17th Annual INDY HEMATOLOGY REVIEW 2020

State of the Art 2020: Emerging Therapies in Hematologic Malignancies

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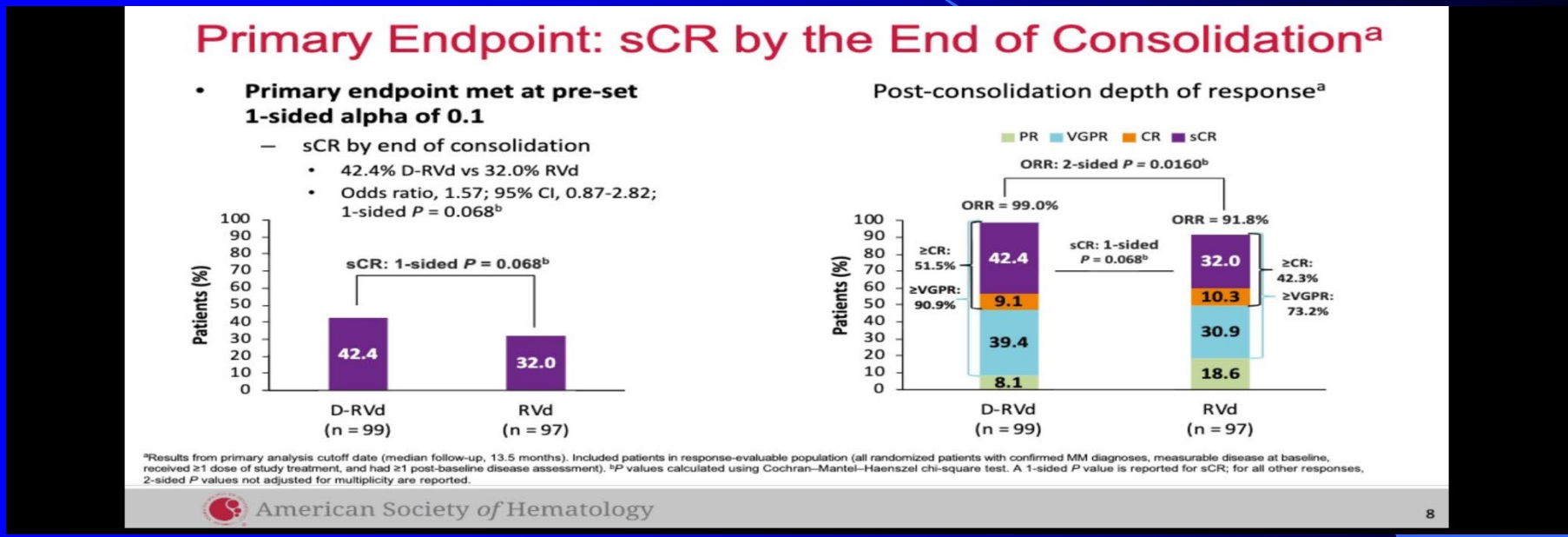
Myeloma: Initial Therapy

- **GRIFFIN**: Phase II Study of Daratumumab + VRd vs VRd Alone for Transplant-Eligible NDMM, N=207, sCR by the end of consolidation: 42.4% vs. 32.0%, no effect on stem cell mobilization, (1-sided *P* = .068), MRD ITT 51% vs. 18.4% (P>0.0001)



- **MASTER:** Phase II, Dara-KRd in Transplant-Eligible NDMM: N=81, 21% African American, 51% High Risk, few discontinuations for toxicity.
- 39% sCR post induction (high risk: 25%) and 95% at MRD-based consolidation.
- **HOVON 143:** Interim Analysis: Phase II, NDMM, frail/unfit, N=46, ixazomib/daratumumab/low-dose dexamethasone, ORR: 74%; mPFS: 23 mos.
- **GEM-CESAR:** Phase II, KRD, for High-Risk Smoldering Myeloma: N=90, End of therapy response (Induction/ASCT/Consolidation): 76% ≥ CR, 63% MRD negative.

