



LEUKEMIA &
LYMPHOMA
SOCIETY™


ADVANCES IN MULTIPLE MYELOMA

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Slide credits to Dr. Rahma Warsame

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WELCOMING REMARKS ADVANCES IN MULTIPLE MYELOMA



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WELCOMING REMARKS

ADVANCES IN MULTIPLE MYELOMA

This program is supported by



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WELCOMING REMARKS

ADVANCES IN MULTIPLE MYELOMA



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DISCLOSURES

Companies	Role
Janssen	Advisory board and independent review committee
Oncopeptides, Sorrento	Data monitoring safety committee
Alynlam, Pfizer, Takeda, BMS	Research dollars

The presentation includes off-label information on treatment regimens

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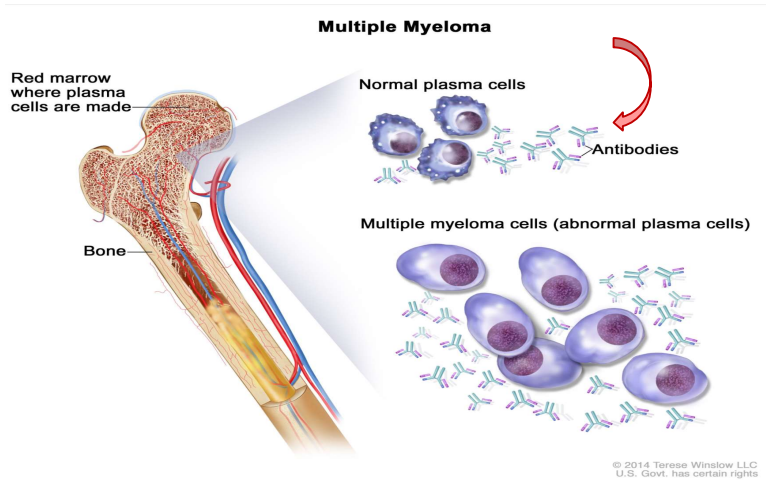
KEY POINTS

- Understand diagnosis and staging of multiple myeloma
- Review treatment paradigm
- Immunotherapy for multiple myeloma
 - Naked antibodies
 - Antibody drug conjugates
 - Bispecific antibodies
 - Chimeric antigen receptor T-cell therapy (CART)
- Future directions

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1. WHAT IS MULTIPLE MYELOMA?



S sixty percent plasma cells
L light chains I/U>100
I igG >10g/dL
M MRI with >1 focal lesion
C calcium high
R renal impairment
A anemia
B bone damage

Kyle RA. *Mayo Clinic Proceedings*. 2003.
 Rajkumar SV. *Lancet Oncol*. 2014

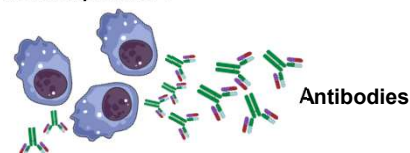
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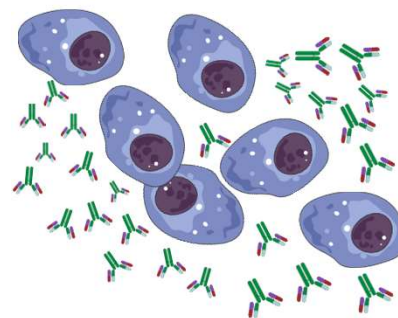
2. MULTIPLE MYELOMA – EPIDEMIOLOGY

- Cancer of plasma cells in the bone marrow that produce monoclonal immunoglobulins/proteins
- Approximately 1-2% of all cancers
- Cancer of older adults
 - Median age at diagnosis 65-74
 - 10% are <50
- More common in African American individuals

Normal plasma cells



Multiple myeloma cells (abnormal plasma cells)



Siegel RL. *Cancer Statistics*. 2021
 Kyle RA. *Mayo Clinic Proceedings*. 2003.
 Waxman AJ. *Blood*. 2010

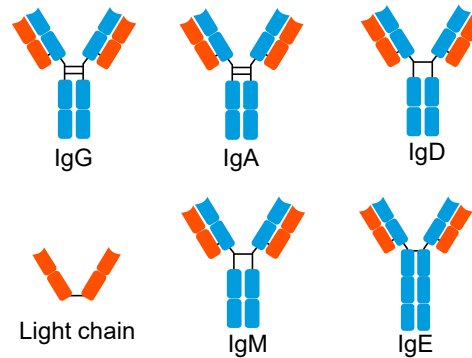
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3. PLASMA CELL – BASICS

Plasma cell: terminally differentiated B-cell that secretes Immunoglobulins (Ig factory)

- Immunoglobulins
 - Heavy chain
 - IgM, IgG, IgA, IgD, IgE
 - Light chain
 - Kappa and lambda



