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CONGRESS COVERAGE: ASH 2020 – FOCUS ON MULTIPLE MYELOMA

Friday, December 11, 2020

FULL REPORT

FACULTY EXPERTS

EPICS

Chair
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Mayo Clinic
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Boston, MA

Sagar Lonial, MD, FACP
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Atlanta, GA

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University Hospital of Nantes
Nantes, France

Suzanne Lentzsch, MD, PhD
Columbia Univ Irving Medical Center
New York, NY

Keith Stewart, MB, ChB, MBA
Princess Margaret Cancer Centre
Toronto, ON, Canada

Peter Voorhees, MD
Levine Cancer Institute
Charlotte, NC

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AGENDA

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Time (EST)	Topic	Presenter
10.00 AM – 10.05 AM (5 min)	Welcome and Introductions	Rafael Fonseca, MD
10.05 AM – 10.15 AM (10 min)	First Line (1): Smoldering and Transplant-Ineligible Multiple Myeloma	Irene Ghobrial, MD
10.15 AM – 10.25 AM (10 min)	Discussion	Moderator: Rafael Fonseca, MD
10.25 AM – 10.30 AM (5 min)	Key Takeaways	
10.30 AM – 10.40 AM (10 min)	First Line (2): Induction in Transplant-Eligible Multiple Myeloma	Peter Voorhees, MD
10.40 AM – 10.55 AM (15 min)	Discussion	Moderator: Rafael Fonseca, MD
10.55 AM – 11.00 AM (5 min)	Key Takeaways	
11.00 AM – 11.10 AM (10 min)	First Line (3): Maintenance and Prognosis	Keith Stewart, MB, ChB, MBA
11.10 AM – 11.25 AM (15 min)	Discussion	Moderator: Rafael Fonseca, MD
11.25 AM – 11.30 AM (5 min)	Key Takeaways	
11.30 AM – 11.35 AM (5 min)	*Break*	
11.35 AM – 11.45 AM (10 min)	Relapsed/Refractory: Small Molecules	Suzanne Lentzsch, MD, PhD
11.45 AM – 12.00 PM (15 min)	Discussion	Moderator: Rafael Fonseca, MD
12.00 PM – 12.05 PM (5 min)	Key Takeaways	
12.05 PM – 12.15 PM (10 min)	Relapsed/Refractory: Antibodies	Philippe Moreau, MD
12.15 PM – 12.25 PM (10 min)	Discussion	Moderator: Rafael Fonseca, MD
12.25 PM – 12.30 PM (5 min)	Key Takeaways	
12.30 PM – 12.40 PM (10 min)	Relapsed/Refractory: CAR Ts	Sagar Lonial, MD, FACP
12.40 PM – 12.50 PM (10 min)	Discussion	Moderator: Rafael Fonseca, MD
12.50 PM – 12.55 PM (5 min)	Key Takeaways	
12.55 PM – 1.00 PM (5 min)	Summary and Closing Remarks	Rafael Fonseca, MD

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First Line (1): Smoldering and Transplant-Ineligible Multiple Myeloma

Abstract 57: Longitudinal Immunogenomic Profiling of Tumor and Immune Cells for Minimally-Invasive Monitoring of Smoldering Multiple Myeloma (SMM): The Immunocell Study.
R. Termini, et al

EPICS

Background

> Most current models to predict risk of transformation in SMM are commonly established at diagnosis and not reevaluated over time,

Abstract 57: Longitudinal Immunogenomic Profiling of Tumor and Immune Cells for Minimally-Invasive Monitoring of Smoldering Multiple Myeloma (SMM): The Immunocell Study. R. Termini, et al (cont.)

EPICS

Results (contd)

> In addition to the 150 PB samples analyzed at baseline, another 139 specimens were processed at 6, 12, and 18 mo. The fluctuation

Abstract 548: Treatment of High Risk (HR) Smoldering Multiple Myeloma (SMM) With Carfilzomib, Lenalidomide, and Dexamethasone (KRd) Followed by Lenalidomide Maintenance (-R): A Phase 2 Clinical and Correlative Study. D. Kazandjian, et al

EPICS

Background

> High-risk SMM is a plasma cell disorder with a 5-yr risk of progression to symptomatic MM of ~75% without therapy. Early treatment

Abstract 548: Treatment of High Risk (HR) Smoldering Multiple Myeloma (SMM) With Carfilzomib, Lenalidomide, and Dexamethasone (KRd) Followed by Lenalidomide Maintenance (-R): A Phase 2 Clinical and Correlative Study. D. Kazandjian, et al (cont.)

