Advances in myeloma therapy

WHAT'S NEW IN 2025

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Penn Medicine

Disclosures

- **Consulting:**
  - Abbvie
  - BMS
  - Takeda Oncology
  - GSK
  - Johnson & Johnson
  - Genentech
- **Research support:**
  - Active Biotech
  - Takeda Oncology

Topics

- **Overview of myeloma and therapy**
- **Recent advances in myeloma therapy**
  - Treatment of smoldering myeloma
  - Immunotherapy (CAR T cells and T cell engagers)
  - Belantamab mafodotin (Blenrep)
- **Experimental therapies for relapsed myeloma**
- **Clinical trials available at Penn**

International Myeloma Foundation's 2025 Philadelphia Miracles for Myeloma Virtual/In-Person 5K Run/Walk

Date: Saturday May 3rd 2025
Time: Race Start: 8:00AM
Location: FDR Park, 1500 Pattison Avenue, Philadelphia
Register: https://events.myeloma.org

Scan HERE to Join Dr. Dan Vogl's Team- Penn Myeloma Program!

ALSO:
IMF Patient and Family Seminar
May 2-3, 2025
DoubleTree by Hilton Philadelphia Center City

Support Civic Health

Our Government Affects Our Health

Funding for research

Medicare and Medicaid funding

Regulation of drugs and devices

Regulation of vaccines

Regulation of private insurance

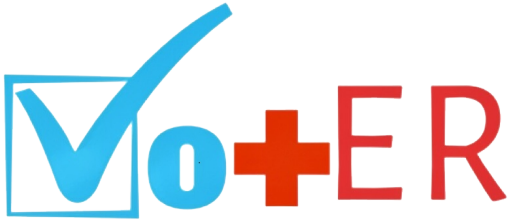
Telemedicine

What You Can Do

Contact your elected representatives

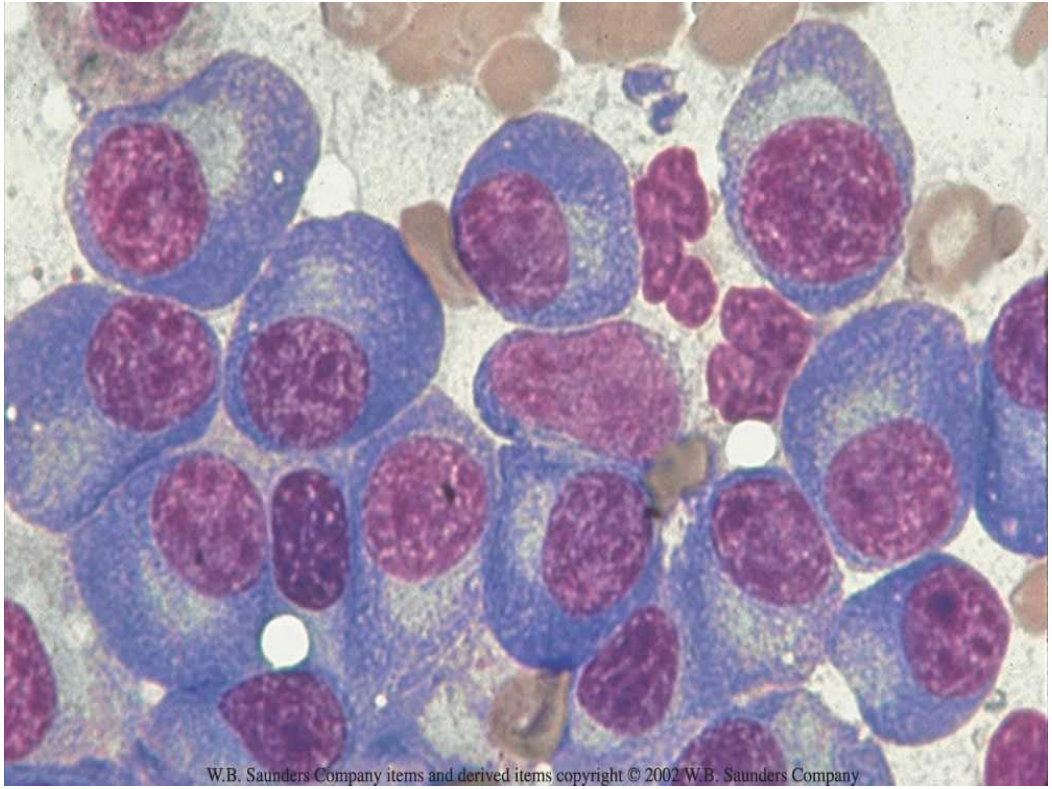
Vote

To register and request a mail-in ballot:
go to vot-er.org/PENN
or text “VOTE PENN” to 34444.



Overview of myeloma and therapy

Myeloma = Cancer of malignant plasma cells



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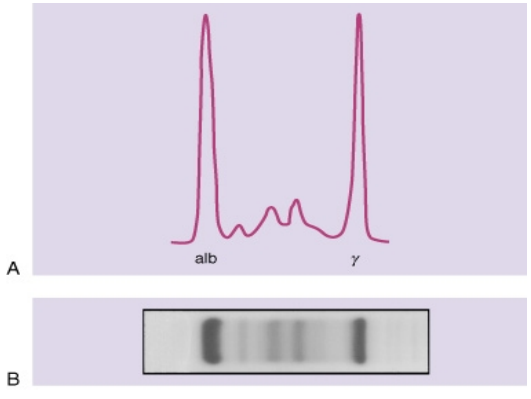
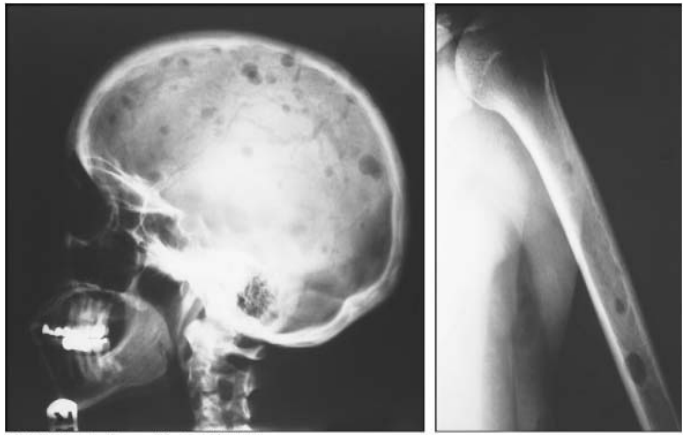
Multiple Myeloma – Clinical Features

- **Abnormal protein in blood and/or urine**
  - "M-spike" = "Myeloma protein," "M-protein," "monoclonal protein"
  - Free light chains
- **Plasma cells in the bone marrow**
- **CRAB criteria**
  - High **c**alcium levels
  - Kidney (**r**enal) injury
  - **A**nemia (low red blood cells)
  - **B**one destruction ("lytic bone lesions")
- **Increased risk of infection**
- **Neurologic Injury**
  - Spinal Cord Compression
  - Peripheral Neuropathy
- **Increased blood viscosity**





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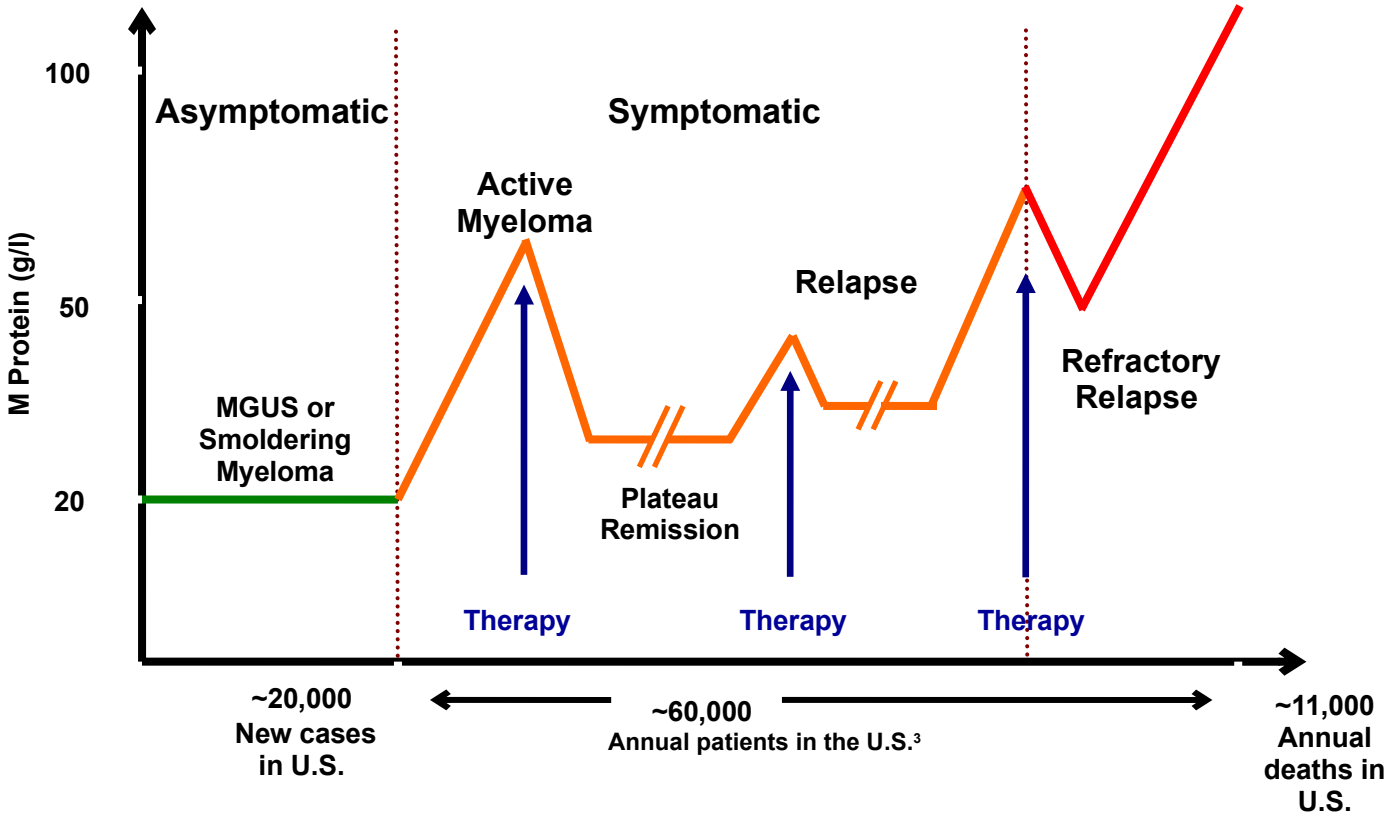
Management of Disease Symptoms