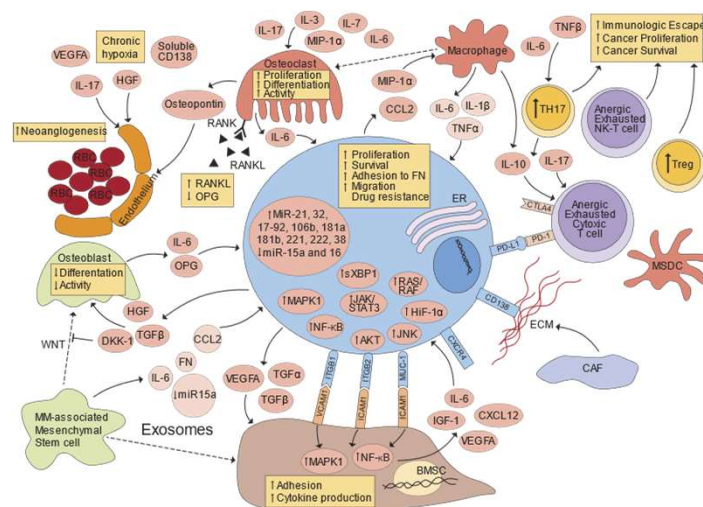
Handy-dandy tumor maker that can be followed in blood and/or urine

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MYELOMA BONE MARROW MILIEU

Bone marrow microenvironment of MM patients differs in cellular and non-cellular composition from healthy individuals

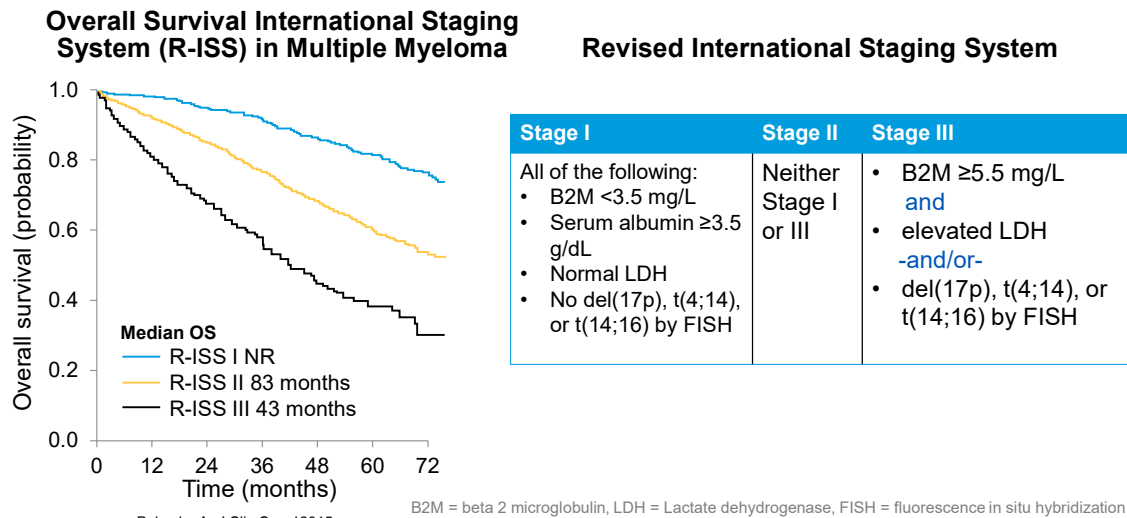


Redrawn from: Bianchi et al: Blood 2015; (125): 3049-3058

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4. MULTIPLE MYELOMA – RISK STRATIFICATION



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MM RISK STRATIFICATION - FISH

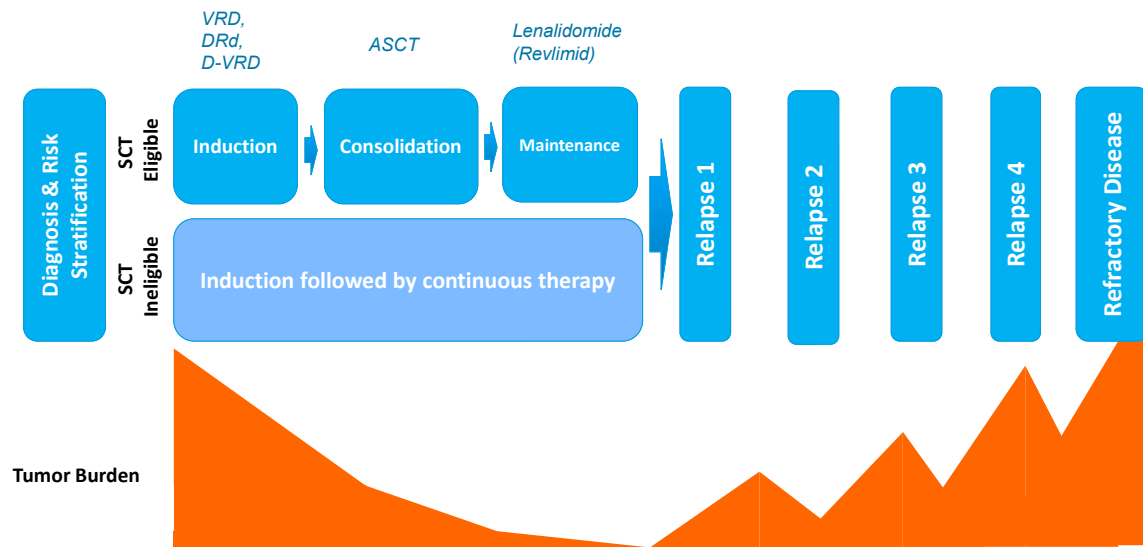
- High Risk genetic abnormalities
 - t(4;14)
 - t(14;16)
 - t(14;20)
 - Del 17p or p53 mutation
 - Gain 1q (amplification or duplication)
- R-ISS stage 3
- High risk plasma cell S-phase
- Standard Risk
 - All others including:
 - Trisomies
 - t(11;14)
 - t(6;14)

