AN EVENING WITH THE EXPERTS @ INDY HEMATOLOGY REVIEW 2019

State of the Art 2020: Emerging Therapies in Blood Cancers and Blood Disorders

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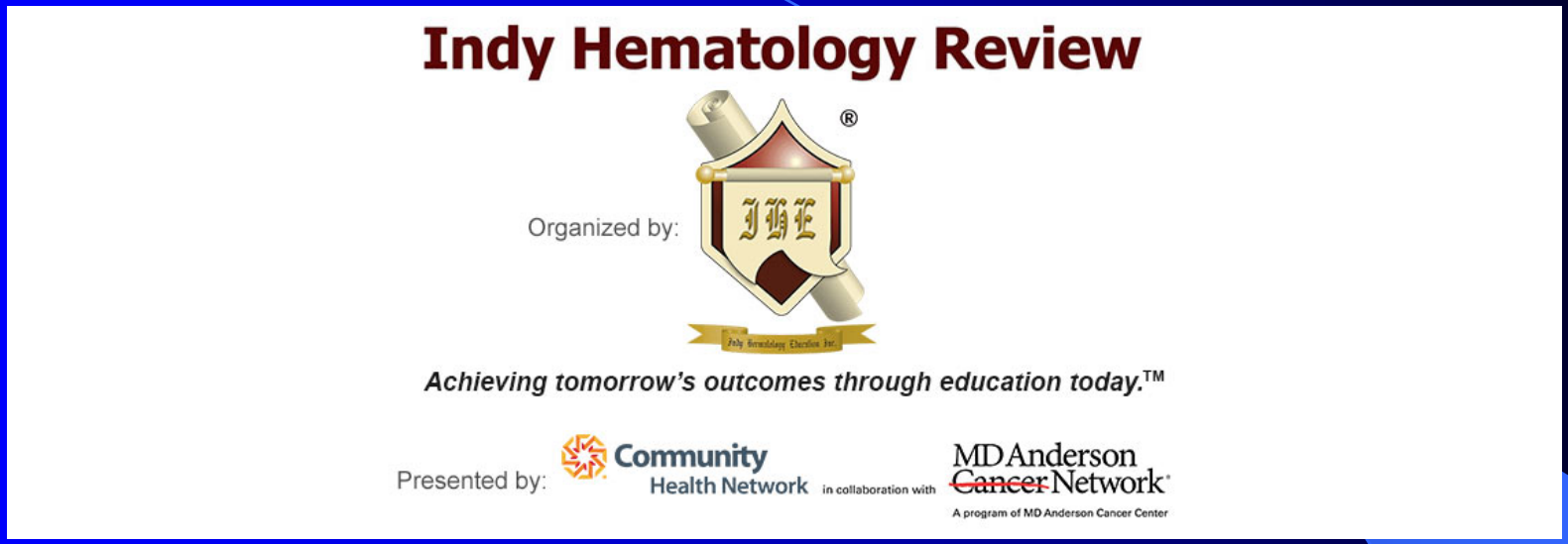