- **Radiation and pain medication for bony pain**
- **denosumab (Xgeva) or bisphosphonates, such as zoledronate (Zometa), for bone pain or fractures**
  - Risk of jaw osteonecrosis (area of dead bone, sometimes requiring surgery)
- **Red blood cell growth factors for anemia**
- **Kidney Protection**
  - Hydration (drink plenty of fluids)
  - Avoid NSAIDs (ibuprofen, Advil, Alleve, etc.)
  - Avoid contrast for x-rays
- Prevent and Treat Infections
  - Antibiotics
  - Vaccinations
    - Influenza
    - RSV
    - Pneumococcus (Prevnar 20, Capvaxive)
    - Shingrix
    - COVID-19

Treatment should be individualized

Myeloma – Treatment and Progression



1. Adapted from International Myeloma Foundation; 2001. Reprinted with permission.
2. American Cancer Society. *Cancer Facts & Figures*; 2003. 3. Millennium Pharmaceuticals, Inc., 2003.

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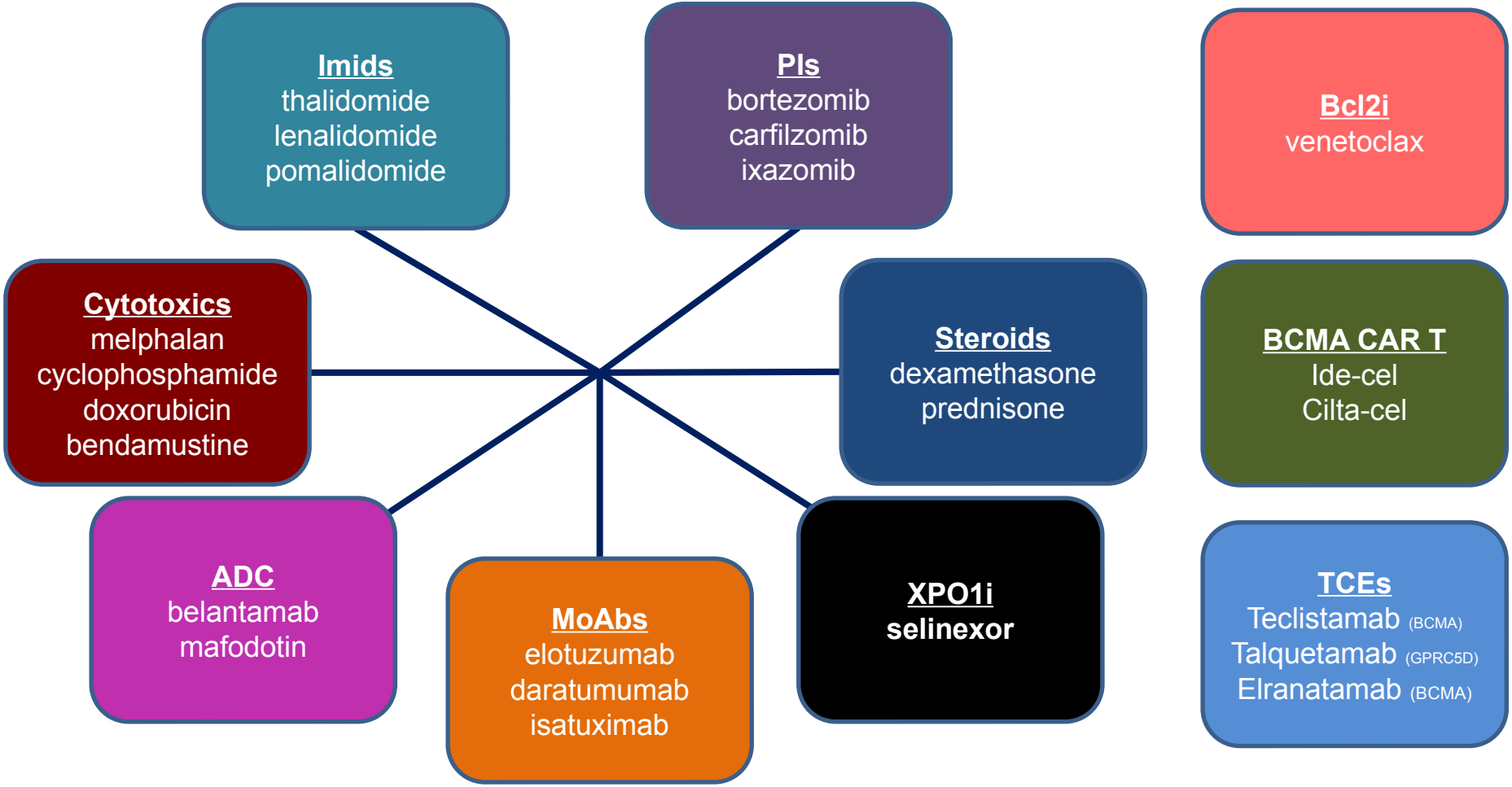

Imids
thalidomide
lenalidomide
pomalidomide
PIs
bortezomib
carfilzomib
ixazomib
Bcl2i
venetoclax
Cytotoxics
melphalan
cyclophosphamide
doxorubicin
bendamustine
Steroids
dexamethasone
prednisone
BCMA CAR T
Ide-cel
Cilta-cel
ADC
belantamab
mafodotin
MoAbs
elotuzumab
daratumumab
isatuximab
XPO1i
selinexor
TCEs
Teclistamab (BCMA)
Talquetamab (GPRC5D)
Elranatamab (BCMA)

Initial therapy paradigm

TRANSPLANT ELIGIBLE

Induction	Transplant	Maintenance
Rd Vd RVd VTd CyBorD	MEL200 x1 MEL200 x2	Lenalidomide Thalidomide Bortezomib Observation
RVd	**MEL200 x1**	**Lenalidomide**
Dara/RVd (RVd) (KRd)	**MEL200 x1**	**Lenalidomide Dara/Len**

TRANSPLANT INELIGIBLE

Induction		Maintenance
Rd Vd RVd VTd CyBorD	MP MPT VMP MPR	Lenalidomide Thalidomide Bortezomib Observation
RVd		**Lenalidomide**
Dara/Rd (Dara/RVd) (RVd)		**Lenalidomide Dara/Len**

Triplet therapies for relapsed myeloma

- melphalan/prednisone/thalidomide
- melphalan/prednisone/lenalidomide
- cyclophosphamide/prednisone/thalidomide
- pomalidomide/cyclophosphamide/prednisone

- bortezomib/melphalan/prednisone
- cyclophosphamide/bortezomib/dexamethasone
- cyclophosphamide/carfilzomib/dexamethasone
- PLD/bortezomib/dexamethasone
- bendamustine/bortezomib/dexamethasone

- bortezomib/thalidomide/dexamethasone
- bortezomib/lenalidomide/dexamethasone
- bortezomib/pomalidomide/dexamethasone
- carfilzomib/lenalidomide/dexamethasone
- carfilzomib/pomalidomide/dexamethasone
- ixazomib/lenalidomide/dexamethasone
- ixazomib/pomalidomide/dexamethasone

