2024 meeting.

PRACTICE Changing:

- MENIN INHIBITORS in R/R KMNT2r/NPM1 mutant AML; REVUMENIB
- NIVOLUMAB as initial therapy in HODGKINS LYMPHOMA (SWOG1836)
- FIRST LINE ANTI CD38 MONOCLONAL ANTIBODY THERAPY: DARATUMUMAB (PERSEUS)
- FIXED DURATION THERAPY IN CLL: Ibrutinib and Venetoclax; FLAIR
- GENE THERAPY IN SCD: Exagamglogene autotemcel (exa-cel), and Lovotibeglogene Autotemcel (Lovo-cel)
- REDUCED-INTENSITY HAPLO-IDENTICAL HSC TRANSPLANTION in SCD: BMT CTN 1507
- DANICOPAN (APHA) and IPTACOPAN (APPLY-PNH) in PNH
- MPNS: BEYOND JAK INHIBITION: Navitoclax + Ruxolitinib (TRANSFORM-1:), and Pelabresib + Ruxolitinib (MANIFEST-2:)
- BEYOND ESAs in MDS ASSOCIATED ANEMIA: luspatercept (COMMANDS), and Imetelstat (IMERGE)
- Axatilimab (high-affinity anti–CSF-1R monoclonal antibody) in Chronic GVHD (AGVAE-201)

Potentially Practice Changing:

- FIRST LINE ANTI CD38 MONOCLONAL ANTIBODY THERAPY : ISATUXIMAB (IsKIA)
- Ibrutinib +Venetoclax for relapsed in Mantle Cell Lymphoma: SYMPATICO
- Marstacimab (Anti-Tissue Factor Pathway Inhibitor) in Severe Hemophilia without Inhibitors
- BCR/abl ALLOSTERIC INHIBITOR THERAPY IN CML: ASCIMINIB
- POMALIDOMIDE in Hereditary Hemorrhagic Telangiectasia

Practice Confirming

- BISPECIFIC antibodies in lymphomas: Glofitamab, Epcoritamab, Mosunetuzumab, Odronextamab
- BISPECIFIC antibodies in Multiple Myeloma: Teclistimab, Elranatamab, Talquetamab
- BLINATUMUMAB as Initial therapy in ALL

Stay Tuned

- Selenexor in AML
- Itacitinib for the Prevention of ICANS
- CD19-Targeting CAR T-Cell Therapy in Transformed Waldenström Macroglobulinemia/ Lymphoplasmacytic Lymphoma
- Anti-Amyloid Monoclonal Antibody, Combined with Anti-Plasma Cell Dyscrasia Therapy in Patients with Light-Chain Amyloidosis (CAEL-101)
- Valemetostat (EZH1/2 inhibitor) in R/R PTCL

Ruemu E. Birhiray, MD
Chair, Indy Hematology Review

CONTINUING EDUCATION INFORMATION

The continuing education portion of this activity is being supported by ineligible companies in the form of independent medical education grants. All companies and relationships will be disclosed and mitigated prior to the start of the activity.

PHYSICIANS

In order to receive CE, you must attend the entire Symposium from 7:30 am – 7:15 pm. Successful completion of this CME activity requires participants to complete a Post-Evaluation.

Successful completion of this CME activity, which includes participation in the evaluation component, enables the participant to earn up to 10.0 Medical Knowledge MOC points in the American Board of Internal Medicine's (ABIM) Maintenance of Certification (MOC) program. It is the CME activity provider's responsibility to submit participant completion information to ACCME for the purpose of granting ABIM MOC credit.