TARGETING RELAPSED/REFRACTORY MYELOMA

CD38

- **CANDOR:** N = 466, Phase III, **Carfilzomib, Dexamethasone ± Daratumumab** in R/R MM
- ORR 84.3vs74.7%, > VGPR 69.2 vs 48.7%, > CR28.5 vs., 10.4%, MRD negative at 12 mos (10^{-5}) 17.6 vs. 3.9% (37% reduction in risk of progression /death, MRD-negative CR @12 mos ~10-fold > with KdD vs Kd)

BCMA: B-cell maturation antigen: TNF superfamily cell-surface receptor required for PC survival/signaling

CAR T THERAPY:

- **CARTITUDE-1: JNJ-4528** CAR T-cells with 2 BCMA-targeting domains for increased avidity plus a 4-1BB costimulatory domain (identical to LCAR-B28M), Phase I/IIb, N=29, Median time to first response: 1 month
  - ORR: 100% with ≥ 69% CR rate, 100% of evaluable patients MRD negative, 27 of 29 PFS @ 6 mo
- **LEGEND-2:** Phase1, **LCAR-B38M** CART-T-cells, ORR 88% @ 25 mos, mPFS: 19.9 mos, mOS: 36.1 mos

BITE ANTIBODY:

- **CC93269:** Humanized, IgG1 T-cell engager that binds BCMA and CD3ε on T-cells
  - ORR in 10-mg group: 88.9% (sCR/CR: 44.4% with 100% MRD), CRS: 76.7%, majority grade 1/2.

ANTIBODY DRUG CONJUGATE (ADC):

- **DREAMM-2: Belantamab mafodotin**, BCMA targeting ADC, Phase II, N=196, ORR 31-34%
- **DREAMM-6: Belantamab mafodotin + Vd (ASCO2020):** ORR of 78%, VGPR of 50%, and CBR of 83%

XPO-1

- **STOMP:** Phase I/II, **Selinexor, Pomalidomide/Dexamethasone** in R/RMM, N=51, ORR 56%, CBR 78%

BCL-2:

- **Phase I/II: Venetoclax + Dexamethasone + Daratumumab± Bortezomib in t(11;14) R/R MM (ASH2019):** 87% refractory to dara, 48% ≥ PR and 35% ≥ VGPR, 12-mo DoR of 61% and mTTP ~ 11 mos
- **BELLINI Phase III, Ven+Bort/Dex in RRMM (ASCO 2020):** Improved PFS, ORR, MRD but worse OS except in t(11:14)

Chronic Leukemia

- **FIRST LINE THERAPY in CLL/SLL**
- **ELEVATE TN**
- Phase III, N=535, Acalabrutinib ± obinutuzumab significantly improved PFS compared with obinutuzumab + chlorambucil in treatment-naive CLL, ORR: 93.9 vs 85.5 vs 78.5% (P < .0001; P = .0763), fewer deaths in either acalabrutinib treatment arms.
- **Venetoclax + ibrutinib**
- Phase II, as first-line, fixed-duration treatment in high-risk CLL/SLL, ≥ 65 yrs of age, del(17p), mutated TP53, del(11q), and/or unmutated IGHV
- N=80, MRD response of 75% in ITT population
- **CAPTIVATE**
- Phase II, First-line Ibrutinib Plus Venetoclax in CLL/SLL, N=164, MRD: PB 75% and BM 72%
- **Acalabrutinib, Venetoclax, and Obinutuzumab (AVO):**
- Phase II therapy in treatment-naive CLL, N=37, 48% undetectable MRD in BM after 8 cycles
- **RELAPSES/REFRACTORY CLL/SLL**
- **LOXO-305**: BRUIN, Phase I, next-generation, non-covalent BTK inhibitor: N=16, ORR 77%
- **TRANSCEND CLL 004**: PhaseI/II, Lisocabtagene Maraleucel; N=23, ORR: 81.5%, CR 45.5%
- **SEQUOIA: Zanabrutinib**, Phase III, Arm C, TN-CLL: N=109, ORR 90%
- **RELAPSES/REFRACTORY CML**
- **Asciminib:** CML in ABL Kinase Inhibitor Failures, Phase I, N=141, MMR 48% (mT315I = 28%)

Lymphoma

- **GO2971: Mosunetuzumab (BTCT4465A):** AntiCD20 BiTE: Phase I/Ib Study in R/R NHL: N=270, Aggressive NHL responses: ORR: 37.1%, CR: 19.4% (n=124), Indolent NHL responses: ORR: 62.7%, CR: 43.3% (n=67)

- **TRANSCEND NHL 001**: Phase I Study of Lisocabtagene Maraleucel in R/R LBCL, N=269
- ORR: 73%, CR 53%, DoR @ 12: 54.7%, CAR+ T-cells at 1 yr in 53%
- **ZUMA-2:** Trial of KTE-X19 CAR T-Cell Therapy in Relapsed/Refractory Mantle Cell Lymphoma.
- N=68, ORR of 93%, CR: 67%. 43% of initial cohort in remission with ≥ 2 years f/u.