- bortezomib/panobinostat/dexamethasone
- carfilzomib/panobinostat/dexamethasone

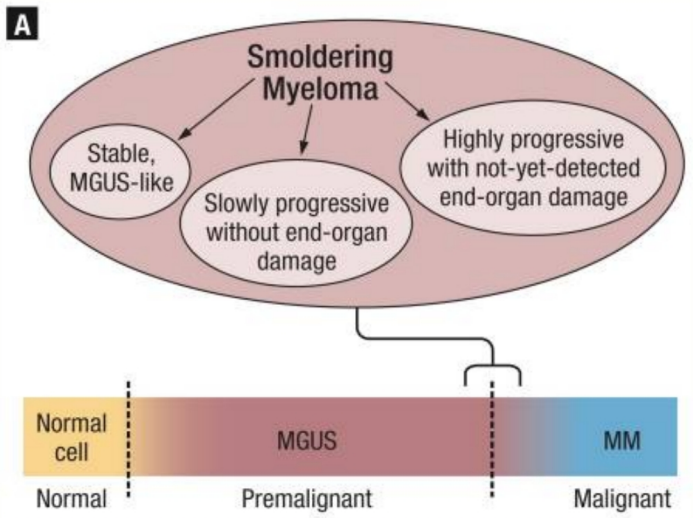
- daratumumab/bortezomib/dexamethasone
- daratumumab/lenalidomide/dexamethasone
- daratumumab/pomalidomide/dexamethasone
- elotuzumab/lenalidomide/dexamethasone
- elotuzumab/bortezomib/dexamethasone
- elotuzumab/pomalidomide/dexamethasone

Choosing wisely – triplets for relapsed myeloma

- No data comparing triplets or sequencing
- General principles
  - Most patients should receive triplets
  - Carefully assess treatment history
    - What worked?
    - What caused side effects?
  - Consider pace of progression and symptom burden
  - Include cost and convenience in the decision
- My favorite triplets
  - Any proteasome inhibitor / Imid combination
  - Cyclophosphamide / proteasome inhibitor combinations
  - Daratumumab or isatuximab combinations

Earlier treatment of smoldering myeloma

Smoldering Myeloma



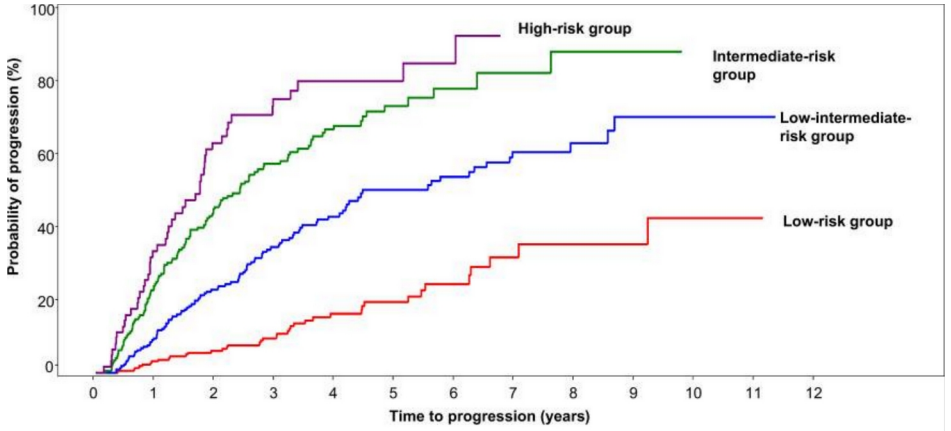
- **One of:**
  - ≥10% Bone Marrow Plasma Cells
  - ≥3 g/dL M-spike
- **Must not meet CRAB Criteria**
  - Anemia (Hgb <10 g/dL)
  - Renal failure (GFR <40)
  - Lytic bone lesions
  - Corrected Calcium >11 g/dL
- **Must not meet SLiM Criteria**
  - ≥60% Bone Marrow Plasma Cells
  - sFLC-ratio >100 or <0.01
  - Bone marrow lesions on whole body MRI or PET-CT

Waxman et al, Clin Lymph Myel, 2010

Risk Stratification – the “2/20/20” Criteria

Risk Factors:

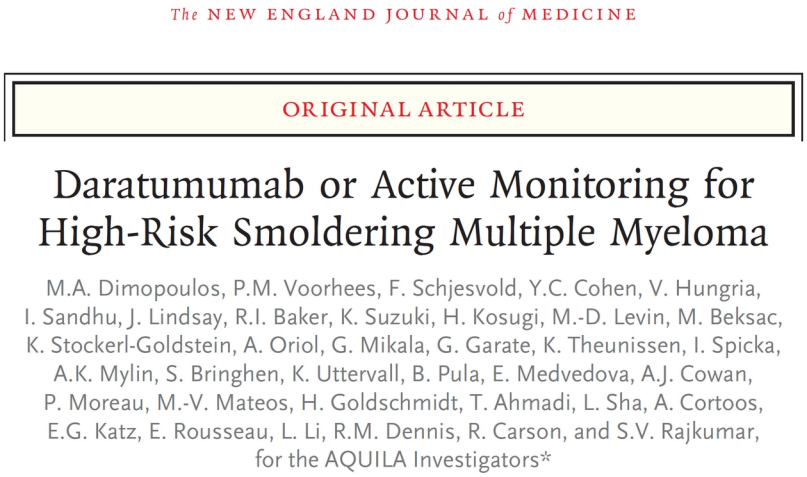
- M-protein >2 g/dL
- Bone marrow plasma cells >20%
- sFLC Ratio >20 or <0.05
- High-Risk Cytogenetics [t(4;14), t(14;16), del17p]



Risk Stratification groups	Number of risk factors	Hazard Ratio (95% CI)	Risk of progression (2 years)	# of patients
Low	0	Reference	6.0%	225 (32.7%)
Low-intermediate	1	4.16 (2.26 – 7.67)	22.8%	224 (32.5%)
Intermediate	2	9.82 (5.46 – 17.7)	45.5%	177 (25.7%)
High	3-4	15.5 (8.23 – 29.0)	63.1%	63 (9.1%)

Mateos et al, Blood Cancer J 2020

Daratumumab for High-Risk Smoldering Myeloma



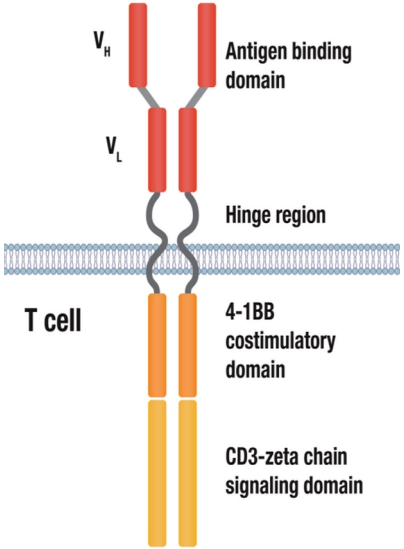
- Compared to observation, daratumumab led to:
  - Response rate 63%
  - Longer time to progression
  - Improved overall survival
  - More infections
- BUT:
  - Myeloma treatment at progression not standardized
  - Some patients may have been progressing already

Immunotherapy for relapsed myeloma (CAR T cells and T cell engagers)

What is a CAR?