<https://www.msmart.org/>

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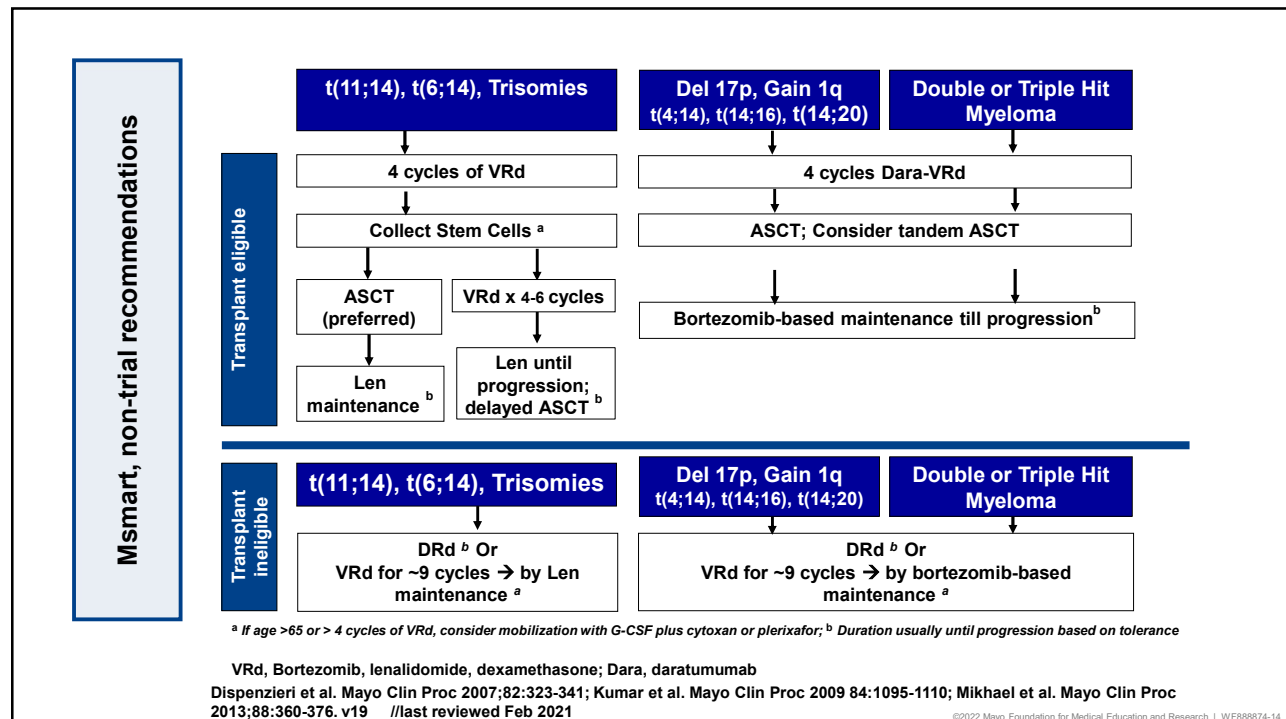
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5. MYELOMA TREATMENT PARADIGM