Learning Objectives (ACCME, ANCC, ACPE)

Upon completion of this activity, the participant should be able to:

1. Analyze the new data and research available from respected institutions.
2. Assess new therapies available to treat patients and know how to incorporate these therapies into practice.
3. Evaluate new drug therapies including the mechanism of action (MOA).
4. Identify barriers that may prevent healthcare professionals from implementing new therapies into their practice and understanding steps they can take to address these barriers.
5. Modify current practice to improve patient outcomes by incorporating the most current therapies for hematologic malignancies to increase equitable optimal management of treatment plans and care to patients to minimize risk and adverse effects (e.g., toxicity) and improve patient outcomes, survival and quality of life.
6. Evaluate the best treatment options for AML patients where transplantation is not an option.
7. Identify the emerging and targeted therapies for the treatment of Relapsed and Refractory AML and describe how to put these treatment options into practice.
8. Identify the emerging treatment options for Myelodysplastic Syndromes and describe how to put these treatment options into practice.
9. Discuss treatment options for managing patients with Chronic Myeloid Leukemia in the current landscape.
10. Identify the new treatment options for Multiple Myeloma and describe how to put these treatment options into practice.
11. Describe management of adverse reactions to Multiple Myeloma therapy.
12. Review the emerging treatment options for Relapsed / Refractory Multiple Myeloma and describe how to put these treatment options into practice.
13. Evaluate the most current and treatment options for Waldenstrom's Macroglobulinemia.
14. Assess and adjust diagnostic and treatment strategies for patients with Amyloidosis to include latest options.
15. Describe the current landscape surrounding treatment recommendations for patients with Paroxysmal Nocturnal Hemoglobinuria and Aplastic Anemia.
16. Identify the most effective therapies needed to manage bleeding and clotting disorders such as Sickle Cell Disease.
17. Evaluate the diagnosis for Myeloproliferative Neoplasms including how best to treat this disease.
18. Improve the management of patients with Myelofibrosis, Philadelphia Chromosome Negative Myeloproliferative Neoplasms and Systemic Mastocytocsis in their practice.
19. Identify the emerging treatment options for Acute Lymphoblastic Leukemia and describe how to put these treatment options into practice.
20. Explain how to effectively implement new Immune Effector Cell therapies for Lymphoid Malignancies in a community practice.
21. Evaluate the diagnosis for cellular blood disorders including how best to treat Initial and Relapsed Chronic Lymphocytic Leukemia.
22. Explain when it is important to "watch and wait" vs. treating patients with Indolent Lymphoma and Mantle Cell Lymphoma.
23. Adjust diagnostic and treatment strategies for patients with Hodgkin's Lymphoma to include latest options.
24. Identify the emerging treatment options for Aggressive B and T Cell Lymphomas and describe how to put these treatment options into practice.
25. Explain how to effectively implement new Immune Effector Cell therapies for Multiple Myeloma in a community practice.
26. Discuss when it is important to refer vs. treat patients who have had Hematopoietic Transplantation and are on Cellular therapies.

Physician Accreditation Statement

This live activity has been planned and implemented in accordance with the accreditation requirements and policies of the Accreditation Council for Continuing Medical Education (ACCME) through the joint providership of Purdue University College of Pharmacy and Indy Hematology Education, Inc. Purdue University is accredited by the ACCME to provide continuing medical education for physicians.

Credit Designation Statement

Purdue University College of Pharmacy designates this live activity for a maximum of *10 AMA PRA Category 1 Credit(s)™*. Symposium – 7:30 am – 7:15 pm. Purdue University College of Pharmacy designates this live activity for a maximum of *1.0 AMA PRA Category 1 Credit(s)™* (Town Hall Interactive Meeting - 7:30 - 8:30 pm). Physicians should claim only the credit commensurate with the extent of their participation in the activity.

Faculty and Disclosure / Conflict of Interest Policy

To ensure compliance with the ACCME Standards for Integrity and Independence in Accredited Continuing Education, Purdue University requires that all individuals in a position to control the content of an educational activity disclose all financial relationships occurring within the past 24 months with ineligible companies whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients. All relevant conflicts of interest identified are thoroughly assessed by Purdue University to ensure fair balance, scientific rigor, and accepted patient care recommendations of the educational activity.

Disclosures will be provided prior to the start of the activity. All relevant conflicts of interest will have been mitigated prior to the start of the activity.

None of the planners, reviewers, Indy Hematology Education, and Purdue University College of Pharmacy staff have relevant financial relationship(s) with ineligible companies to disclose unless listed below.

NURSES

In order to receive CE, you must attend the entire Symposium from 7:30 am – 7:15 pm. Successful completion of this CME activity requires participants to complete a Post-Evaluation.