EPICS

Results (cont.)

> Grade 3–4 toxicities occurring in >1 patient included neutropenia (19%), lymphopenia (13%), thromboembolism (12%), anemia (8%),

Abstract 551: The Phase 3 TOURMALINE-MM2 Trial: Oral Ixazomib, Lenalidomide, and Dexamethasone (IRd) vs Placebo-Rd for Transplant-Ineligible Patients With Newly Diagnosed Multiple Myeloma (NDMM). T. Facon, et al

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Background

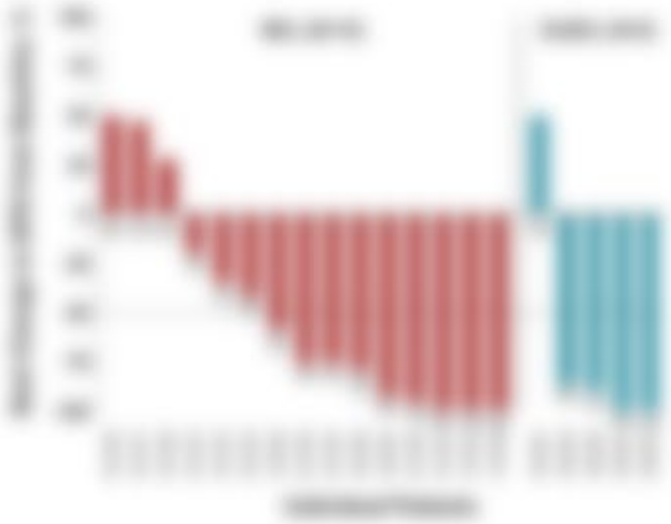
> Continuous Rd-based regimens are among the standards of care in

Background

- Phase I dose-escalation study of VLS-101, a ROR1-targeting ADC, in patients with heavily pretreated MCL and DLBCL
- Primary objective was to refine estimates of MTD and recommended dosing regimen

Results

- 32 patients were enrolled, including 15 patients with MCL
- DLTs were G4 neutropenia and G3 diarrhea
- G4 neutropenia occurred in 28% of patients; G-CSF successfully ameliorated neutropenia
- On-study reversible G3 neuropathy occurred in 9% of patients; no G4 neuropathy occurred
- ORR was 47% (3 CR, 4 PR) for MCL cohort and 80% (2 CR, 2 PR) for DLBCL cohort
- 8 responding patients have ongoing responses ranging from 23 weeks to 58 weeks



Key takeaways: VLS-101 demonstrated a manageable and predictable safety profile and encouraging efficacy, with durable responses in advanced MCL and DLBCL. Experts mentioned neuropathy as a potential concern and the need to identify the best histologies in which to test this agent.

Abstract 551: The Phase 3 TOURMALINE-MM2 Trial: Oral Ixazomib, Lenalidomide, and Dexamethasone (IRd) vs Placebo-Rd for Transplant-ineligible Patients With Newly Diagnosed Multiple Myeloma (NDMM). T. Facon, et al (cont'd).

EPICS

Results (cont.)

> Median overall survival (OS) was not reached in either arm (HR 0.998) after a median follow-up of ~58 mo and with 136 and 148

Abstract 552: Reduction in Absolute Involved Free Light Chain and Difference Between Involved and Uninvolved Free Light Chain Is Associated With Prolonged Major Organ Deterioration Progression-Free Survival in Patients With Newly Diagnosed Al Amyloidosis Receiving Bortezomib, Cyclophosphamide, and Dexamethasone With or Without Daratumumab: Results From ANDROMEDA. R. Comenzo, et al