- **BRUIN: LOXO-305**, Non-Covalent BTK Inhibitor in MCL, N=6, ORR 50% (3/6), CR 17% (1/6)
- **GO29834**: Phase Ib/II, in R/R FL of polatuzumab vedotin, obinutuzumab and lenalidomide.
- N=56, ORR 83%, CR 61%, 83% PFS @ 12 mo.

- **Tazemetostat:** EZH2 Inhibitor Phase II in R/R FL, N=99, ORR (MT): 45%, (WT) 83%
- **Brentuximab Vedotin Plus Nivolumab in Hodgkin Lymphoma**
- ***First line Therapy:*** Older patients, N=18, ORR 100%, CR 77%, mDoR NR
- ***Relapsed/Refractory HD:*** N=91, ORR 85%, CR 67%.

- **Cerdulatinib with R/R PTCL and CTCL**: Dual inhibition of SYK and JAK, ORR: 35%
- **Filo: Idelalisib plus obinutuzumab in R/R Waldenström macroglobulinemia**: ORR 69%

Acute Leukemia

ACUTE MYELOGENOUS LEUKEMIA

- **QUAZAR AML-001:** Phase III, N=472, **CC-486 maintenance** vs. placebo, after First CR in ND AML
- Significant improvement in OS and RFS mOS extended 9.9 mos, and mRFS extended 5.3 mos.
- **ECOG-ACRIN E2906:** Phase II, **1 yr maintenance Decitabine** (3 days/cycle) after CR/Cri after 7+3 (or Clofarabine) induction Older AML Patients. N=120, 87.5% FLT3-ITD^{neg} Superior OS (P = .06), trend to improved DFS (P = .12) compared to observation alone
- **Enasidenib + Azacitidine vs Azacitidine** in ND AML with IDH2 mutations, Phase II, N=
- Significantly improved ORR (71% vs 42%; *P* = .0064) and CR (53% vs 12%; *P* = .0001).
- **FLAG-IDA Plus Venetoclax**: ND AML or in R/R AML, Phase Ib/II Study, N=30,
- CR/Cri in R/R AML 70-75%, ND AML 85%, 3 deaths in CR reported. Ongoing dose modified Phase II study, with improved safety.

ACUTE LYMPHOBLASTIC LEUKEMIA

- **COG AALL1331:** Phase III, **Blinatumomab vs Chemotherapy** maintenance for children and AYA with R/R B-ALL, N=208.
- Superior DFS and OS, higher rates of MRD and bridging to HSCT, lower AEs and toxoicity
- **GIMEMA LAL 2116 D-ALBA:** Frontline **Dasatinib + Blinatumomab** in ND Ph+ ALL, Phase II,
- N=63, 60.4% CMR/PNQ status after 2 cycles, OS and DFS: 95.2% and 89.7%, @ mF/u 14mos.
- **M16-106: Venetoclax Plus Navitoclax** in R/R ALL and Lymphoblastic Lymphoma, Phase I, N=45
- CR/CRi/CRp: 49%, MRD negative CR: 29%, mDoR: 9.1 mos

Myelodysplastic Syndromes and Myeloproliferative Neoplasms

MPN

- **Luspatercept in Myelofibrosis**: Phase II, N=76, Hg response in all patients independent of RBC transfusion dependence.
  - Effects more profound in patients who also received ruxolitinib.
- **MANIFEST, CPI-0610**, N=54, Phase II
- Bromodomain and Extraterminal Domain Inhibitor (BETi), onotherapy or "Add-on" to Ruxolitinib, in Refractory or Intolerant Advanced Myelofibrosis.
- N=54, 24.9% reduction in SV @ 24 weeks and a 58.8% improvement in TSS for TD myelofibrosis.
- 43% converted from TD to TI following treatment with the combination

MDS

- **GFM** : **APR-246 Plus Azacitidine** in TP53-mutated MDS and AML, Phase II, N=53
- CR in 49% (MDS: 66%, AML: 44%), MRD (Negative TP53 by NGS): 39%, 100% in CR
- **Venetoclax ± Azacitidine** in MDS: Phase Ib, N=64,
- ORR: 40% ORR vs 8% with venetoclax only, 12-mo OS with venetoclax + azacitidine was 65%
- **MEDALIST** Long-term analysis: N=229, RBC-TI ≥ 8 Wks
- Luspatercept-treated patients attained RBC-TI compared with placebo (47.7% vs 15.8%)