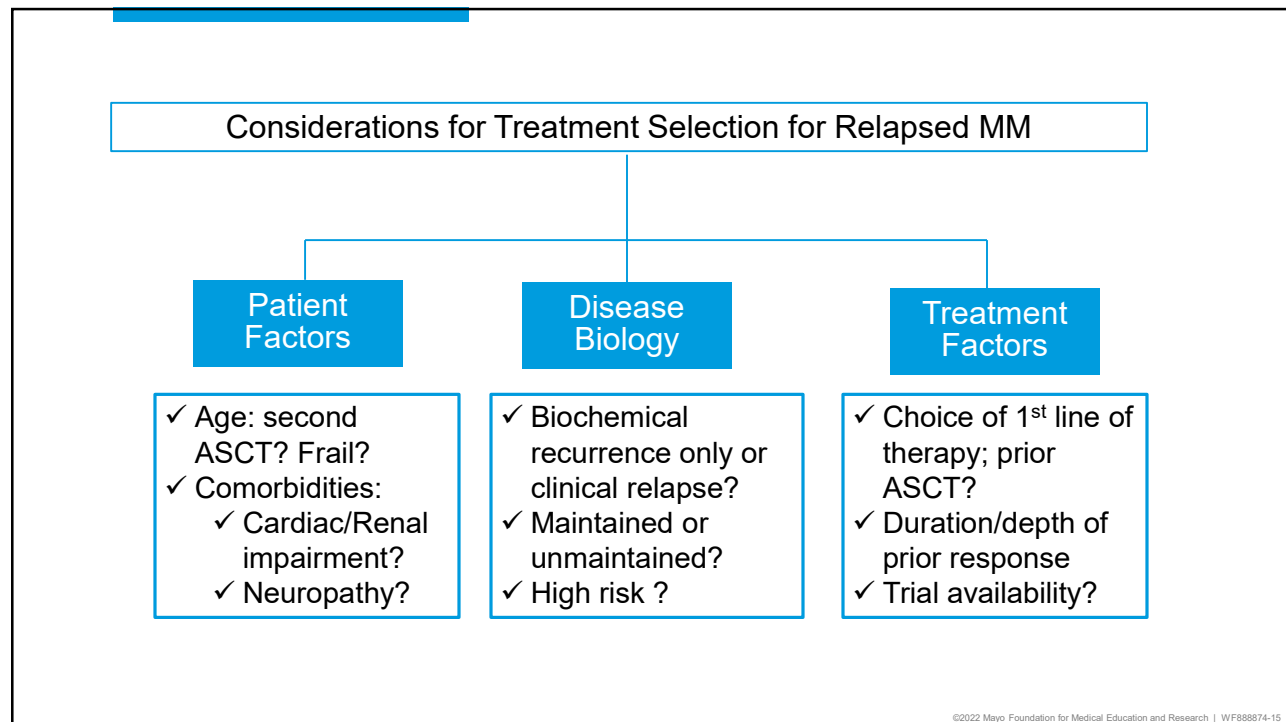


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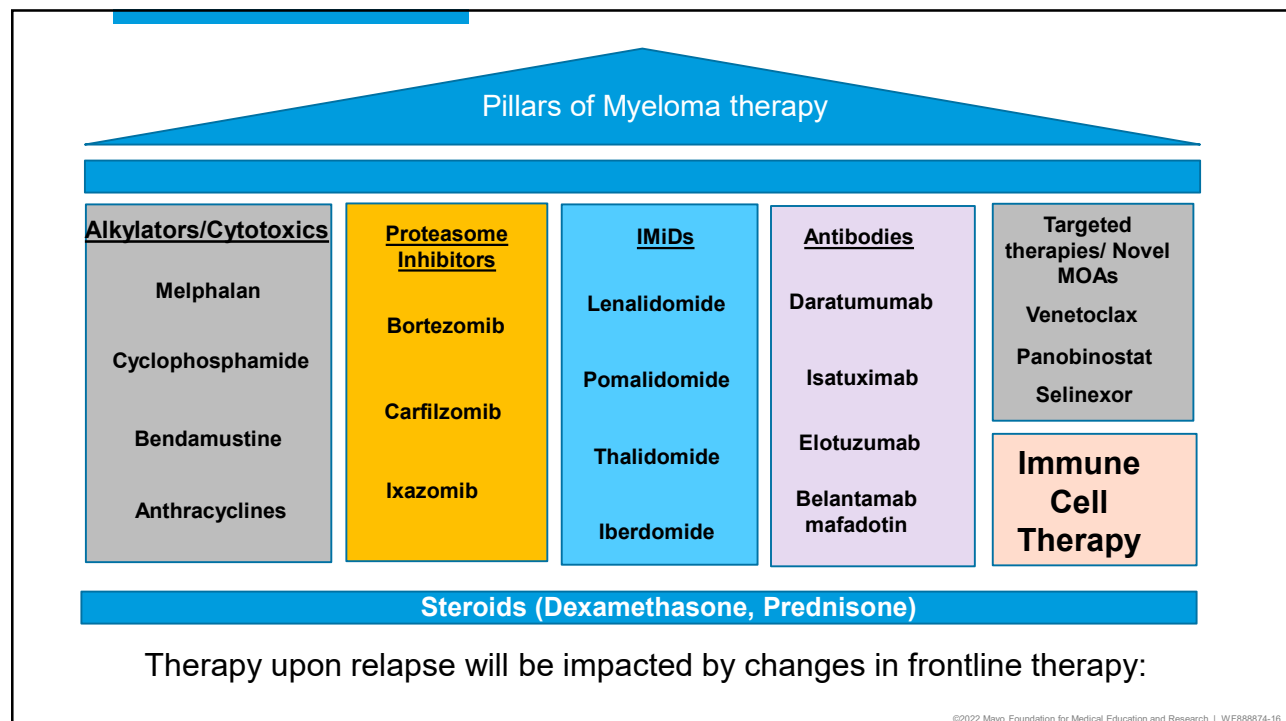
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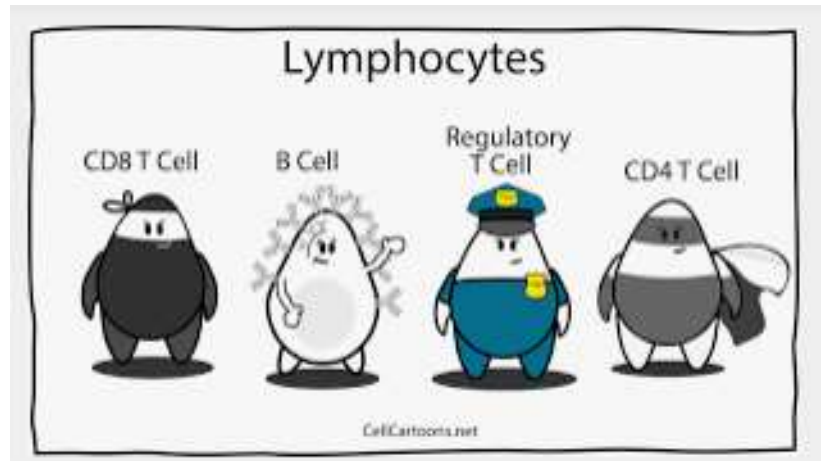