EPICS

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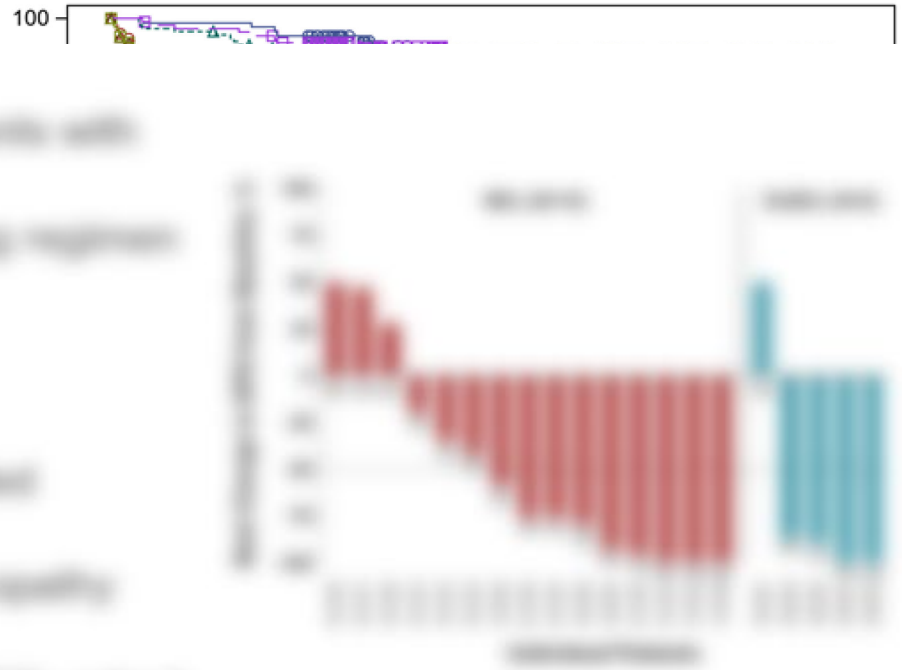
Figure. MOD-PFS by hematologic response



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FIRST LINE (1): SMOLDERING AND TRANSPLANT-INELIGIBLE MULTIPLE MYELOMA – DISCUSSION (1/2)

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Management of SMM

> Experts agreed that improvements are needed to identify high-risk SMM patients

FIRST LINE (1): SMOLDERING AND TRANSPLANT-INELIGIBLE MULTIPLE MYELOMA – DISCUSSION (2/2)

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Management of transplant-ineligible patients

> Some experts reported using DARA-Rd for most older, transplant-ineligible patients, especially after the

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First Line (2): Induction in Transplant-Eligible Multiple Myeloma

Abstract 141: Survival Analysis of Newly Diagnosed Transplant-Eligible Multiple Myeloma Patients in the Randomized Forte Trial. F. Gay, et al

EPICS

Background

> PI-based induction/consolidation proved to be effective in NDMM patients eligible for melphalan 200 mg/m^2 plus ASCT (MEL200-ASCT). High response rates have been reported with carfilzomib plus lenalidomide-dexamethasone (KRd) or cyclophosphamide-dexamethasone (KCd)

Abstract 142: Upfront Autologous Hematopoietic Stem-Cell Transplantation Improves Overall Survival in Comparison With Bortezomib-Based Intensification Therapy in Newly Diagnosed Multiple Myeloma: Long-term Follow-up Analysis of the Randomized Phase 3 EMN02/HO95 Study. M. Cavo, et al

EPICS

Background

Abstract 143: Early Versus Late Autologous Stem Cell Transplant in Newly Diagnosed Multiple Myeloma: Long-term Follow-up Analysis of the IFM 2009 Trial. A. Perrot, et al

EPICS

Background

> The IFM 2009 study prospectively evaluated the combination of 8 cycles of lenalidomide, bortezomib, and dexamethasone (RVd) vs 3 cycles of RVd plus

Abstract 144: A Prospective Phase 2 Study to Assess Minimal Residual Disease After Ixazomib, Lenalidomide and Dexamethasone Treatment for Newly Diagnosed Transplant Eligible Multiple Myeloma Patients. R. Silvennoinen, et al

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FIRST LINE (2): INDUCTION IN TRANSPLANT-ELIGIBLE MULTIPLE MYELOMA – DISCUSSION (1/2)

EPICS

Goals of frontline therapy

> Many experts believe SCT currently remains the SOC for treatment of MM, citing PFS data from the FORTE,

FIRST LINE (2): INDUCTION IN TRANSPLANT-ELIGIBLE MULTIPLE MYELOMA – DISCUSSION (2/2)

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Differentiating therapeutic options

> Many experts are impressed with the use of carfilzomib upfront for transplant-eligible patients

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First Line (3): Maintenance and Prognosis

Abstract 491: Impact of Minimal Residual Disease (MRD) by Multiparameter Flow Cytometry (MFC) and Next-Generation Sequencing (NGS) on Outcome: Results of Newly Diagnosed Transplant-Eligible Multiple Myeloma (MM) Patients Enrolled in the Forte Trial. S. Oliva, et al