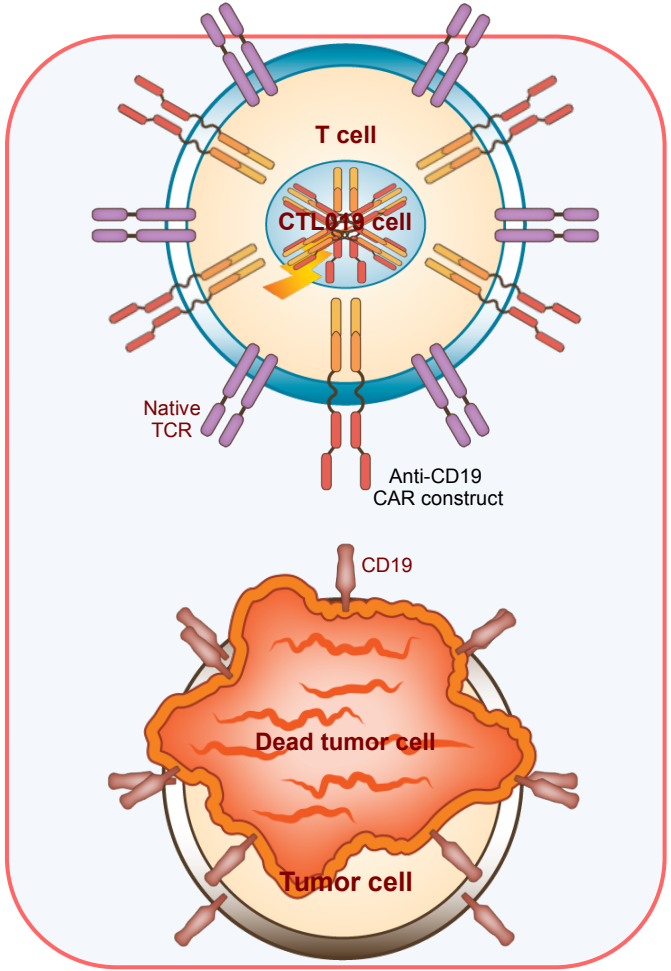
Chimeric **A**ntigen **R**eceptor

Chimera



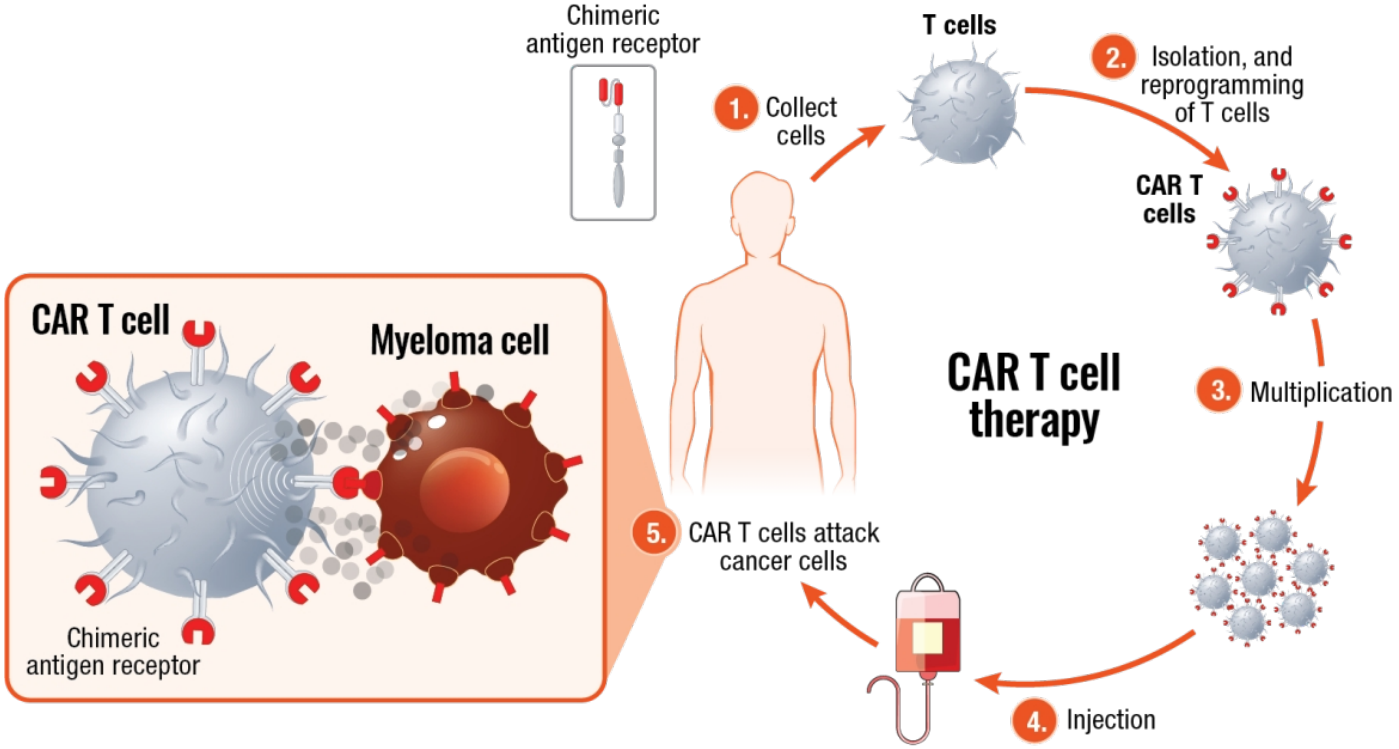
Building CAR T cells

“Living drug”



Courtesy of D. Porter

CAR T-Cell Therapy



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T cell Toxicities

Cytokine release syndrome (CRS, 70-100%)

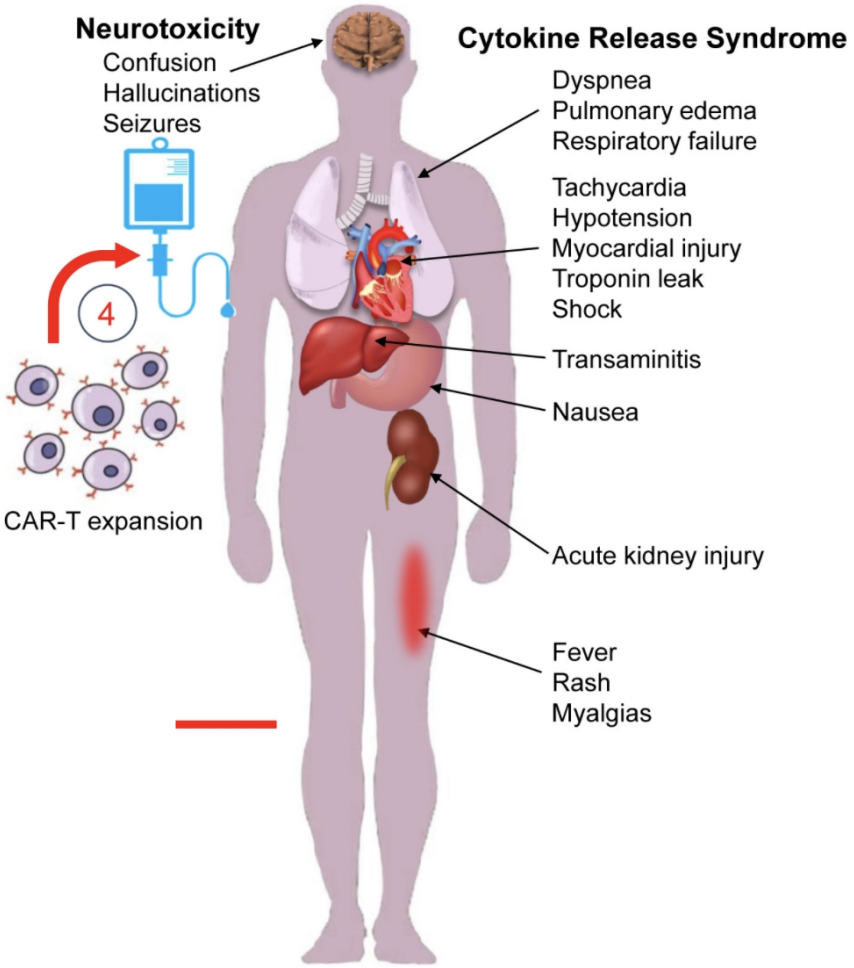
- Occurs between 1 hour and 10 days after infusion
- Lasts between 3-5 days
- Symptoms:
  - Fever, chills, HA, fatigue and malaise
  - Low blood pressure, low oxygen levels
- Treatment: tocilizumab

Neurotoxicity (ICANS, 10-30%)

- Occurs between 2 days to ~30 days
- Lasts between 1-14 days
- Symptoms:
  - Confusion and word finding difficulties
  - Unconsciousness, seizures
- Treatment: steroids

Low blood counts

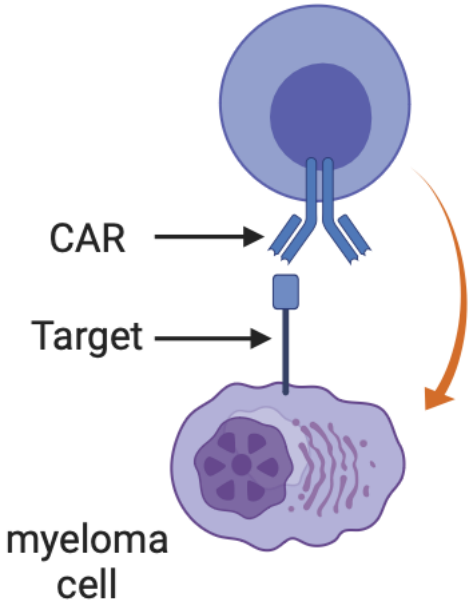
Infections



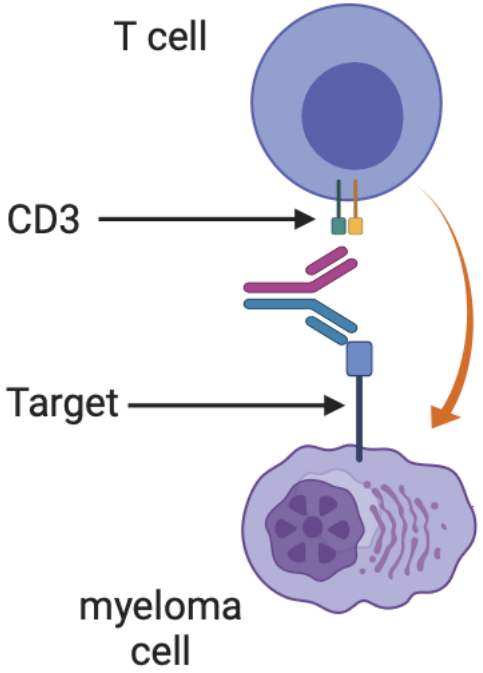
CAR T Cell

BCMA
Ide-cel*
Cilta-cel*
GC012F
ALLO-715
CART-ddBCMA

GPRC5D
BMS-986393
MCARH109



Bispecific Antibody



BCMA
Teclistamab*
Elranatamab*
Linvoseltamab
ABBV-383

GPRC5D
Talquetamab*
Forimtamig

FCRH5
Cevostamab

*Therapies with marketing authorization
Images created with BioRender
Courtesy of A Garfall