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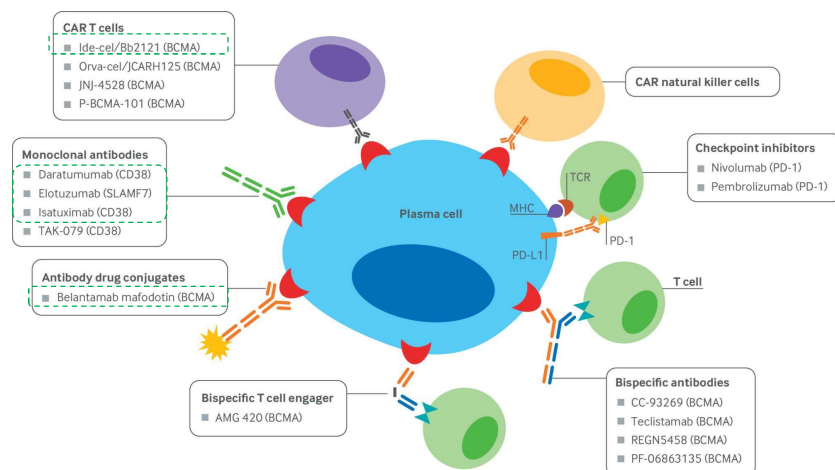
6. RETRAIN THE IMMUNE SYSTEM TO **KILL** MM



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EMERGING IMMUNOTHERAPIES IN MULTIPLE MYELOMA

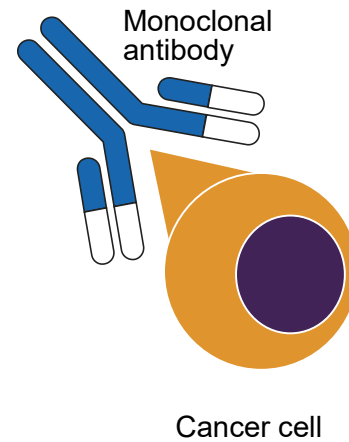


Shah A, Mailankody S. *BMJ* 2020; 370

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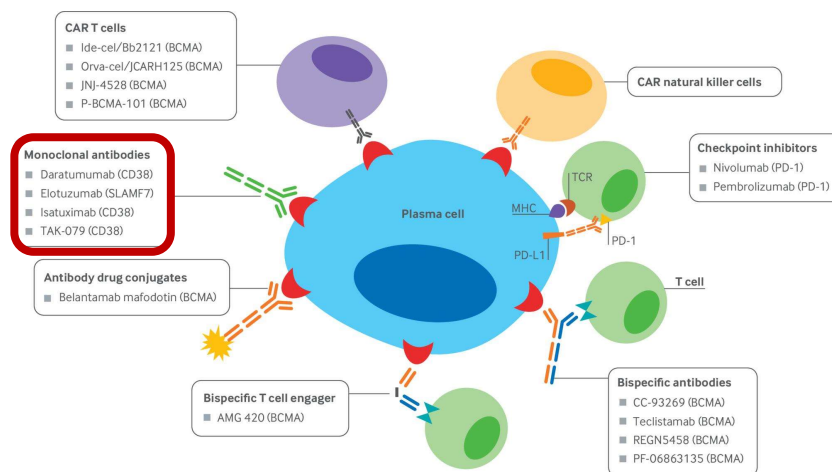
NAKED ANTIBODIES



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EMERGING IMMUNOTHERAPIES IN MULTIPLE MYELOMA



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CD38 T-MABS ARE EVERYWHERE!

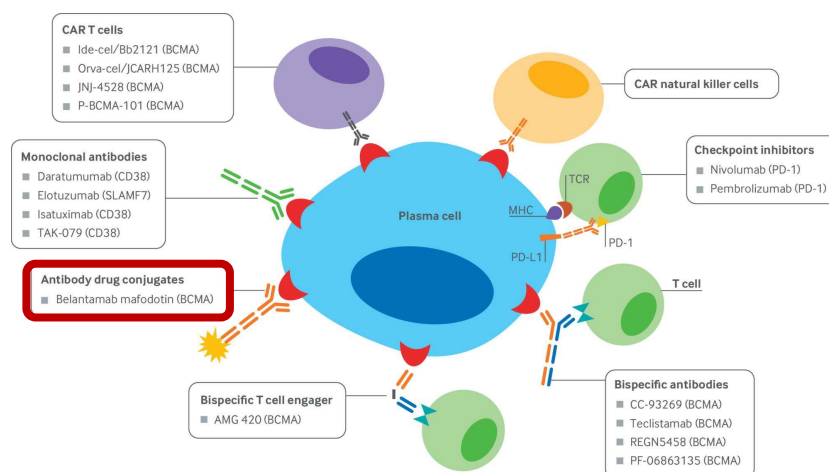
T-mAb	Newly diagnosed MM	RRMM
Daratumumab	D-VTd	D-Pd
	D-VMP	D-Kd
	D-Rd	D-Vd
	Master: KRd ± Dara	D-Rd
	Perseus: VRd ± Dara	
Isatuximab	Isa-Kia (KRd ± Isa)	Isa-Pd
	(VRd ± Isa)	Isa-Kd
	(VCd ± Isa)	