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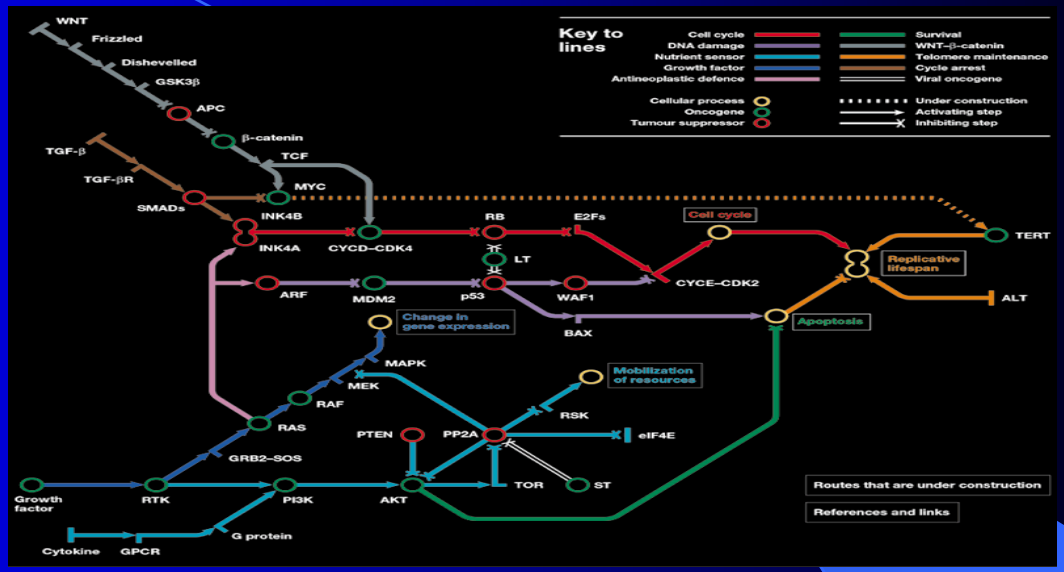
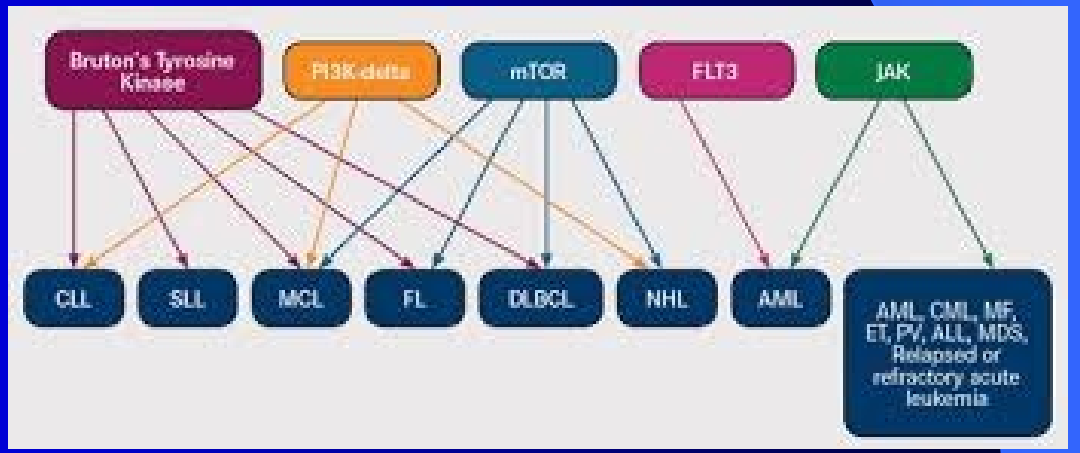
Treatment Strategies for Blood Cancers

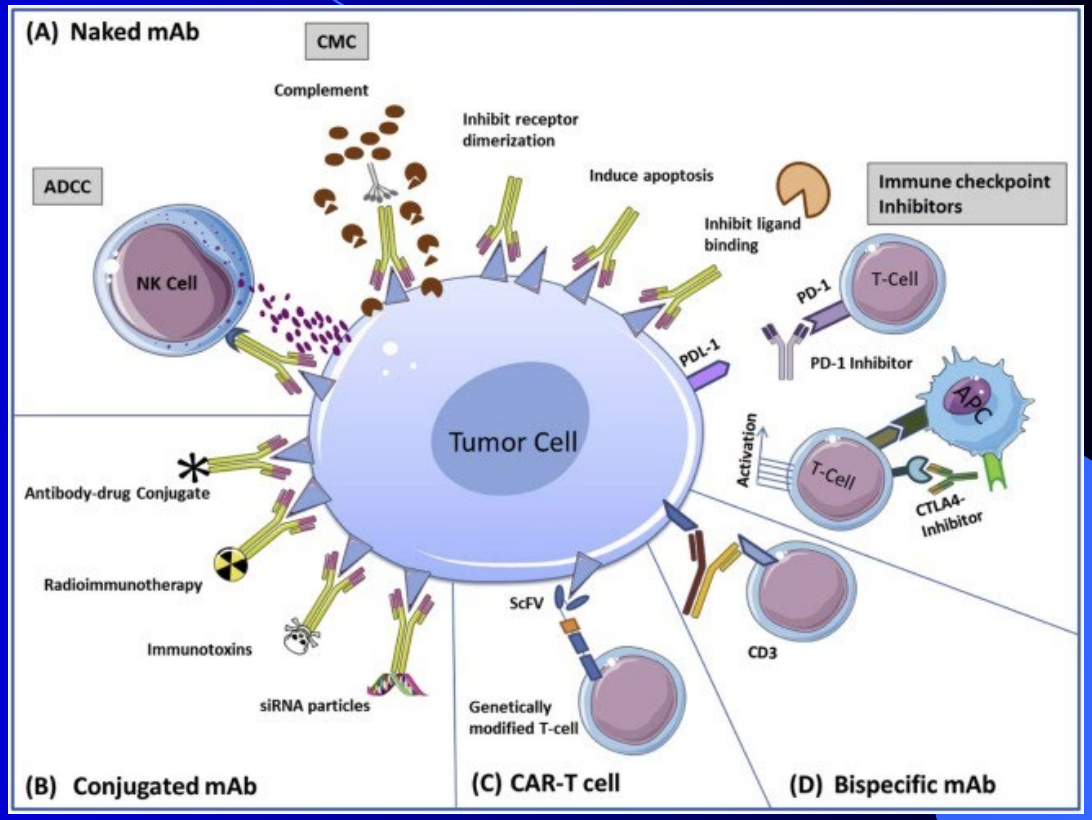
- **Chemotherapy:** Chemicals designed to kill rapidly dividing and cancer cells.
- **Tyrosine Kinase Inhibitors/Signal Transduction Pathway Inhibitors:** Drugs designed to inhibit driver pathways that promote cancer cell growth