How we give bispecific antibodies

- **Step up dosing**
  - 2-3 lower doses given 48-72 hours apart
  - Allows CRS and neurologic toxicity at lower intensity
  - Close expert supervision
    - inpatient stay (6-8 nights)
    - outpatient dosing (7-10 visits over 2 weeks)
  - Immediate access to tocilizumab

- **Ongoing dosing**
  - Weekly, every 2 weeks, sometimes every 4 weeks
  - Any oncology infusion center
  - Subcutaneous injection, no premedications or observation

- **Infection prevention:**
  - Antibiotics (acyclovir or valacyclovir / Bactrim, dapsone, or atovaquone)
  - Monthly IVIG infusions

FDA-approved T cell therapies

	Response Rate	Progression-Free Survival	Toxicity

Ide-cel (ABECMA)	73%	11-13 m	• CRS/neurotoxicity (potentially severe)
			  • ICANS
			  • Others (Parkinsonism, CN palsy)
			• Infections
			• Cytopenias (potentially severe)

Cilta-cel (CARVYKTI)	97%	~34 m	
Teclistamab (TECVAYLI)	63%	12-24 m	• CRS/neurotoxicity (unlikely severe) • Infection risk (perhaps higher) • Cytopenias (unlikely severe)
Elranatamab (ELREXFIO)	61%	~15 m	
Talquetamab (TALVEY)	~72%	~12m	• Oral/taste toxicity (potentially severe) • Skin and nail toxicity

Studies of early-line CAR T cells (overall conclusions)

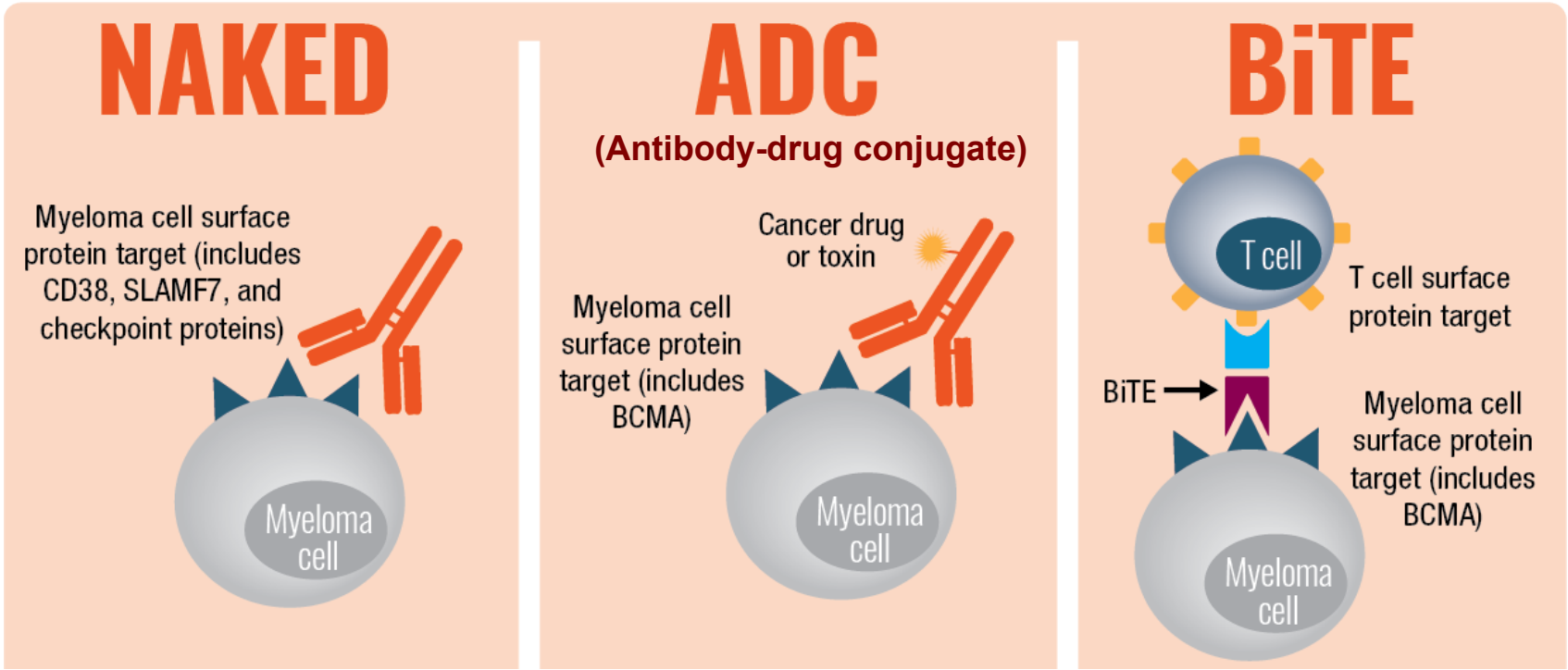
- **Efficacy**
  - CAR T cell therapy (cilta-cel) improves overall survival in multiple myeloma
  - Cilta-cel continues to appear more effective than ide-cel
  - Appears better earlier in treatment, but not transformational or curative
- **Safety**
  - CAR T cells appear safer in earlier lines compared to late-line usage
  - Infections are comparable to other standard therapies (worse earlier, better later)
  - ~10% cilta-cel patients have long-lived and/or life-threatening toxicities
- **Our practice at Penn:**
  - cilta-cel in 3rd line for most patients, 2nd line for high-risk patients (not using much ide-cel)

When do we use bispecific antibodies?

- Patients who need rapid disease control
- Patients who do not want to bear risk of CAR T cell therapy
- Patients who cannot access CAR T cell therapy
- Older/frail patients who may not tolerate CAR T cell therapy
- Patients relapsing after CAR T cell therapy
- Bridging therapy to enable CAR T cell therapy

Belantamab mafodotin (BLENREP)

What is an antibody-drug conjugate (ADC)?



Belantamab mafodotin (BLENREP, GSK2857916)

Antibody-drug conjugate targeting B cell maturation antigen (BCMA)

Approved August 2020 based on response rate of 31-34%

Withdrawn from market 11/2022 after a randomized trial failed to show better outcomes compared to pomalidomide/dexamethasone

Two new randomized trials:

- Belantamab/pomalidomide/dex compared to bortezomib/pomalidomide/dex

  Better responses, progression-free survival

- Belantamab/bortezomib/dex compared to daratumumab/bortezomib/dex

  Better responses, progression-free survival, overall survial

Belantamab administration and side effects

Administration

- Intravenously over ~1 hour
- Every 3-12 weeks (or even longer)

Side effects:

- infusion reactions (first dose)
- low platelets
- eye problems
  - Dry, gritty feeling
  - Light sentivitiy
  - Blurry vision

- Patients generally feel well

Dealing with eye toxicity

- Reversible over time
- Mostly annoying, sometimes interferes with daily tasks
- Almost all patients need a dose reduction and regular dose interruptions

- REMS program / enrollment
- Eye exam before every dose
- Preservative-free eye drops
- Hold dose for even moderate toxicity
- Responses tend to continue despite dose holds
- Restart even after recurrent toxicity

DREAMM-7: Belantamab with bortezomib and dexamethasone

Changes in vision Resolved in Patients with Complete Follow Up

20/20

20/50

20/200

Reprinted from Shi C, et al. *J Vis.* 2020;20(8):29. Copyright © 2020 The Authors.

BVd	Bilateral worsening of BCVA in patients with normal baseline 20/25 or better	
	20/50 or worse[a]	**20/200 or worse[a]**
Patients, n/N (%)	84/242 (35)	5/242 (2)
Time to onset of first event, median (range), days	79 (16-1320)	105 (47-304)
Time to resolution of first event to baseline, median (range), days[b]	64 (8-908)	87 (22-194)
Time to improvement of first event, median (range), days[c]	22 (6-257)	19 (8-26)
First event resolved, n/N (%)[b]	78/84 (93)	4/5 (80)
First event improved, n/N (%)[c]	81/84 (96)	5/5 (100)
Follow-up ended with event ongoing, n/N (%)	2/84 (2)	0

BCVA, best-corrected visual acuity; BVd, belantamab mafodotin, bortezomib, and dexamethasone; CTCAE, Common Terminology Criteria for Adverse Events;
[a] In patients with normal BCVA (20/25 or better in ≥1 eye) at baseline. [b] Resolution defined as a return to normal BCVA (20/25 or better in ≥1 eye). [c] Improvement was defined as BCVA of better than 20/50 (or 20/200) in at least one eye. [d] Graded using CTCAE version 5.0.