Randomized trials on-going in MM maintenance, MGUS, and SMM spaces

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EMERGING IMMUNOTHERAPIES IN MULTIPLE MYELOMA

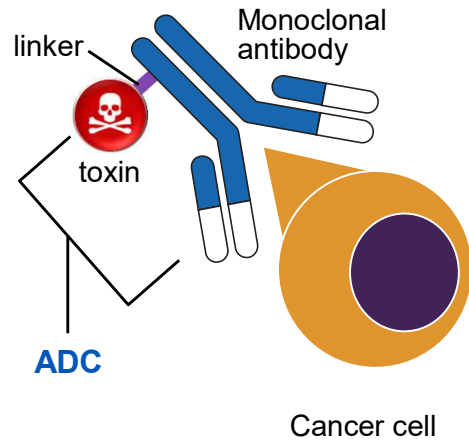


Shah A, Mailankody S. *BMJ* 2020; 370

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ANTIBODY DRUG CONJUGATE



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ANTIBODY DRUG CONJUGATE (ADC)

Benefits

- Targeted release of chemotherapy/immunotoxin/immunotherapy
- Attracts immune cells that clear cancer even if the treatment does not
- Dead cancer cells attract even more immune effector cells enhancing its potential response

Risk

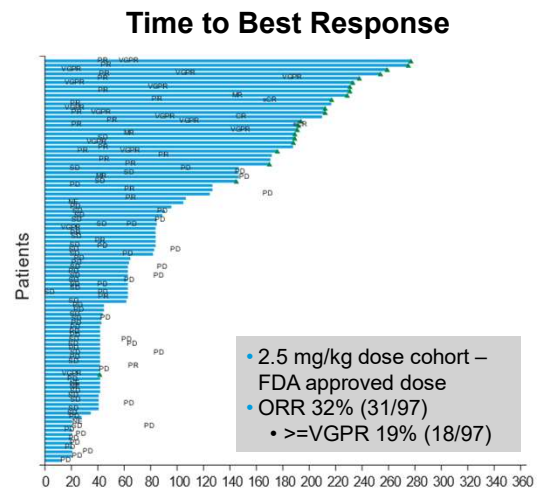
- Still not 100% specific for myeloma cells and can cause tissue specific toxicity

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BELANTAMAB

- BCMA ADC
 - Humanized IgG1 anti-BCMA monoclonal antibody & monomethyl auristatin F (toxin)
 - IV infusion over 3 minutes every 3 weeks
- Progression free survival 2.8 months
- Continued response can be seen in patients with ADC on hold

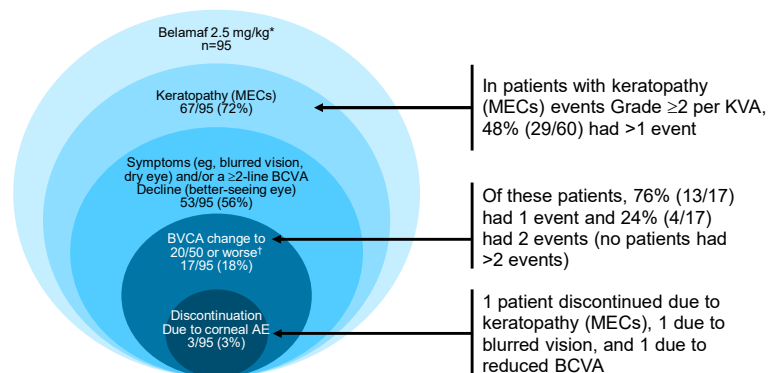


Redrawn from: Lonial et al. Lancet Oncol 2020; 21: 207

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BELANTAMAB OCULAR TOXICITY



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BELANTAMAB + POM/DEX (ALGONQUIN STUDY, NCT03715478)

Eligibility criteria

≥1 prior line, Len refractory,
PI exposed or refractory,
Mild/moderate renal
impairment allowed

Most frequent AE's

Keratopathy 96.9%, blurred vision
87.5%, fatigue 59.4%, neutropenia
(62.5%), thrombocytopenia (50%),
fever (46.9%), diarrhea (34.4%),
constipation (34.4%), and dry eye
(28.1%)