Treatment Strategies for Blood Cancers

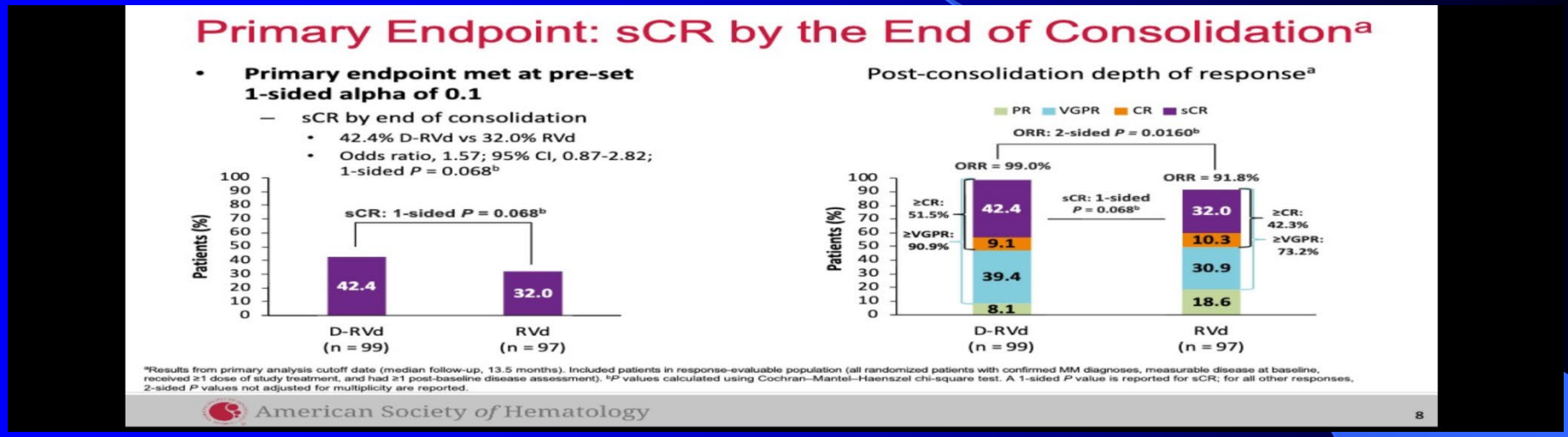
- **Monoclonal antibodies:** Antibody proteins targeting cancer cell surface proteins
- **Antibody Drug Conjugates:** Antibodies linked to chemotherapeutic agents targeting cell surface proteins to improve directed killing of cancer cells
- **BITE antibodies:**
- Antibodies designed to link immune T-cells to target cancer cells
- **CAR-T cells:**
- Individually designed T cells with antibody receptors targeting cancer cells



Myeloma: Initial Therapy

ADDING DARATUMAB TO CHEMO:

- **GRIFFIN TRIAL**: **Daratumumab** + VRd vs VRd Alone for Transplant-Eligible Myeloma: sCR by the end of treatment: 42.4% vs. 32.0%, no effect on stem cell collection



- **MASTER TRIAL: Daratumumab** +KRd in Transplant-Eligible Myeloma: 21% African American, 51% High Risk,.
- 39% sCR post induction and 95% at MRD-based consolidation.
- **HOVON 143 TRIAL:** Non transplant, frail/unfit patients with Myeloma: **Ixazomib/daratumumab**/low-dose dexamethasone, ORR: 74%; mPFS: 23 mos.