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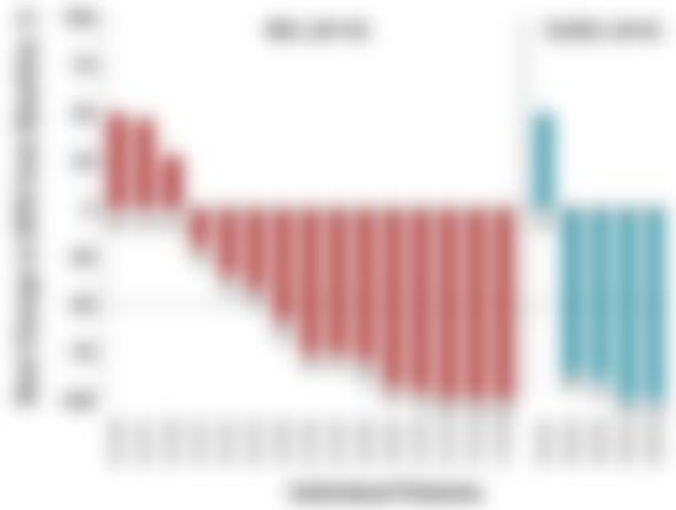
Background

> In MM, the role of MRD by multiparameter flow cytometry

A. PFS results in ITT pre-maintenance patients

MFC NGS



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Abstract 550: Consolidation Treatment With VRD Followed by Maintenance Therapy Versus Maintenance Alone in Newly Diagnosed, Transplant-Eligible Patients With Multiple Myeloma (MM): A Randomized Phase 3 Trial of the European Myeloma Network (EMN02/HO95).

P. Sonneveld, et al

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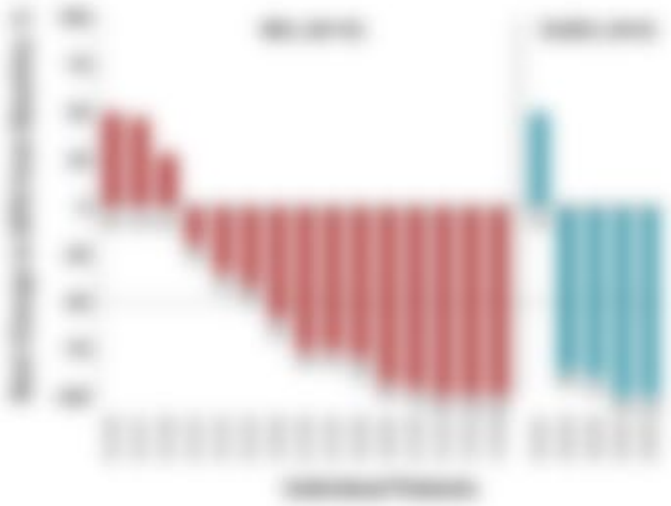
Background

> The role of consolidation treatment for transplant-eligible

Results

Progression free survival



Abstract 61: High-Dose Melphalan Significantly Increases Mutational Burden in Multiple Myeloma Cells at Relapse: Results From a Randomized Study in Multiple Myeloma. M. Samur, et al

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Background

> HDM followed by ASCT as first-line therapy in young (<66 yr) MM patients significantly improves PFS (IFM/DFCI 2009 study). However, the impact of alkylating

Abstract 549: Daratumumab (DARA) Plus Lenalidomide, Bortezomib, and Dexamethasone (RVd) in Patients With Transplant-Eligible Newly Diagnosed Multiple Myeloma (NDMM): Updated Analysis of GRIFFIN After 12 Months of Maintenance Therapy. J. Kaufman, et al

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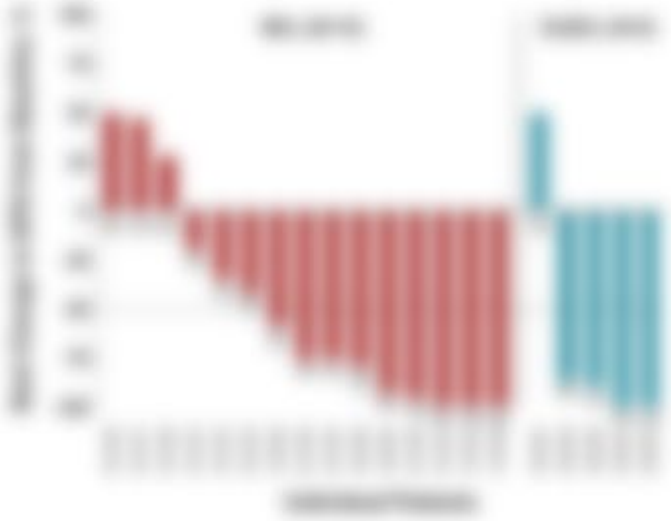
Background

> DARA, a human immunoglobulin Gκ mAb

Results

Figure. Summary of updated response rates[a] (A) and MRD-negativity rates[b] (B) over time in GRIFFIN.