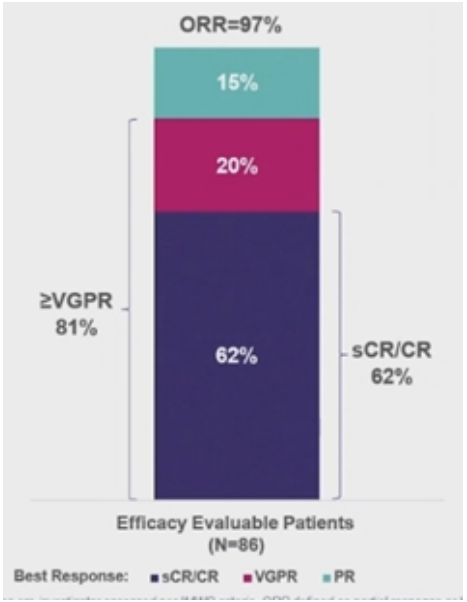
New therapies in clinical trials (whirlwind tour)

Anito-cel (CART-ddBCMA) for rel/ref MM

iMMagine-1 Phase 2 registration study

Median 4 lines, 87% triple-class refractory, 0% BCMA tx

Median f/up = 9.5 months



	PFS Rate (%) (95% CI)	OS Rate (%) (95% CI)
6-Month	93.3% (84.4%, 97.2%)	96.5% (89.6%, 98.9%)
12-Month	78.5% (63.5%, 87.9%)	96.5% (89.6%, 98.9%)

CRS 83% (≥Gr3=1%)
ICANS 9% (≥Gr3=1%)
3 deaths:
-HLH/hemorrhage, CRS, fungal infections

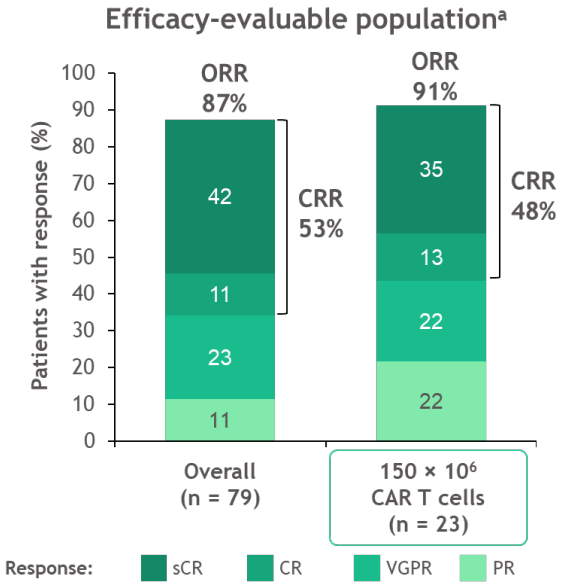
No delayed neurotoxicity

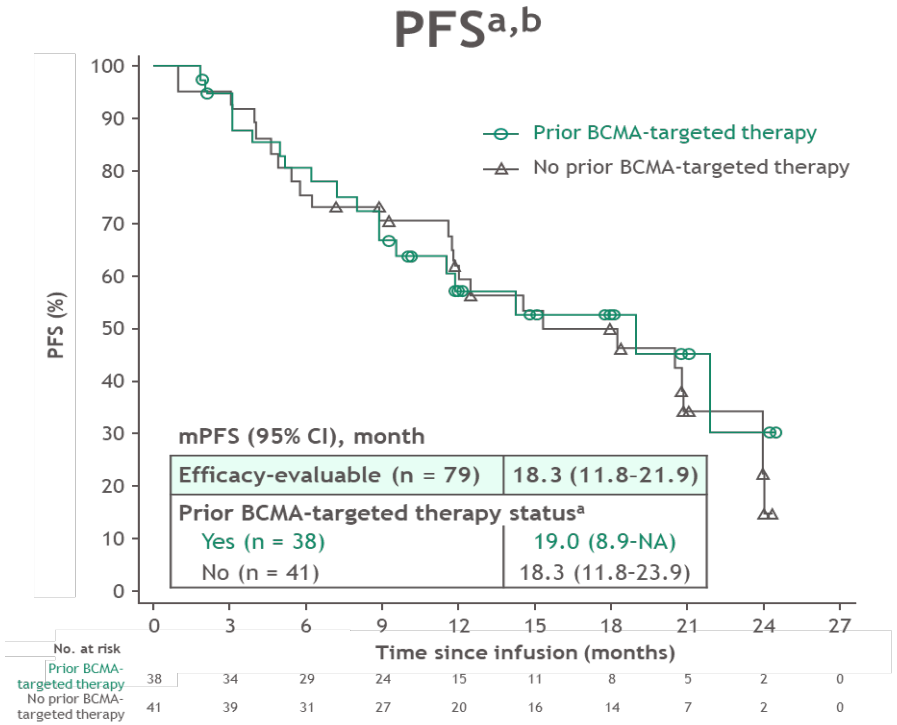
Phase 3 anito-cel vs SOC in 1-3 priors opened late 2024

Freeman et al, ASH 2024, #1031

Phase 1 of arlocabtagene autoleucel (arlo-cel,BMS-986393)

GPRCRD-targeted autologous CAR T cells
Median 5 lines, 76% triple-class refractory
49% prior BCMA tx

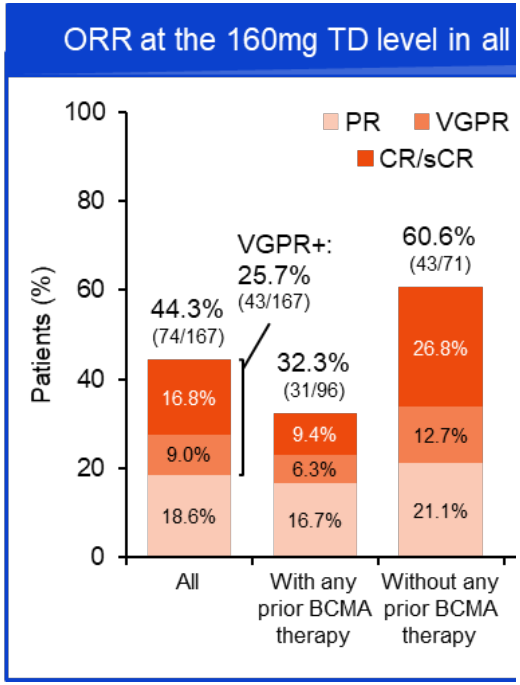


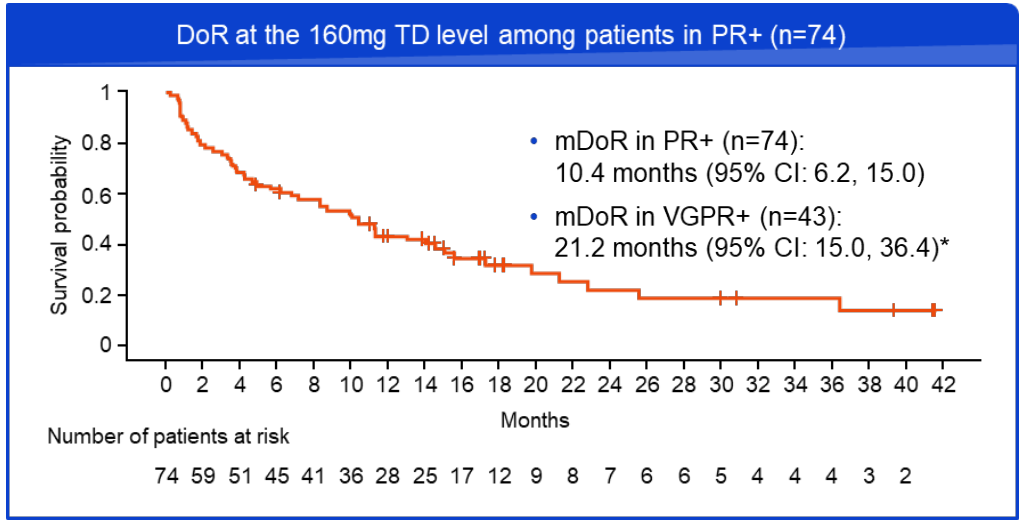


Bal et al, ASH 2024, #922

Cevostamab (FcRH5 x CD3 bsAb) phase 1 update

At RP2D (160mg q3wks IV x 17 cycles)
Median 6 lines, 96% triple-class refractory
58% prior BCMA tx