High-Risk Smoldering Myeloma GEM-CESAR:

KRD, N=90, End of therapy response (Induction/ASCT/Consolidation): 76% ≥ CR, 63% MRD negative.

TARGETING MYELOMA CELL PROTEINS RELAPSED/REFRACTORY MYELOMA

ANTI-CD38 ANTIBODY DARATUMUMAB

- **CANDOR: Carfilzomib, Dexamethasone ± Daratumumab** in relapsed Myeloma
- ORR 84.3vs74.7%, > VGPR 69.2 vs 48.7%, > CR28.5 vs., 10.4%, MRD negative at 12 mos 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: Cell surface protein required for myeloma cell survival/signaling

CAR T THERAPY:

- **CARTITUDE-1: JNJ-4528** CAR T-cells targeting domains for increased for improved binding:
  - ORR: 100% with ≥ 69% CR rate, 100% of evaluable patients MRD negative.
- **LEGEND-2: LCAR-B38M** CART-T-cells, ORR 88%, mPFS: 19.9 mos, mOS: 36.1 mos

BITE ANTIBODY: "Immune Matchmaker"

- **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.

TARGETING MYELOMA CELL PROTEINS RELAPSED/REFRACTORY MYELOMA

ANTIBODY DRUG CONJUGATE (ADC): ANTIBODIES BEARING TOXINS

- **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%

PROMOTING CANCER CELL DEATH

XPO-1: INHIBITING CANCER CELL SURVIVAL BY PROMOTING RETENTION OF CANCER KILLING PROTEINS IN CELLS

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

BCL-2: INHIBITING CANCER CELL ANTI-DEATH PROTEINS

- **Phase I/II: Venetoclax + Dexamethasone + Daratumumab± Bortezomib in t(11;14) R/R MM (ASH2019):** 48% ≥ PR and 35% ≥ VGPR, 12-mo DoR of 61% for 11mos
- **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**
- Acalabrutinib ± obinutuzumab significantly improved progression/death compared with obinutuzumab + chlorambucil in initial treatment of CLL, ORR: 93.9 vs 85.5 vs 78.5%, fewer deaths in either acalabrutinib treatment arms.
- **Extended Follow-Up of E1912**: Ibrutinib + Rituximab versus FCR in younger patients with CLL: PFS superior for IR over FCR (HR, 0.39; 95%; P <.0001), Improved PFS in IGHV-unmutated patients.
- **Venetoclax + ibrutinib**
- First-line, fixed-duration treatment in high-risk CLL/SLL, ≥ 65 yrs of age, High risk CLL, MRD response of 75%.
- **CAPTIVATE**
- First-line Ibrutinib Plus Venetoclax in CLL/SLL MRD: Blood: 75% and Bone marrow: 72%
- **Acalabrutinib, Venetoclax, and Obinutuzumab (AVO):**
- Treatment-naive CLL, N=37, 48% undetectable MRD in BM after 8 cycles
- **RELAPSES/REFRACTORY CLL/SLL**
- **LOXO-305**: BRUIN, Next-generation, non-covalent BTK inhibitor: ORR 77%
- **SEQUOIA: Zanabrutinib**, Phase III, Arm C, TN-CLL: N=109, ORR 90%
- **CAR-T THERAPY: TRANSCEND CLL 004**: Lisocabtagene Maraleucel CART-T therapy; ORR: 81.5%, CR 45.5%
- **RELAPSES/REFRACTORY CML (FAILURE AFTER TKI THERAPY)**
- **Asciminib:** Allosteric inhibitor of BCR/abl: Phase I, N=141, MMR 48% (mT315I = 28%)