Abstract 2276: Updated Analysis of Daratumumab Plus Lenalidomide and Dexamethasone (D-Rd) Versus Lenalidomide and Dexamethasone (Rd) in Patients With Transplant-Ineligible Newly Diagnosed Multiple Myeloma (NDMM): The Phase 3 MAIA Study. S. Kumar, et al

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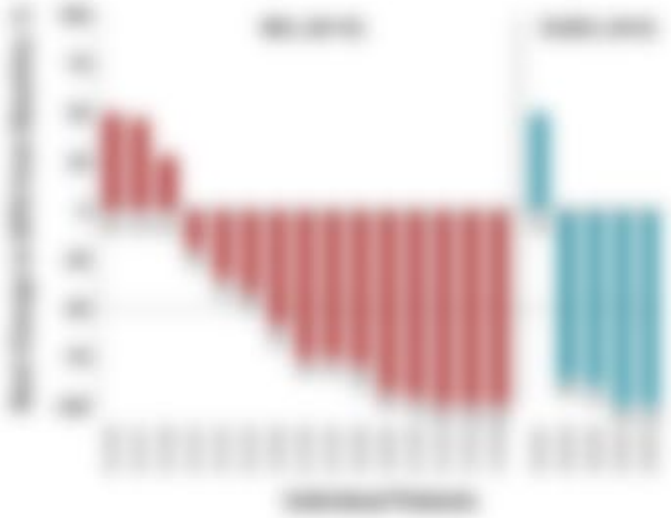
Background

> DARA is a human, CD38-targeting, immunoglobulin G1κ mAb approved as monotherapy in

Results: Updated PFS With D-Rd and Rd in MAIA



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FIRST LINE (3): MAINTENANCE AND PROGNOSIS – DISCUSSION (1/2)

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MRD

> Experts agreed that MRD is a significant prognostic marker but believe it can be further improved upon, and

FIRST LINE (3): MAINTENANCE AND PROGNOSIS – DISCUSSION (2/2)

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Consolidation therapy

> Experts were divided on the role of consolidation therapy for their patients

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Relapsed/Refractory: Small Molecules

Abstract 415: Randomized Phase 2 Study of Weekly Carfilzomib 70 mg/m^2 and Dexamethasone Plus/Minus Cyclophosphamide in Relapsed and/or Refractory Multiple Myeloma (RRMM) Patients (GEM-KyCyDex). M.V. Mateos, et al

EPICS

Background

> Carfilzomib dosed at 56 mg/m^2 twice a week in combination with dexamethasone (Kd) is a SOC for RRMM after 1–3 prior lines on the basis of

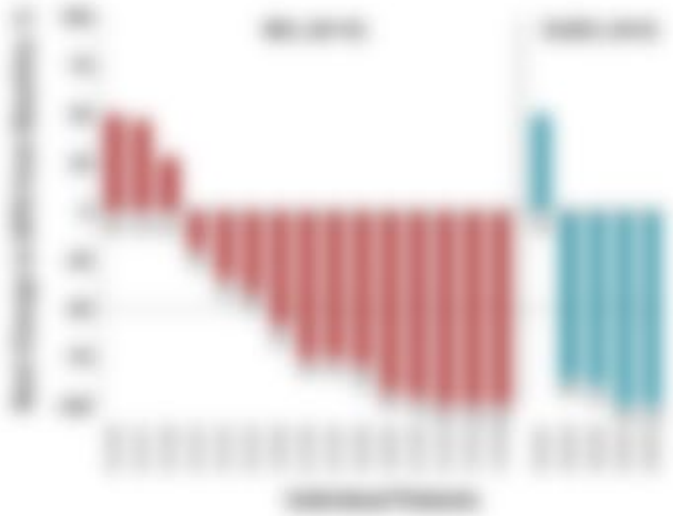
Abstract 2325: Carfilzomib, Dexamethasone, and Daratumumab Versus Carfilzomib and Dexamethasone in Relapsed or Refractory Multiple Myeloma: Updated Efficacy and Safety Results of the Phase 3 Candor Study. M.A. Dimopoulos, et al

EPICS

Background

> The randomized, open-label, multicenter, phase III CANDOR

Results



Background

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Key takeaways: VLS-101 demonstrated a manageable and predictable safety profile and encouraging efficacy, with durable responses in advanced MCL and DLBCL. Experts mentioned neuropathy as a potential concern and the need to identify the best histologies in which to test this agent.