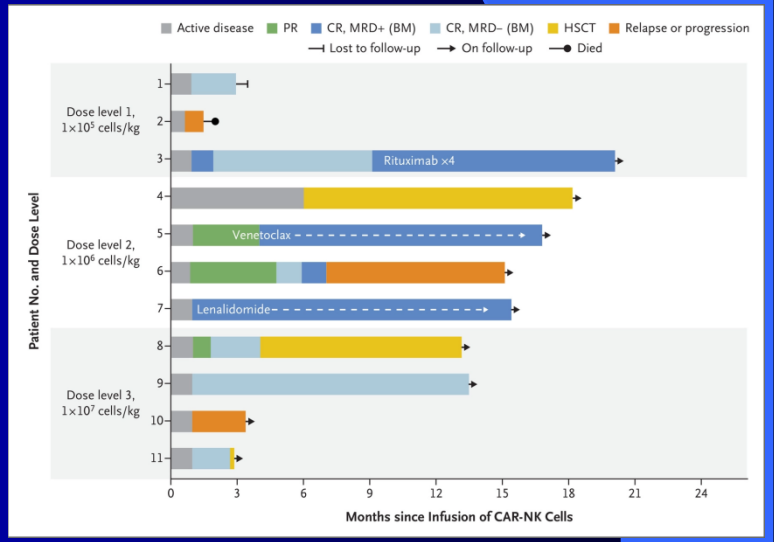
Malignant/Non Malignant Hematology

- **Updated Phase III Study of Avatrombopag**: N=49
- Median cumulative duration of PLT ≥ 50,000/μL (primary endpoint): 12.4 wks with avatrombopag vs 0 wks with placebo (P < .0001)
- **Novel BTKi PRN1008** : R/R Primary or Secondary ITP, Phase I, N=31
- ORR: 39%, Response rate increased to 54% with PRN1008 BID dosing for ≥ 12 wks
- **Phase III Northstar-3 (HGB-212): Betibeglogene Autotemcel** in Severe Transfusion-Dependent β-Thalassemia, Interim results: N=17
- 9/11 patients with ≥ 6 mos of follow-up off transfusions for ≥ 3 mos
- **CARDINAL**: **Sutimlimab,** first-in-class inhibitor of classical CP, Phase III, in transfusion dependent Cold Agglutinin Disease, N=24
- 70.8% Transfusion Independence from wks 5-26, markedly increased Hb, controlled hemolysis.
- **BCL11A Targeted Gene Therapy in Sickle Cell Disease**: N=15, Pilot Study, HSC transduction efficiency ≥ 93%, Effective HbF induction, significantly decreased clinical sickling signs/symptoms
- **Adjuvant Oral Arginine in Pediatric SCD**, in Severe vaso-occlusive pain episodes (VOE) versus placebo, N=68, Statistically significant decrease in mean total opioid dose use, a shorter time-to-crisis resolution, and shorter length of hospital stay, without serious AEs.
- **Bevacizumab Highly Effective for Chronic Bleeding in Hereditary Hemorrhagic Telangiectasia**
- N= 140, RBC transfusions and iron infusions decreased by 86% and 66%, with bevacizumab therapy.
- **SOAR: Fostamatinib**, SYK Inhibitor, for Warm Antibody Autoimmune Hemolytic Anemia (wAIHA)
- N=25, ORR 48% (Hg >10 without transfusion)

Hematopoietic Stem Cell Transplantation and Cellular Therapy

- **"Breaking the Glass Ceiling of Age in Transplant in Multiple Myeloma,"**
- **Autologous Hematopoietic Cell Transplantation in Older patients with Multiple myeloma.**
- N=16,000, CIBMTR database. ASCT is safe and effective in patients >70 years, with improved outcomes with 200 mg/m2, compared to 140 mg/M2.
- Reduced dose Melphalan results in significantly worse outcomes and survival: NRM at 100 days (1% vs 0%; P = .003), PFS at 2 years (64% vs 69%; P = .003) and OS at 2 years (85% vs 89%, P = .01).
- African Americans are twice as likely to have myeloma than Caucasians, but have significantly lower autologous hematopoietic cell transplantation.
- **STaMINA Long-term Follow-up (ASCO2020):** PFS benefit for ASCT/ASCT cohort (in high risk group), No OS difference