Table 1: Summary of corneal events, ocular symptoms and efficacy data by cohort

Cohort	Median number for treatment cycles (range)	≥G3 Keratopathy (%)	≥G3 blurred vision n (%)	AEs leading to dose holds	AEs leading to dose reductions	≥VGPR n/N (%)	ORR n/N (%)	6-month PFS (%)
1.92 SINGLE n=12	13.5 (2-23)	5 (41.7%)	4 (33.3%)	7 (58.3%)	0 (0%)	7/11 (63.6%)	9/11 (81.8%)	80%
2.5 SINGLE n=7	27 (13-29)	7 (100%)	4 (57.1%)	7 (100%)	7 (100%)	7/7 (100%)	7/7 (100%)	100%
2.5 LOADING N=5	9 (5-17)	4 (80%)	0 (0%)	5 (100%)	5 (100%)	4/5 (80%)	5/5 (100%)	80%
2.5 BIMONTHLY (N=12)	6 (4-10)	10 (83.3%)	2 (16.7%)	7 (58.3%)	5 (41.7%)	9/12 (75%)	11/12 (91.7%)	100%
2.5 TRIMONTHLY N=11	6 (1-10)	8 (72.7%)	2 (18.2%)	4 (36.4%)	5 (45.5%)	4/7 (57.1%)	5/7 (71.4%)	75%
2.5 SPLIT	12.5 (3-22)	7 (87.5%)	4 (50%)	8 (100%)	6 (75%)	6/8 (75%)	7/8 (87.5%)	85.7%
3.4 SPLIT N=5	7.5 (1-21)	3 (60%)	2 (40%)	3 (60%)	1 (20%)	3/4 (75%)	4/4 (100%)	75%
All cohorts N=60	8 (1-29)	44 (73.3%)	18 (30%)	41 (68.3%)	29 (48.3%)	40/54 (74.1%)	48/54 (88.9%)	86.5%

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MODAKAFUSP ALFA IS A NOVEL, FIRST-IN-CLASS IMMUNOCYTOKINE DESIGNED TO DELIVER IFNA2B TO CD38+ CELLS

Modakafusp alfa

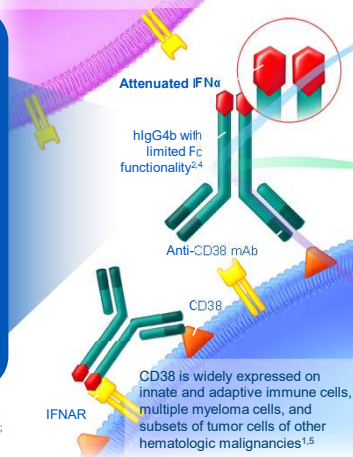
Binds with high affinity to unique epitope of CD38^{1,2}

Signals through IFNAR² to:

- activate innate and adaptive immune cells¹
- direct anti-proliferative/apoptotic signals to tumor cells^{2,3}

Fc, fragment crystallizable; hlgG4b, human immunoglobulin 4b; IFN, interferon; IFNAR, interferon α receptor; mAb, monoclonal antibody; MDSC, myeloid-derived suppressor cell; NK, natural killer; Treg, regulatory T cell

The CD38-targeted attenuated IFNα fusion protein displays a 10,000-fold greater specificity than native IFNα for CD38+ vs CD38- cells²



Innate immune cell activation^{1,3,5}

NK cell, Macrophage, Monocyte, MDSC, Dendritic cell

Adaptive immune cell activation^{1,3,5}

B cell, CD4, CD8, Treg

Multiple myeloma cell binding

Multiple myeloma cell death^{2,3}

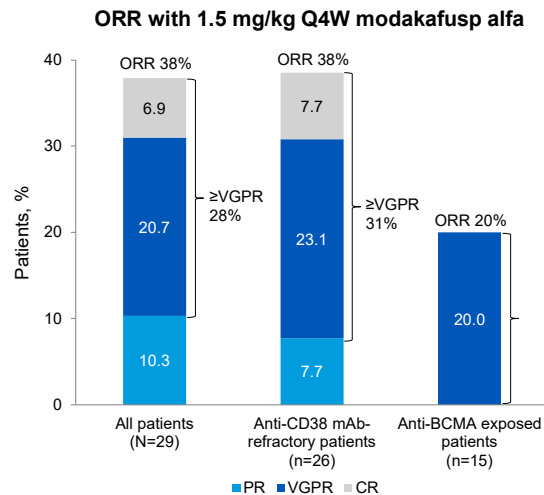
1. Vogt DT, et al. Blood. 2020;136(Suppl. 1):3197
2. Pogue SL, et al. PLoS One. 2016;11:e0162472
3. Anguille S, et al. Leukemia. 2011;25:739-748
4. Crescoli S, et al. Curr Allergy Asthma Rep. 2016;16:7
5. Calabretta E, Carlo-Stella C. Cells. 2020;9:802

Vogt DT, et al. Blood 2021;138(Suppl.1):898

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TAK-573: NOVEL ANTI-CD38 AND IFN α (modakafusp-alfa)