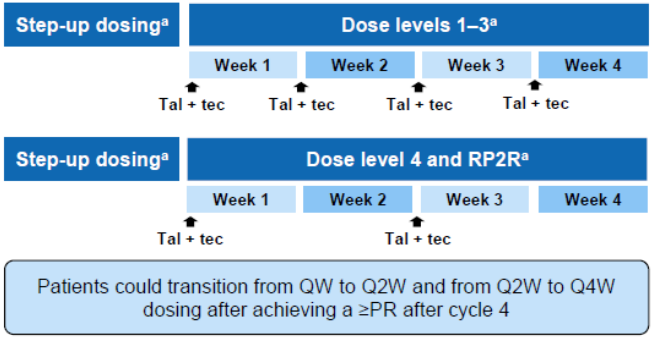
At RP2 step-up (n=30):
CRS 63% (0% Gr 3-4)

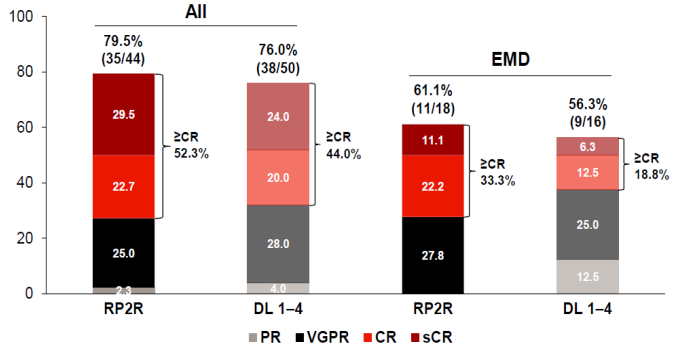
N (%) of patients	n=167
AE of infection	91 (54.5)
Gr 3–5 AE of infection	32 (19.2)
Gr 3	24 (14.4)
Gr 4	2 (1.2)
Gr 5 (fatal)	6 (3.6)
SAE of infection	37 (22.2)
AE of infection leading to treatment discontinuation	10 (6.0)

Richter et al, ASH 2024, #1021

RedirecTT-1: ph1b of Teclistamab + Talquetamab for RRMM

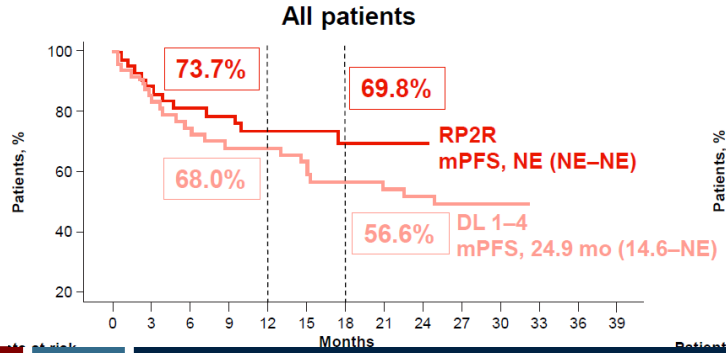
Median 4 lines, 86% triple-class refractory
29% prior BCMA tx

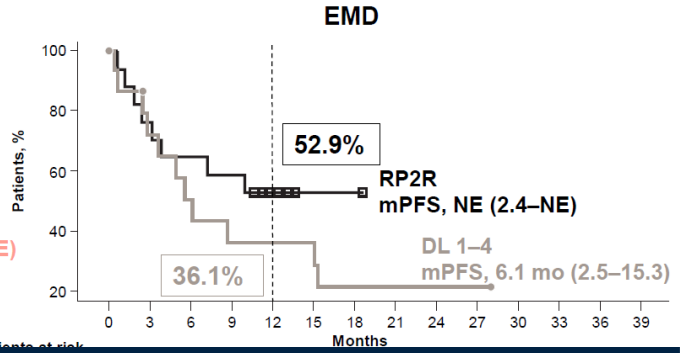




Grade 3/4 infections:
– 47.7% (RP2R), 63.8% (all doses)
Grade 5 infections:
– 6.8% (n=3; RP2R), 11.7% (n=11; all doses)
Infection prophylaxis given per institutional guidelines
– 81.9% received antiviral prophylaxis (all doses)
56.6% had hypogammaglobulinemia[b]
– 56.6% received ≥1 dose of IVIG

Progression-free survival



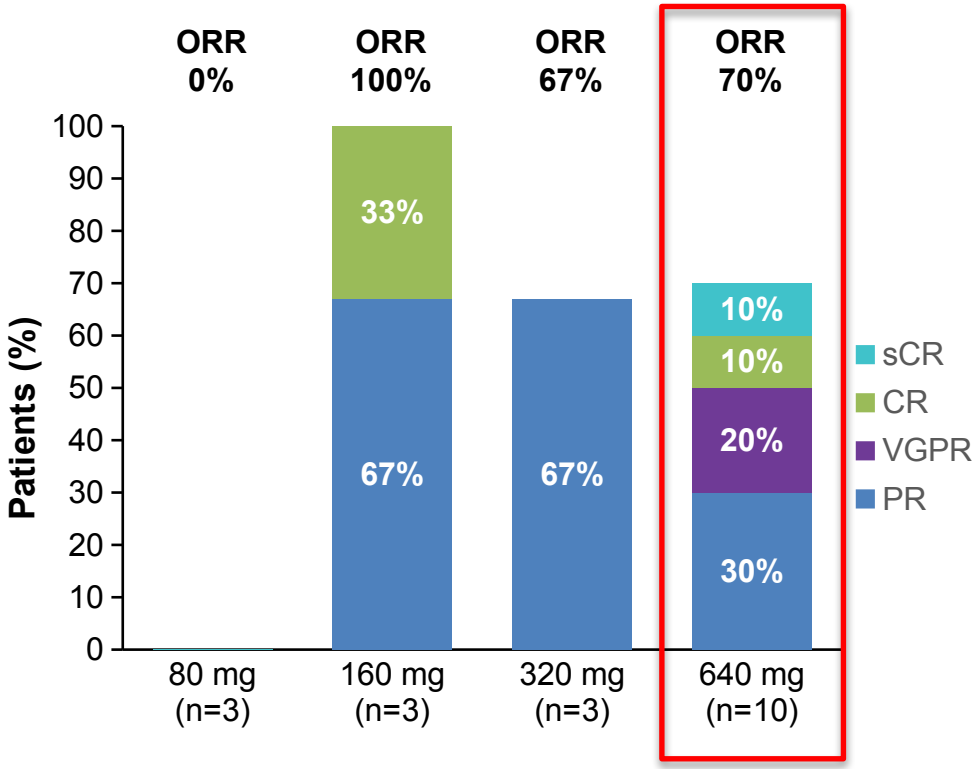


Y Cohen et al, IMS 2024, #OA-03

Penn Medicine

Sonrotoclax (BGB-11417) for t(11;14) myeloma

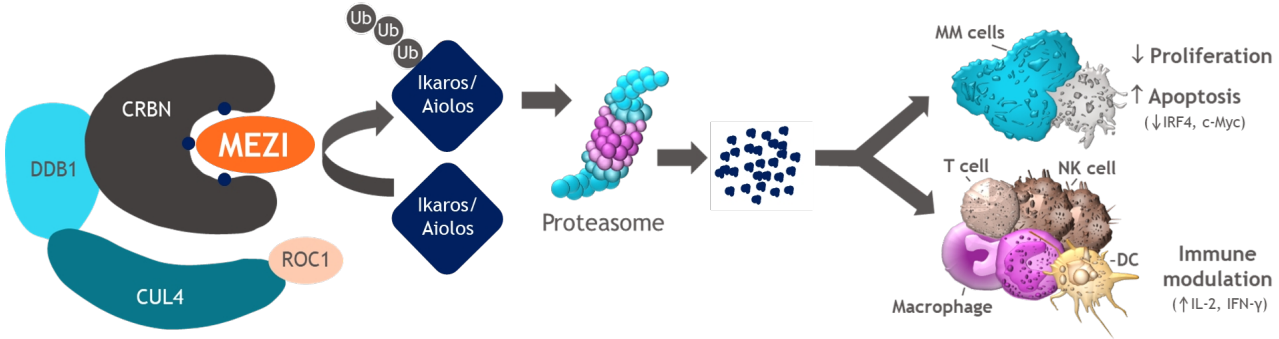
- More potent and selective BCL2 inhibition *in vitro*
- Sonrotoclax + dexamethasone phase 1b/2 study in t(11;14) R/R MM
- Median treatment duration:
  All patients: 5.1 months (range, 1.2-21.1 months)
  640 mg: 5.5 months (range, 2.4-15.1 months)
- The longest DoR was 18.9 months, which was still ongoing at data cutoff



Quach, American Society of Hematology Annual Meeting 2023, Abstract 1011

Mezigdomide

- MEZI is a novel, oral CELMoD™ agent that is a potent inducer of Ikaros and Aiolos degradation, resulting in immune-modulatory effects and enhanced tumoricidal activity in myeloma cells[1-3]
- In patients with triple-class RRMM, MEZI + DEX had a manageable safety profile and a promising ORR of 41%[4]



BORT, bortezomib; CD, cluster of differentiation; CFZ, carfilzomib; c-Myc, cellular Myc; CRBN, cereblon; CUL4, cullin 4; DC, dendritic cell; DDB1, DNA damage-binding protein 1; DEX, dexamethasone; IFN, interferon; IL, interleukin; IRF4, interferon regulatory factor 4; mAb, monoclonal antibody; MEZI, mezigdomide; MM, multiple myeloma; NK, natural killer; ORR, overall response rate; PI, proteasome inhibitor; ROC1, regulator of cullins-1; RRMM, relapsed/refractory multiple myeloma; Ub, ubiquitin.