Lymphoma

- **Immune Engager BiTE:**
- **GO2971: Mosunetuzumab:**: Phase I/Ib Study in Relapsed NHL: Aggressive NHL responses: ORR: 37.1%, CR: 19.4%, Indolent NHL responses: ORR: 62.7%, CR: 43.3%
- **CART- Cells Immunotherapy:**
- **TRANSCEND NHL 001**: Lisocabtagene Maraleucel in R/R LBCL, 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.
- **TARGETED THERAPY FOR R/R INDOLENT LYPHOMA**
- **BRUIN: LOXO-305**, Non-Covalent BTK Inhibitor in MCL, N=6, ORR 50% (3/6), CR 17% (1/6)
- **GO29834**: R/R FL of **Polatuzumab vedotin**, obinutuzumab and lenalidomide. ORR 83%, CR 61%, 83% PFS @ 12 mo.
- **Tazemetostat:** EZH2 Inhibitor in R/R FL, N=99, ORR (MT): 45%, (WT) 83%
- **FiLo: Idelalisib plus obinutuzumab in R/R Waldenström macroglobulinemia**: ORR 69%
- **TARGETED THERAPY FOR T-CELL LYMPHOMA**
- **Cerdulatinib with R/R PTCL and CTCL**: Dual inhibition of SYK and JAK, ORR: 35%
- **IMMUNOTHERAPY FOR HODGKINS LYMPHOMA**
- **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%.

Acute Leukemia

ACUTE MYELOGENOUS LEUKEMIA

- **MAINTENANCE THERAPY**
- **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
- **TARGETED THERAPY**
- **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. Dose modified study ongoing.

ACUTE LYMPHOBLASTIC LEUKEMIA

- **COG AALL1331:** Phase III, Anti-CD19 BITE: **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 (Inflammatotry protein trap) 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%)

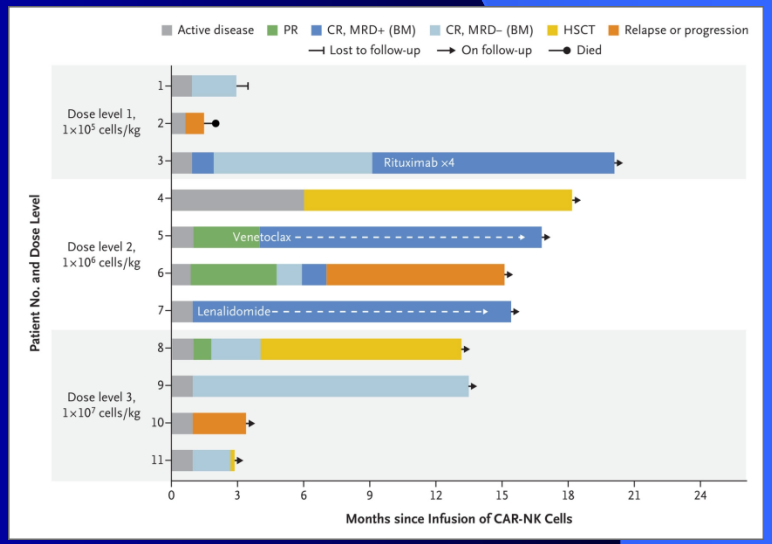
Malignant/Non Malignant Hematology

- **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) Gene Therapy: 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
- 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.
- **CARDINAL**: **Sutimlimab,** first-in-class inhibitor of classical CP, Phase III, in transfusion dependent Cold Agglutinin Disease, N=24
- **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 (Potential "OFF THE SHELF" THERAPY).
- 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%; 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.
- **L-MIND**: Tafasitamab (anti-CD19) + lenalidomide, Phase II, in RR DLBCL, ORR; 60%, CR; 43% and PR;18%.
- **ENDURANCE:** Phase III: Carfilzomib (20/36mg/M2 TW)/Len/Dex vs Bortezomib/Len/Dex without early ASCT, non high risk NDMM similar PFS.
- **KarMMa:** Idecabtagene Vicleucel,R/R Multiple Myeloma, Phase II, N = 158, ORR: 73%; CR: 33%, mDoR: 10.7mos; mPFS: 8.8mos , mOS 19.4mos (CR/SCR: mPFS: 20.2 mos)

What does it all mean? *My thoughts*

- **PRACTICE changing:**
- *Upfront Daratumumab in transplant eligible MM with RVD, and KRD*
- *Belantamab Mafodotin in R/R Myeloma*
- *Upfront Acalabrutinib in CLL, and Ibrutinib + Rituximab in younger patients with CLL*
- *Venetoclax in t(11:14) RRMM (or NDMM)*
- *Blinatumomab maintenance in RR B-ALL*
- *Tafasitamab and Lenalidomide in R/R DLBCL*
- *Tazemetostat: In EZH2 mutated FL*
- **Potentially Practice changing:**
- *Sutimlimab in Cold Agglutinnin Disease*
- *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*
- *CAR-T Therapy in Myeloma and 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*