- **CAR-Transduced Natural Killer Cells in CD19-Positive R/R Lymphoid Malignancies**
- Phase I/II, N=17
- HLA-mismatched anti-CD19 CAR-NK cells derived from cord blood.
- Retroviral vector: Encodes anti-CD19 CAR, interleukin-15, and inducible caspase 9.
- ORR 73%, 7/17 CR (3 CLL, 4 NHL)
- No CRS, neurotoxicity, or GVHD, or increased inflammatory cytokines, including interleukin-6



Update from ASCO 2020 and Beyond

- **Epcoritamab CD3 x CD20 Bispecific Antibody:** Phase I/II in R/R B-Cell NHL, q1, then q 4 wks s.c, ORR in evaluable patients: DLBCL @ ≥ 12 mg, 50.0%; FL @ ≥ 0.76 mg, 85.7%. Neurotoxicity, 6.9% and CRS, 56.9% (all grade 1/2)
- **ASPEN:** Phase III, in Waldenström's Macroglobulinemia: Zanubrutinib vs. Ibrutinib, CR + VGPR: IRC, 28.4% vs 19.2% (*P* = .0921, Primary Endpoint) NS statistically; PFS at 12 mos: 89.7% vs 87.2%; OS at 12 mos: 97.0% vs 93.9%.
- Lower rates of AF/flutter, bleeding, diarrhea, and HTN, higher rate of neutropenia with zanubrutinib.
- **KEYNOTE-204:** Phase III, in R/R cHL, Pembrolizumab significantly improves PFS vs. Brentuximab vedotin, mPFS: 13.2 vs 8.3 mos (HR: 0.65; 95% CI: 0.48-0.88; P = .00271). ORR: 65.6% vs 54.2% (P = .0225); mDoR: 20.7 vs 13.8 mos.
- **BOSTON:** Phase III, in RRMM, Selinexor, Bortezomib, and Dexamethasone vs Bortezomib and Dexamethasone: 30% improved PFS, HR 0.70, P = .0075.
- **ENDURANCE:** Phase III: Carfilzomib (20/36mg/M2 TW)/Len/Dex vs Bortezomib/Len/Dex without early ASCT, non high risk NDMM similar PFS.
- **L-MIND**: Tafasitamab (anti-CD19) + lenalidomide, Phase II, in RR DLBCL, ORR; 60%, CR; 43% and PR;18%.

What does it all mean? *My thoughts*

- **PRACTICE changing:**
- *Upfront Daratumumab in transplant eligible MM*
- *Upfront Carfilzomib in NDMM (with ASCT - MASTER TRIAL) but ENDEAVOR (without ASCT)?*
- *Upfront Acalabrutinib in CLL*
- *Venetoclax in t(11:14) RRMM (or NDMM)*
- *Blinatumomab maintenance in RR B-ALL*
- *Sutimlimab in Cold Agglutinnin Disease*
- *Tafasitamab and Lenalidomide in R/R DLBCL*
- **Potentially Practice changing:**
- *Belantamab mafodotin in RRMM*
- *Maintenance therapy after induction therapy for AML: Decitabine/CC-486*
- *Enasidenib in IDH2 mutant NDAML,*
- *Upfront Blinatumomab and Dasatinib in ND Ph+ B-ALL*
- *Frontline Brentuximab vedotin plus Nivolumab in HL, Pembrolizumab in RR cNHL*
- *KTE-X19 CAR-T in RR MCL*
- *Bevacizumab in Hereditary Hemorrhagic Telangiectasia*
- *Upfront therapy for High Risk Asymtomatic Multiple Myeloma with Curative Intent ?*
- **Stay tuned**
- *Mosunetuzumab in RR lymphoma and Cerdulatinib in RR PTCL/CTCL*
- *Gene Therapy in SCD and Thalassemia and NK Cell – CAR-T Cell*