Nurses Accreditation Statement

Purdue University Continuing Nursing Education is accredited as a provider of nursing continuing professional development by the American Nurses Credentialing Center's Commission on Accreditation.

This program is approved for 9.5 contact hours (Symposium: 7:30 am – 7:15 pm). This program is approved for 1.0 contact hour (Town Hall Interactive Meeting: 7:30 pm - 8:30 pm).

PHARMACISTS

In order to receive CE, you must attend the entire Symposium from 7:30 am – 7:15 pm. Successful completion of this CME activity requires participants to complete a Post-Evaluation.

Pharmacists Accreditation Statement

Purdue University College of Pharmacy is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. This is a knowledge based, continuing education activity of Purdue University, an equal access/ equal opportunity institution.

Symposium: 7:30 am - 7:15 pm.

Universal Activity Number (UAN): 0018-9999-24-001-L01-P

This program is approved for 9.5 contact hours (0.95 CEU's).

Town Hall Interactive Meeting: 7:30 pm - 8:30 pm.

Universal Activity Number (UAN): 0018-9999-24-001-L01-P

This program is approved for 1.0 contact hours (0.10 CEU's).

WEBSITE: http://www.indyhematologyreview.com/

POST EVALUATION AND SURVEY

All participants that successfully complete the CME, CNE or CPE activity, and complete the post evaluation component, no later than **March 15, 2024**, are eligible to receive Continuing Education Credits. In addition, participants wanting Medical Knowledge MOC points in the American Board of Internal Medicine's (ABIM) Maintenance of Certification (MOC) program must also complete the additional post survey, no later than **March 15, 2024**. All Continuing Education Credit/MOC is forfeited if participant does not complete post evaluation and/or survey no later than **March 15, 2024**. **NO EXCEPTIONS!**

NOTE: While it offers CME credits, this activity is not intended to provide extensive training or certification in the field.

EDUCATIONAL GRANTS

The 2024 INDY HEMATOLOGY REVIEW is supported by Educational Grants from:

AstraZeneca
Bristol Myers Squibb
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JOIN US FOR THE
22ND ANNUAL INDY HEMATOLOGY REVIEW
SATURDAY, MARCH 8, 2025
THE WESTIN INDIANAPOLIS

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NOTES:

NOTES:

MonoFerric®
(ferric derisomaltose)
injection

IV IRON REPLACEMENT IN JUST ONE DOSE[1,*]

Monoferric is FDA approved for 1000 mg in a single, rapid infusion[1]

**Intravenous infusion over at least 20 minutes. Repeat dose if iron deficiency anemia reoccurs.*

FDA-APPROVED IV IRON REPLACEMENT THAT CAN ADMINISTER UP TO 1000 mg WITH A SINGLE INFUSION IN ≥20 MINUTES[1]

VISIT WWW.MONOFERRIC.COM TO LEARN HOW MONOFERRIC PROVIDES A **SLOW AND CONTROLLED RELEASE OF IRON FOR PATIENTS WITH IRON DEFICIENCY ANEMIA[1,2]**

INDICATIONS

Monoferric is indicated for the treatment of iron deficiency anemia (IDA) in adult patients:

- who have intolerance to oral iron or have had unsatisfactory response to oral iron
- who have non-hemodialysis dependent chronic kidney disease (NDD-CKD)

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

Monoferric is contraindicated in patients with a history of serious hypersensitivity to Monoferric or any of its components. Reactions have included shock, clinically significant hypotension, loss of consciousness, and/or collapse.

WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions

Serious hypersensitivity reactions, including anaphylactic-type reactions, some of which have been life-threatening and fatal, have been reported in patients receiving Monoferric. Patients may present with shock, clinically significant hypotension, loss of consciousness, and/or collapse. Monitor patients for signs and symptoms of hypersensitivity during and after Monoferric administration for at least 30 minutes and until clinically stable following completion of the infusion. Only administer Monoferric when personnel and therapies are immediately available for the treatment of serious hypersensitivity reactions. Monoferric is contraindicated in patients with prior serious hypersensitivity reactions to Monoferric or any of its components. In clinical trials in patients with IDA and CKD, serious or severe hypersensitivity were reported in 0.3% (6/2008) of the Monoferric treated subjects. These included 3 events of hypersensitivity in 3 patients; 2 events of infusion-related reactions in 2 patients and 1 event of asthma in one patient.