Abstract 417: ANCHOR (OP-104): Melflufen Plus Dexamethasone (dex) and Daratumumab (dara) or Bortezomib (BTZ) in Relapsed/Refractory Multiple Myeloma (RRMM) Refractory to an IMiD and/or a Proteasome Inhibitor (PI) – Updated Efficacy and Safety. E. Ocio, et al

EPICS

Background

> Patients with RRMM often develop resistance to standard treatments, underscoring the need for novel therapies with new mechanisms of action (MOA).

Abstract 726: Selinexor in Combination With Pomalidomide and Dexamethasone (SPd) for Treatment of Patients With Relapsed Refractory Multiple Myeloma (RRMM). C. Chen, et al

EPICS

Abstract 294: Safety and Preliminary Efficacy Results From a Phase II Study Evaluating Combined BRAF and MEK Inhibition in Relapsed/Refractory Multiple Myeloma (rrMM) Patients With Activating BRAF V600E Mutations: The GMMG-Birma Trial. M. Raab, et al

EPICS

Background

- The treatment of patients with RRMM remains challenging and response is often limited in depth and duration. In contrast to many other

Abstract 295: Safety and Preliminary Efficacy Results From a Phase Ib/II Study of Cobimetinib as a Single Agent and in Combination With Venetoclax With or Without Atezolizumab in Patients With Relapsed/Refractory Multiple Myeloma. F. Schjesvold, et al

EPICS

Background

> Mitogen-activated protein kinase (MAPK) pathway mutations are present in more than 50% of patients with RRMM (Xu.

Abstract 416: Circularly Permuted TRAIL (CPT) Combined With Thalidomide and Dexamethasone in Patients With Relapsed/Refractory Multiple Myeloma: A Randomized, Double-Blind, Placebo-Controlled Phase 3 Study (CPT-MM301). W. Chen, et al

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Abstract 724: First Results of Iberdomide (IBER; CC-220) in Combination With Dexamethasone (DEX) and Daratumumab (DARA) or Bortezomib (BORT) in Patients With Relapsed/Refractory Multiple Myeloma (RRMM). N. van de Donk, et al

EPICS

Background

> IBER is an oral, potent novel cereblon E3 ligase modulator (CELMoD) agent with marked synergistic tumoricidal and immune-stimulatory effects in

RELAPSED/REFRACTORY: SMALL MOLECULES – DISCUSSION (1/2)

EPICS

Differentiating therapeutic options

[illegible]

RELAPSED/REFRACTORY: SMALL MOLECULES – DISCUSSION (2/2)

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> Experts are very excited for the data presented in Abstract 295 and note that these results confirm

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Relapsed/Refractory: Antibodies

Abstract 412: Apollo: Phase 3 Randomized Study of Subcutaneous Daratumumab Plus Pomalidomide and Dexamethasone (D-Pd) Versus Pomalidomide and Dexamethasone (Pd) Alone in Patients (Pts) With Relapsed/Refractory Multiple Myeloma (RRMM). M. Dimopoulos, et al

EPICS

Background

> IMiD-based regimens are a SOC for RRMM. DARA is a CD38-targeted mAb approved for treatment of patients with RRMM. The subcutaneous (SC) formulation of

Abstract 413: A Randomized Phase II, Open Label Study of Daratumumab, Weekly Low-Dose Oral Dexamethasone and Cyclophosphamide With or Without Pomalidomide in Patients With Relapsed and Refractory Multiple Myeloma. M. Sebag, et al

EPICS

Background

> Lenalidomide (LEN) has become the standard first-line therapeutic choice for MM, whether as first line for transplant-ineligible patients or as maintenance