Co-Chair Indy Hematology Review Challenging Cases

Michael C. Wiemann, MD, FACP

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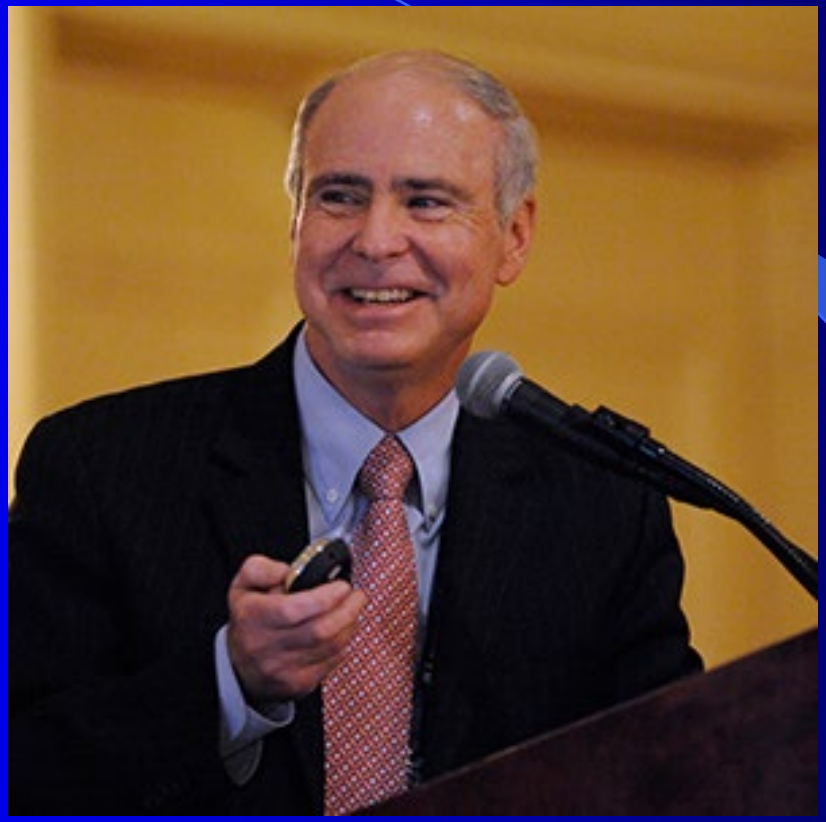
Multiple Myeloma



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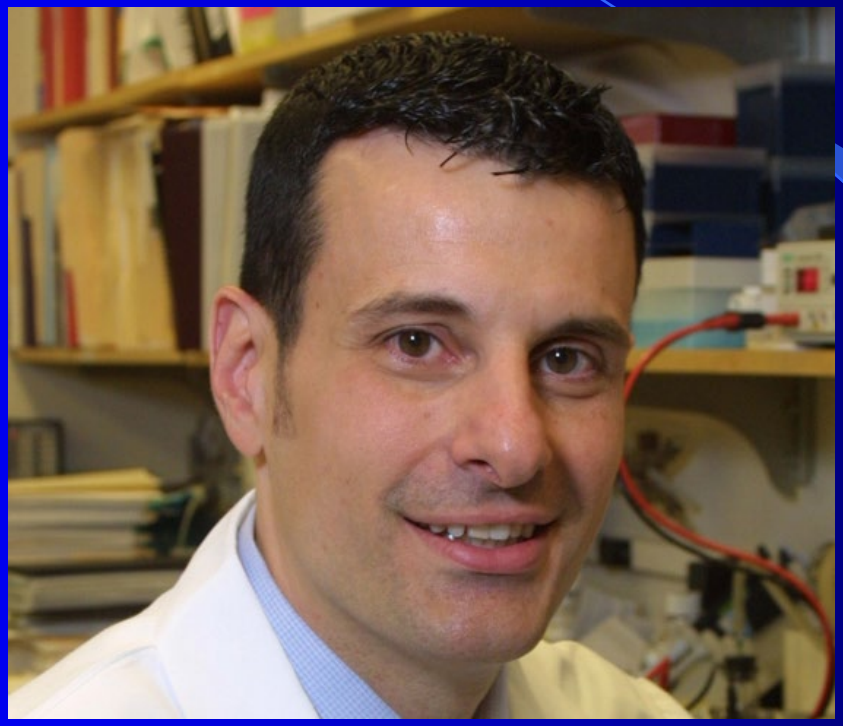
Waldenström's Macroglobulinemia



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Indolent Lymphomas

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Chronic Lymphocytic Leukemia