Iron Overload

Excessive therapy with parenteral iron can lead to excess iron storage and possibly iatrogenic hemosiderosis or hemochromatosis. Monitor the hematologic response (hemoglobin and hematocrit) and iron parameters (serum ferritin and transferrin saturation) during parenteral iron therapy. Do not administer Monoferric to patients with iron overload.

ADVERSE REACTIONS

Adverse reactions were reported in 8.6% (172/2008) of patients treated with Monoferric. Adverse reactions related to treatment and reported by ≥1% of the treated patients were nausea (1.2%) and rash (1%). Adjudicated serious or severe hypersensitivity reactions were reported in 6/2008 (0.3%) patients in the Monoferric group. Hypophosphatemia (serum phosphate <2.0 mg/dL) was reported in 3.5% of Monoferric-treated patients in Trials 1 & 2.

To report adverse events, please contact Pharmacosmos at 1-888-828-0655. You may also contact the FDA at www.fda.gov/medwatch or call 1-800-FDA-1088.

Please see Brief Summary of Prescribing Information on adjacent pages.

1. Monoferric (ferric derisomaltose) Prescribing Information; Pharmacosmos Therapeutics Inc., Morristown, NJ: 2020.
2. Jahn MR, Andreasen HB, Fütterer S, et al. *Eur J Pharm Biopharm.* 2011;78(3):480-491.

PHARMACOSMOS THERAPEUTICS

MonoFerric®
(ferric derisomaltose)
injection

BRIEF SUMMARY OF PRESCRIBING INFORMATION

MONOFERRIC (ferric derisomaltose) injection

INDICATION AND USAGE: Monoferric is an iron replacement product indicated for the treatment of iron deficiency anemia in adult patients:

- who have intolerance to oral iron or have had unsatisfactory response to oral iron.
- who have non-hemodialysis dependent chronic kidney disease.

DOSAGE AND ADMINISTRATION: For patients weighing 50 kg or more: Administer 1,000 mg of Monoferric by intravenous infusion over at least 20 minutes as a single dose. Repeat dose if iron deficiency anemia reoccurs.

For patients weighing less than 50 kg: Administer Monoferric as 20 mg/kg actual body weight by intravenous infusion over at least 20 minutes as a single dose. Repeat dose if iron deficiency anemia reoccurs.

The dosage of Monoferric is expressed in mg of elemental iron. Each mL of Monoferric contains 100 mg of elemental iron.

Only administer Monoferric when personnel and therapies are immediately available for the treatment of serious hypersensitivity reactions.

DOSAGE FORMS AND STRENGTHS: Monoferric is a sterile, dark brown, non-transparent aqueous solution available as:

- Injection: 1,000 mg iron/10 mL (100 mg/mL) single-dose vial

CONTRAINDICATIONS: Monoferric is contraindicated in patients with a history of serious hypersensitivity to Monoferric or any of its components. Reactions have included shock, clinically significant hypotension, loss of consciousness, and/or collapse.

WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions: Serious hypersensitivity reactions, including anaphylactic-type reactions, some of which have been life-threatening and fatal, have been reported in patients receiving Monoferric. Patients may present with shock, clinically significant hypotension, loss of consciousness, and/or collapse. Monitor patients for signs and symptoms of hypersensitivity during and after Monoferric administration for at least 30 minutes and until clinically stable following completion of the infusion. Only administer Monoferric when personnel and therapies are immediately available for the treatment of serious hypersensitivity reactions. Monoferric is contraindicated in patients with prior serious hypersensitivity reactions to Monoferric or any of its components. In clinical trials in patients with IDA and CKD, serious or severe hypersensitivity were reported in 0.3% (6/2008) of the Monoferric treated subjects. These included 3 events of hypersensitivity in 3 patients; 2 events of infusion-related reactions in 2 patients and 1 event of asthma in one patient.