1. Hansen JD, et al. *J Med Chem* 2020;63:6648-6676. 2. Lu G, et al. *Science* 2014;343:305-309. 3. John LB, Ward AC. *Mol Immunol* 2011;48:1272-1278. 4. Richardson PG, et al. *N Engl J Med* 2023;389:1009-1022. 5. Wong L, et al. *Blood* 2019;134(suppl 1). Abstract 1815. 6. ClinicalTrials.gov. NCT03989414. 7. Richardson PG, et al. *Blood* 2021;138(suppl 1). Abstract 2731. 8. Oriol A, et al. Oral presentation at the International Myeloma Society (IMS) Annual Meeting; September 27-30; 2023; Athens, Greece. Abstract OA-49.

Efficacy of MeziVd and MeziKd

Dose-escalation Cohort A (MeziVd)

	All doses	1.0 mg
ORR,[b] % (95% CI)	75.0 (55.1-89.3)	60.0 (55.1-89.3)
DOR, median (95% CI), months	10.9 (8.8-18.7)	11.6 (5.3-NA)

Overall median PFS **12.3** months

Dose-expansion Cohort D (MeziVd)

	All doses	1.0 mg
ORR,[b] % (95% CI)	85.7 (72.8-94.1)	84.2 (68.7-94.0)
DOR, median (95% CI), months	19.4 (9.7-NA)	19.4 (7.0-NA)

Overall median PFS **17.5** months

Dose-escalation Cohort C (MeziKd)

	All doses	1.0 mg
ORR,[b] % (95% CI)	85.2 (66.3-95.8)	77.8 (40.0-97.2)
DOR, median (95% CI), months	11.9 (6.4-35.9)	11.9 (0.2-NA)

Overall median PFS **13.5** months

[a]Data cutoff: June 28, 2024; [b]ORR refractory to LEN and anti-CD38 mAbs (data cutoff: May 9, 2024): Cohort A = 69.2%, Cohort D = 75.0%.
CI, confidence interval; DOR, duration of response; NA, not applicable; PFS, progression-free survival.

Sandhu I, et al. ASH 2024 [Abstract #1025]

Inobrodib with pomalidomide and dexamethasone

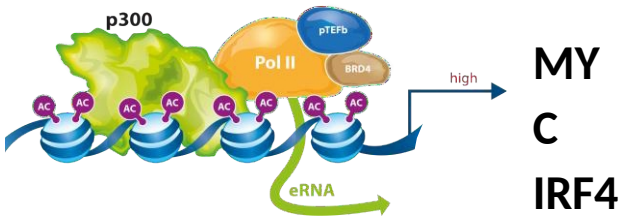
Inobrodib: First-in-class, oral, potent and specific bromodomain inhibitor of p300/CBP, two transcriptional coactivators with key roles in hematological cancers

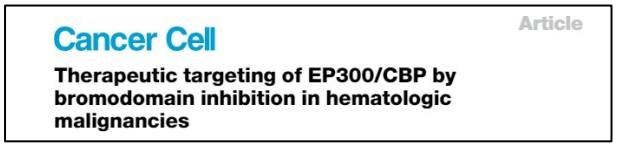
Strong scientific rationale for targeting p300/CBP in myeloma

- selective displacement of p300/CBP from 10% of binding sites[1]
- inhibition of key oncogenic drivers IRF4 and MYC
- exquisite synergy with IMiDs[2]

Clinical activity has been observed in patients with relapsed and refractory myeloma when given as a monotherapy (ORR 25%)[3]

We report on the combination of inobrodib (INO), pomalidamide (POM) and dexamethasone (DEX) in the ongoing Phase I/IIa trial (NCT04068597).

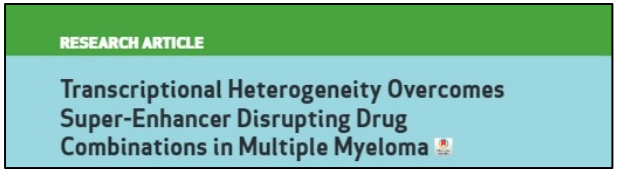



Cancer Cell

Article

Therapeutic targeting of EP300/CBP by bromodomain inhibition in hematologic malignancies

[1]*Nicosia et al, Cancer Cell 2023*


RESEARCH ARTICLE

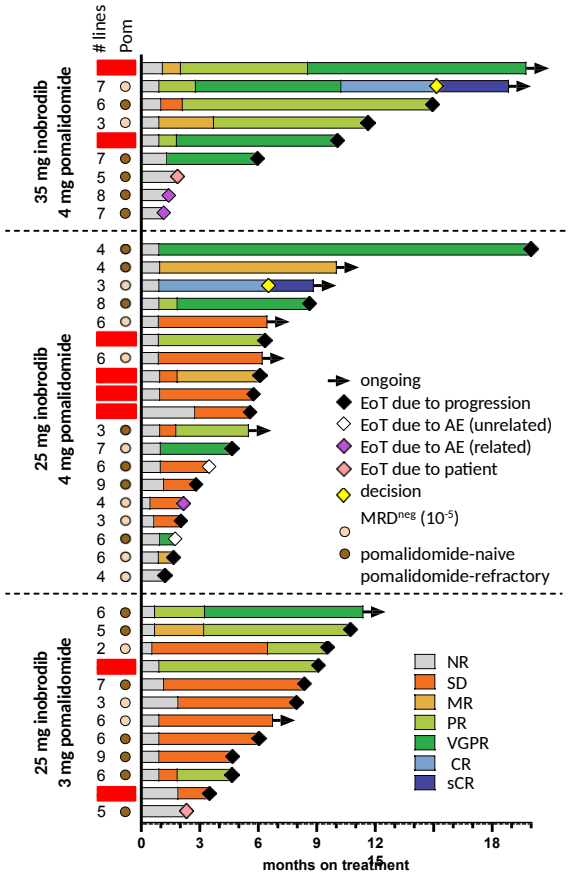
Transcriptional Heterogeneity Overcomes Super-Enhancer Disrupting Drug Combinations in Multiple Myeloma

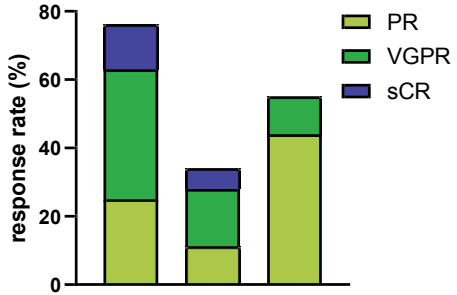
[2]*Welsh et al, Blood Cancer Discovery 2024*

[3]Searle E et al presented at ASH 2023

Searle E, et al. ASH 2024 [Abstract #1023]

InoPd efficacy in relapsed refractory multiple myeloma





Ino (mg)	35	25	25
Pom (mg)	4	4	3
N*	8	18	9
ORR* (%)	75	33	56

Across all cohorts: 49% ORR, mDOR 6.3 months , 63% of pts ≥ 6 mo.

Highest dose cohort: 75% ORR, mDOR 9.7 months

Pom-refractory patients (last line): 4/8 pts responded ≥PR, + 1 MR

* Among evaluable patients

Searle E, et al. ASH 2024 [Abstract #1023]

Current clinical trials at Penn

FOR RELAPSED/REFRACTORY MYELOMA

limited-duration teclistamab (LimiTEC)

anti-GPRC5D antibody/drug conjugate, phase 1

MMSET inhibitor for t(4;14) myeloma, phase 1

trispecific BCMAxGPRC5DxCD3 T cell engaging antibody, phase 1

cevostamab consolidation after BCMA-directed CAR T cells, phase 2 (CLOSING SOON)

allogeneic (off-the-shelf) BCMA-directed CAR T cells, phase 1 (OPENING SOON)

inobrodib (p300/CBP inhibitor) with pomalidomide and dexamethasone, phase 2 (OPENING SOON)

EARLIER LINES OF THERAPY

belantamab mafodotin before and after stem cell transplant

teclistamab vs lenalidomide for maintenance after stem cell transplant (OPENING SOON)

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