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Chronic Myeloid Leukemia

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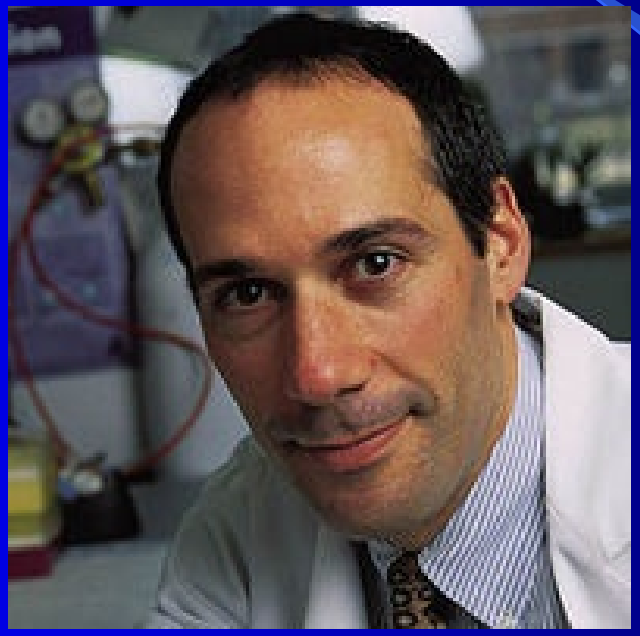
Not so Benign Hematology: Complementopathies and Aplastic Anemia



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Myeloproliferative Neoplasms

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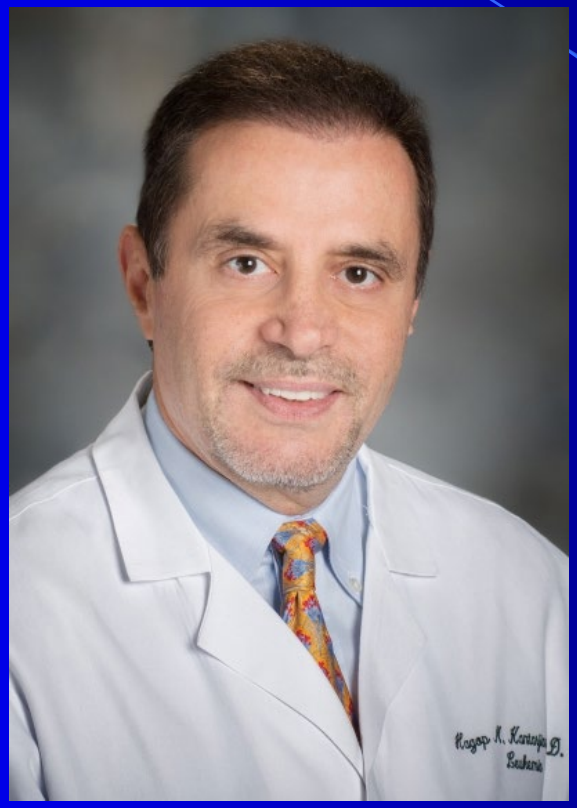
Acute Lymphoblastic Leukemia



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Acute Myeloid Leukemias

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Hematopoietic Stem Cell Transplantation

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Nursing and Allied Health Symposium

Moderators: Donna M. Birhiray, OTR, MBA
Thalia Hammond

Kristi Orbaugh, RN, MSN, RNP, AOCN
Community Hospital Oncology Physicians
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David Reeves, PharmD, BCOP
Associate Professor, Butler University and Clinical Pharmacist at Franciscan Hospital, Indianapolis, IN.

T. Howard Lee Keynote Lecture

EDWARD A. STADMAUER, MD
Roseman, Tarte, Harrow, and Shaffer Families' President's Distinguished Professor of Medicine and Section Chief of the Hematologic Malignancies
University of Pennsylvania Philadelphia, PA

T. HOWARD LEE, MD
Founder and President Emeritus, Hematology Oncology of Indiana, PC
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Hematologic Malignancies Town Hall

Irene Ghobrial, MD,
Professor and Director of the Clinical Investigator research program at Dana-Farber Cancer Institute, Harvard Medical School, Boston, MA

Charles Schaffer MD,
Professor of Medicine and Oncology and The Joseph Dresner Chair for Hematologic Malignancies at Wayne State University School of Medicine and the Karmanos Cancer Institute Detroit, MI

Morie Gertz, MD
Professor of the Art of Medicine and Chair Emeritus Department of Medicine, Mayo Clinic, Rochester, MN.

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18th Annual Indy Hematology Review 2021

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March 20th, 2021

Westin Indianapolis,

Indianapolis,

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And The Winner is ….

Announcements and Acknowledgments

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