Iron Overload: Excessive therapy with parenteral iron can lead to excess iron storage and possibly iatrogenic hemosiderosis or hemochromatosis. Monitor the hematologic response (hemoglobin and hematocrit) and iron parameters (serum ferritin and transferrin saturation) during parenteral iron therapy. Do not administer Monoferric to patients with iron overload.

ADVERSE REACTIONS

Clinical Trials Experience: Because clinical trials are conducted under widely varying conditions, the adverse reaction rates observed cannot be directly compared to rates in other clinical trials and may not reflect the rates observed in clinical practice.

The safety of Monoferric was evaluated in 3008 patients with iron deficiency anemia enrolled in two randomized, actively-controlled trials. Trial 1 enrolled adult patients with iron deficiency anemia with intolerance to oral iron or had an unsatisfactory response to oral iron with a clinical need for repletion of iron stores. Eligible subjects were required to have a baseline hemoglobin of ≤11g/dl, transferrin saturation (TSAT) <20% and serum ferritin level of <100 ng/mL. Trial 2 enrolled adult patients with non-dialysis dependent chronic kidney disease. Eligible subjects also had to have serum ferritin ≤100 ng/mL or ≤300 ng/mL if TSAT ≤30%.

Trial 1 and Trial 2: In the two randomized, actively-controlled clinical trials, Trial 1 and Trial 2, patients were randomized in a 2:1 ratio to intravenous Monoferric (n = 2008) or intravenous iron sucrose (n = 1000) respectively. Monoferric was administered as a single intravenous infusion of 1000 mg diluted in 100 mL 0.9 % sodium chloride and given over approximately 20 minutes (approximately 50 mg iron/min). Iron sucrose was administered as 200 mg undiluted intravenous injections over approximately 2–5 minutes and repeated according to standard practice or physician choice up to a maximum of five times (1000 mg) within the first two weeks starting at baseline.

The data described below reflect exposure to Monoferric in 2008 patients exposed to a 1000 mg single intravenous dose of Monoferric. The mean cumulative intravenous iron exposure was 984 mg.

Trial 1 included 1483 patients with iron deficiency anemia in the safety analysis that had intolerance to oral iron or have had unsatisfactory response to oral iron or with a clinical need for rapid repletion of iron stores. Trial 2 included 1525 patients in the safety analysis who had non-dialysis dependent CKD. The mean (SD) age of the combined study population was 56.4 (18.3) years. The majority of patients were women (75.7%).

Adverse reactions were reported in 8.6% (172/2008) of patients treated with Monoferric.

Adverse reactions related to treatment and reported by ≥1% of the treated patients in the combined analysis of Trial 1 and 2 are listed in Table 1.

Table 1. Adverse Reactions (≥1%) in Patients Receiving Monoferric in Clinical Trials 1 and 2

	Monferric (N = 2008) N (%)	Iron Sucrose (N = 1000) N (%)
Adverse Reaction		
Nausea	24 (1.2)	11 (1.1)
Rash	21 (1)	1 (0.1)

Adjudicated serious or severe hypersensitivity reactions were reported in 6/2008 (0.3%) patients in the Monoferric group.

Hypophosphatemia (serum phosphate <2.0 mg/dL) was reported in 3.5% of Monoferric-treated patients in Trials 1 & 2.

Post-marketing Experience: Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure. The following adverse reactions have been most commonly reported from the post-marketing spontaneous reports with Monoferric:

Cardiac disorders: Tachycardia

Gastrointestinal disorders: Abdominal pain, nausea and vomiting, constipation, diarrhea

General disorders and administration site conditions: Fatigue, pyrexia, chest pain, chills, Fishbane reaction, extravasation, influenza like symptoms, injection site reactions, malaise, pain

Immune System disorders: Anaphylactic/anaphylactoid reaction, hypersensitivity

Investigations: Hepatic enzymes increased

Musculoskeletal and connective tissue disorders: Back pain, muscle spasms, arthralgia, myalgia

Nervous system disorders: Dizziness, headache, paresthesia, dysgeusia, seizure, loss of consciousness, syncope

Psychiatric disorders: Anxiety

Respiratory, thoracic, and mediastinal disorders: Dyspnea, cough, bronchospasm

Skin and subcutaneous tissue disorders: Erythema, urticaria, discoloration skin, rash, pruritus, skin exfoliation, angioedema, sweating

Vascular disorders: Hypertension, hypotension, flushing, phlebitis

Extravasation of Monoferric at the injection site that may lead to irritation of the skin and potentially long lasting brown discoloration at the site of injection has also been reported.