Abstract 2316: Isatuximab Plus Carfilzomib and Dexamethasone vs Carfilzomib and Dexamethasone in Relapsed/Refractory Multiple Myeloma (IKEMA): Interim Analysis of a Phase 3, Randomized, Open-Label Study. P. Moreau, et al

EPICS

Background

> Treatment of RRMM has greatly improved, yet relapse is inevitable and additional effective treatments are needed. Isatuximab (ISA), a mAb targeting a

Abstract 725: Part 1 Results of a Dose Finding Study of Belantamab Mafodotin (GSK2857916) in Combination With Pomalidomide (POM) and Dexamethasone (DEX) for the Treatment of Relapsed/Refractory Multiple Myeloma (RRMM). S. Trudel, et al

EPICS

Background

> Belantamab mafodotin, a first-in-class immunoconjugate targeting B-cell maturation antigen (BCMA), showed clinically meaningful

Abstract 180: Updated Phase 1 Results of Teclistamab, a B-Cell Maturation Antigen (BCMA) x CD3 Bispecific Antibody, in Relapsed and/or Refractory Multiple Myeloma (RRMM). A. Garfall, et al

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Background

> MM inevitably relapses and becomes refractory to treatment, representing a patient population with unmet needs. Teclistamab (JNJ-64007957) is a

Abstract 290: A Phase 1, First-in-Human Study of Talquetamab, a G Protein-Coupled Receptor Family C Group 5 Member D (GPRC5D) X CD3 Bispecific Antibody, in Patients With Relapsed and/or Refractory Multiple Myeloma (RRMM). A. Chari, et al

EPICS

Background

> Despite improved outcomes with current MM treatments, most patients will develop refractory disease, highlighting the need for novel treatments.

Abstract 291: REGN5458, A BCMA X CD3 Bispecific Monoclonal Antibody, Induces Deep and Durable Responses in Patients With Relapsed/Refractory Multiple Myeloma (RRMM).
D. Madduri, et al

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Background

> MM is characterized by expression of the cell surface protein BCMA, a validated target for therapeutic intervention. REGN5458 is a BCMA x CD3

Abstract 181: A Phase 1 First in Human (FIH) Study of AMG 701, an Anti-B-Cell Maturation Antigen (BCMA) Half-Life Extended (HLE) BITE® (bispecific T-cell engager) Molecule, in Relapsed/Refractory (RR) Multiple Myeloma (MM). S. Harrison, et al

EPICS

Background

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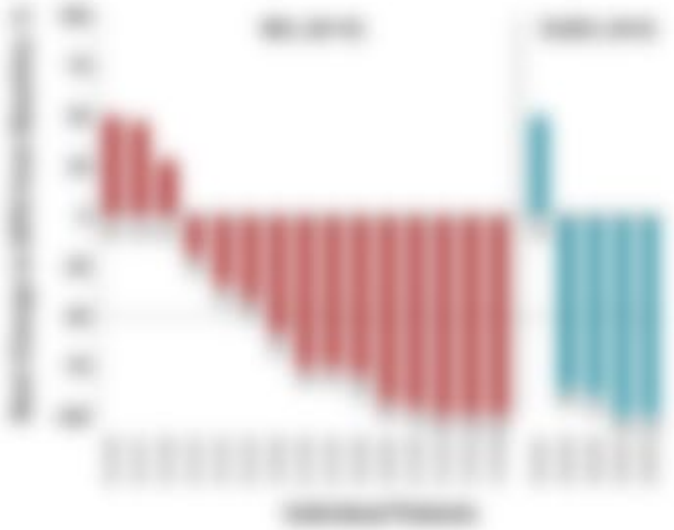
Results: Swimmer Plot for Confirmed Responders (≥PR)



Key takeaways: VLS-101 demonstrated a manageable and predictable safety profile and encouraging efficacy, with durable responses in advanced MCL and DLBCL. Experts mentioned neuropathy as a potential concern and the need to identify the best histologies in which to test this agent.

Abstract 292: Initial Clinical Activity and Safety of BFCR4350A, A FCRH5/CD3 T-Cell-Engaging Bispecific Antibody, in Relapsed/Refractory Multiple Myeloma. A. Cohen, et al

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Treatment for PTCL
J. Ruan, et al

Background

- Phase II study of CC-486, oral azacitidine, plus CHOP in patients with PTCL
- Preliminary results were presented
- Primary endpoint was CR

Results

- 21 patients were treated
- CHOP hematologic toxicities included neutropenia (71.4%), anemia and TBI (14.3% each), and thrombocytopenia (0.0%)
- CHOP nonhematologic toxicities included fatigue (14.3%) and hypocalcemia (14.3%)
- There has been no treatment-related mortality to date
- Estimated 1-year OS for all patients was 90.0%, and the estimated 1-year OS for all patients was 74.0%

Take Home Message: Reports were cautiously optimistic about these data, with one individual calling them really but encouraging. They suggested that much of the toxicities reported could be due to CHOP alone.