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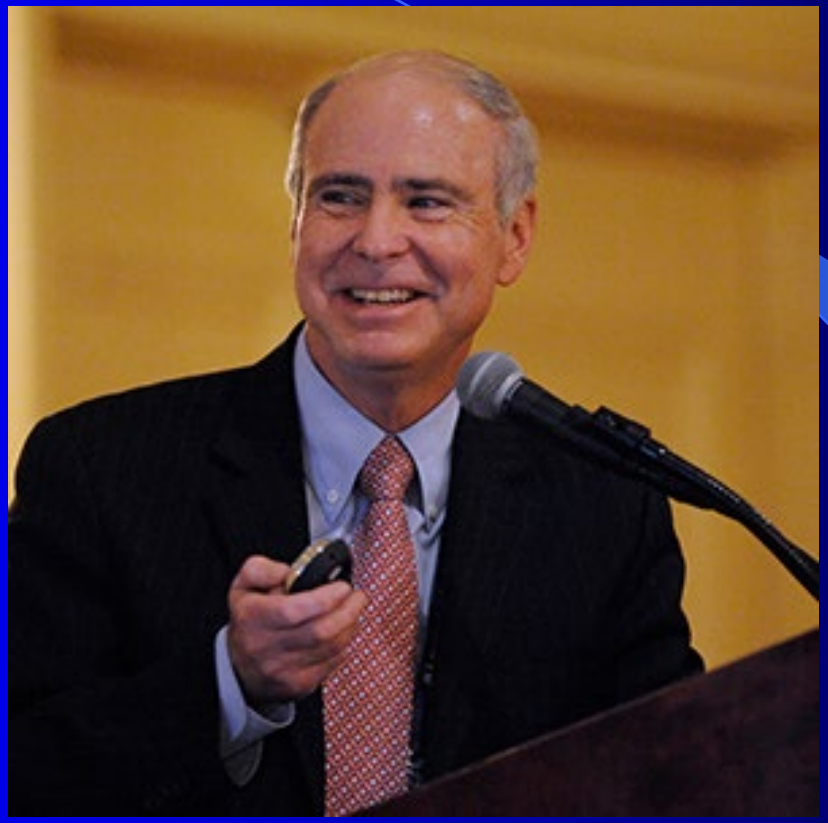
Multiple Myeloma



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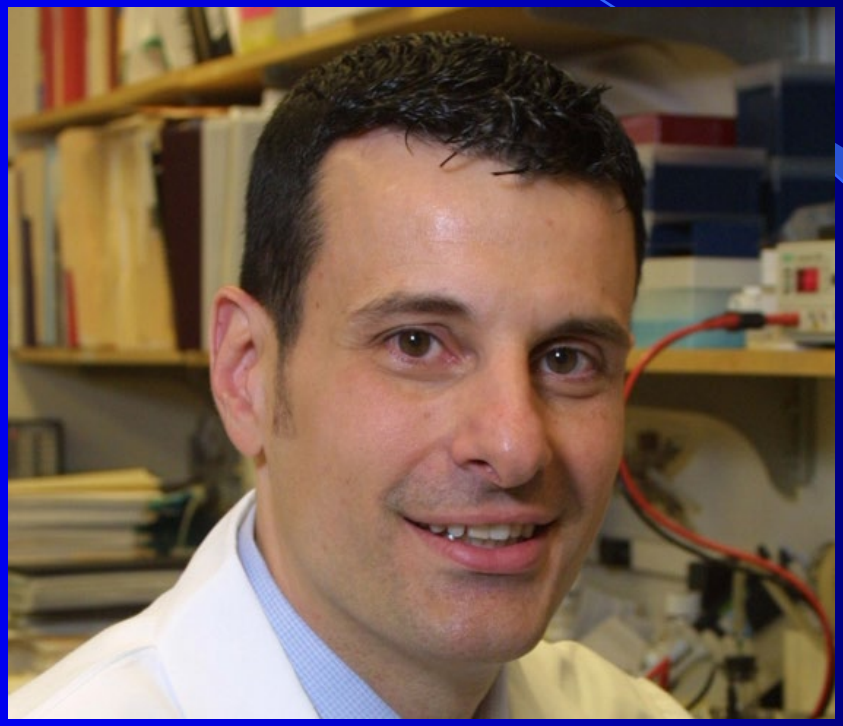
Waldenström's Macroglobulinemia



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TREATMENTS AND CURRENT RESEARCH IN LEUKEMIA

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Surviving Cancer With Art Therapy

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18th Annual Indy Hematology Review 2021

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