USE IN SPECIFIC POPULATIONS

Pregnancy: There are no available data on Monoferric use in pregnant women to evaluate for a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes. Published studies on the use of intravenous iron products in pregnant women have not reported an association with adverse developmental outcomes. However, these studies cannot establish or exclude the absence of any drug-related risk during pregnancy because the studies were not designed to assess for the risk of major birth defects. There are risks to the mother and fetus associated with untreated iron deficiency anemia (IDA) in pregnancy as well as risks to the fetus associated with maternal severe hypersensitivity reactions.

Untreated iron deficiency anemia (IDA) in pregnancy is associated with adverse maternal outcomes such as post-partum anemia. Adverse pregnancy outcomes associated with IDA includes increased risk for preterm delivery and low birth weight.

Severe adverse reactions including circulatory failure (severe hypotension, shock including in the context of anaphylactic reaction) may occur in pregnant women with parenteral iron products (such as Monoferric) which may cause fetal bradycardia, especially during the second and third trimester.

Lactation: The available data on the use of Monoferric in lactating women demonstrate that iron is present in breast milk. However, the data do not inform the potential exposure of iron for the breastfed child or the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Monoferric in addition to any potential adverse effects on the breastfed child from the drug or from the underlying maternal condition.

Pediatric Use: Safety and effectiveness have not been established in pediatric patients.

Geriatric Use: Of the 3934 patients in clinical studies of Monoferric, 29% were 65 years and over, while 13% were 75 years and over. No overall differences in safety or effectiveness were observed between these patients and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

CLINICAL STUDIES: The safety and efficacy of Monoferric for treatment of iron deficiency anemia (IDA) were evaluated in two randomized, open-label, actively-controlled clinical trials performed in a total of 3050 patients with IDA of different etiology. Trial 1 included patients with IDA who had intolerance to oral iron or who had had unsatisfactory response to oral iron or for whom there was a clinical need for rapid repletion of iron stores. Trial 2 included patients with IDA who had non-dialysis dependent chronic kidney disease (NDD-CKD). In these two 8-week trials, patients were randomized 2:1 to treatment with Monoferric or iron sucrose. Monoferric was intravenously administered as a single dose of 1000 mg. The efficacy of Monoferric was established based upon the change in Hb from baseline to Week 8. In Trial 1, the mean change in Hb from baseline to Week 8 was 2.49 g/dL (2.41; 2.56) in the Monoferric group versus 2.49 g/dL (2.38; 2.59) in the IS group with an estimated difference of 0.00 (95% CI -0.13; 0.13), non-inferiority confirmed. In Trial 2, the mean change in Hb from baseline to Week 8 was 1.22 g/dL (1.14; 1.31) in the Monoferric group versus 1.14 g/dL (1.03; 1.26) in the IS group with an estimated difference of 0.08 (95%CI -0.06; 0.23), non-inferiority confirmed.

PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Patient Information).

Prior History of Allergies to Parenteral Iron Products: Question patients regarding any prior history of reactions to parenteral iron products.

Hypersensitivity Reactions: Advise patients to report any signs and symptoms of hypersensitivity that may develop during and following Monoferric administration, such as rash, itching, dizziness, lightheadedness, swelling, and breathing problems.

Monoferric is manufactured under license from Pharmacosmos A/S, Denmark.

This is not all the risk information for Monoferric. Please see www.monoferric.com for Full Prescribing Information.

PHARMACOSMOS
THERAPEUTICS

US-FDI-2200077 08/2022

Being diagnosed with cancer can feel like your world's suddenly stopped. That's why we make sure you talk to an expert within 48 hours. So you can start finding the answers you need. With world-renowned cancer care close to home, your circle of support just got stronger.

Learn more at eCommunity.com/cancer

Community Health Network
MD Anderson Cancer Center
Making Cancer History®