Abstract 293: Initial Results of a Phase I Study of TNB-383B, a BCMA X CD3 Bispecific T-Cell Redirecting Antibody, in Relapsed/Refractory Multiple Myeloma. C. Rodriguez, et al

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Abstract 3206: Preliminary Safety, Efficacy, Pharmacokinetics, and Pharmacodynamics of Subcutaneously (SC) Administered PF-06863135, a B-Cell Maturation Antigen (BCMA)-CD3 Bispecific Antibody, in Patients With Relapsed/Refractory Multiple Myeloma (RRMM). A.M. Lesokhin, et al

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Background

> PF-06863135 (PF-3135) is a full-length, humanized, bispecific mAb (immunoglobulin G2a) targeting BCMA, which is highly expressed on MM cells, and

RELAPSED/REFRACTORY: ANTIBODIES – DISCUSSION (1/2)

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Differentiating therapeutic options

RELAPSED/REFRACTORY: ANTIBODIES – DISCUSSION (2/2)

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> Bispecifics will definitely change how physicians treat MM and may supplant ADCs or other

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Relapsed/Refractory: CAR Ts

Abstract 130: Updated Results From the Phase I CRB-402 Study of Anti-BCMA CAR-T Cell Therapy bb21217 in Patients With Relapsed and Refractory Multiple Myeloma: Correlation of Expansion and Duration of Response With T Cell Phenotypes. M. Alsina, et al

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Background

> CAR T-cell therapy directed against BCMA has shown promising results for the treatment of RRMM. bb21217 is an anti-BCMA CAR T-cell therapy that uses the same

Abstract 131: Idecabtagene Vicleucel (Ide-cel, Bb2121), a BCMA-Directed CAR T Cell Therapy, in Patients With Relapsed and Refractory Multiple Myeloma: Updated Results From Phase 1 CRB-

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Abstract 133: Results From LUMMICAR-2: A Phase 1b/2 Study of Fully Human B-Cell Maturation Antigen-Specific CAR T Cells (CT053) in Patients With Relapsed and/or Refractory Multiple Myeloma. S. Kumar, et al

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Background

> CT053 comprises autologous T cells genetically modified with a second-generation CAR incorporating a fully human BCMA-specific single-chain

Abstract 134: Phase 1/2 Study of the Safety and Response of P-BCMA-101 CAR-T Cells in Patients With Relapsed/Refractory (R/R) Multiple Myeloma (MM) (PRIME) With Novel Therapeutic Strategies. C. Costello, et al

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Background

> P-BCMA-101 is an autologous CAR T therapeutic targeting BCMA and composed of a high percentage of desirable stem cell memory T cells. P-BCMA-101 is manufactured using a novel transposon-based system called piggyBac and is designed to increase efficacy while minimizing toxicity. A phase I/II

Abstract 177: CARTITUDE-1: Phase 1b/2 Study of Ciltacabtagene Autoleucel, a B-Cell Maturation Antigen-Directed Chimeric Antigen Receptor T Cell Therapy, in Relapsed/Refractory Multiple Myeloma. D. Madduri, et al

EPICS

Background

> Ciltacabtagene autoleucel (cilta-cel; JNJ-68284528; LCAR-B38M CAR-T cells) is a CAR T-cell therapy with 2 BCMA-targeting single-domain Abs designed

Abstract 721: Biallelic Loss of BCMA Triggers Resistance to Anti-BCMA CAR T Cell Therapy in Multiple Myeloma. M. Samur, et al

EPICS

Background

> CAR T-cell therapy targeting BCMA has provided deep (73%–100%) responses in RRMM. However, median PFS has been <12 mo, and among the small number of

RELAPSED/REFRACTORY: CAR Ts – DISCUSSION (1/2)

EPICS

Differentiating therapeutic options

RELAPSED/REFRACTORY: CAR Ts – DISCUSSION (2/2)

EPICS

- Experts suggest that CAR T therapy should be given earlier, when there is less tumor burden and