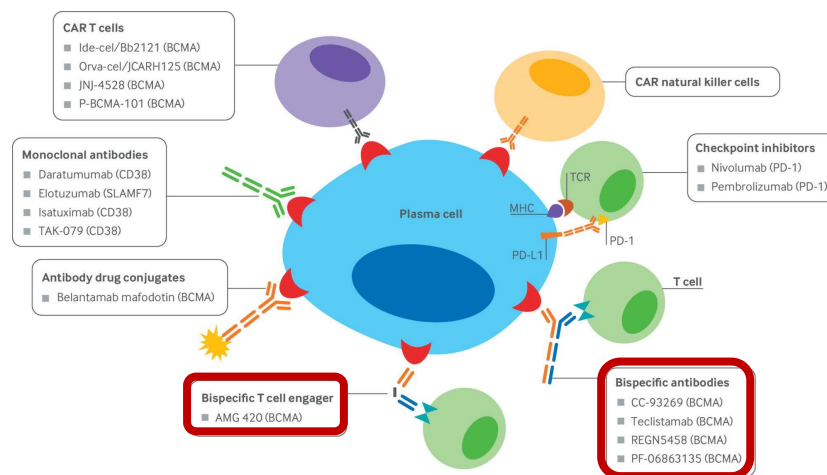


- Humanized CD38 that recognize different epitope from daratumumab and isatuximab
- IgG4 with no Fc function
- Attenuated IFN α molecules
 - Induce innate immune response
 - Induce adaptive immune response
- Key eligibility criteria
 - RRMM, ≥ 3 prior lines of therapy
 - Refractory to at least 1 PI and 1 IMiD
 - Daratumumab washout of 90 days for patients > 5 months of therapy in escalation
 - No daratumumab washout for expansion phase

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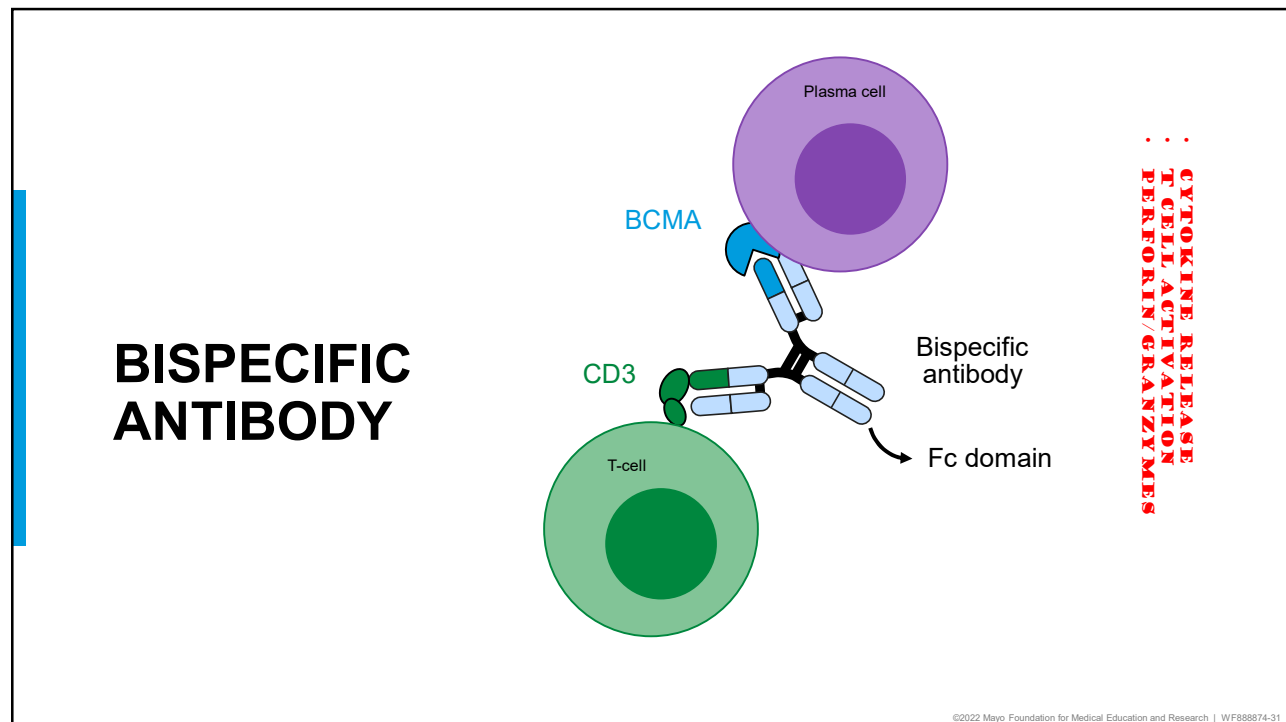
EMERGING IMMUNOTHERAPIES IN MULTIPLE MYELOMA



Shah A, Mailankody S. *BMJ* 2020; 370

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BISPECIFIC ANTIBODIES

- Novel immune therapy approach designed to bind antigens on MM cells and cytotoxic T cells
- Early phase clinical trials targeting BCMA, GPRC5D, and FcRH5 have shown favorable safety profiles
- Most are IV or subcutaneous injections weekly or every other week
- Therapy is ongoing until progression
- Unknown sequence of therapy if benefit after CAR T

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THERAPEUTIC BISPECIFIC T-CELL ENGAGERS FOR MM

BCMA / CD3

Drug	Prior lines	ORR (%) @ therapeutic dose	≥ VGPR (%)	G3+ CRS (%)
AMG-701	6	83	50	9
TNB-33B	6	80	73	0
REGN5458	5	62	NR	0
Teclistamab (JNJ-64007957)	5	65	58	0
Elranatamab (PF-06863135)	8	83	66	0
CC-93269	5	89	33	3
Talquetamab (GPRC5D/CD3)	6	70	60	2
Cevostamab (FcRH5/CD3)	6	53 Not RP2D	32	2

Harison ASH 2020, abs 181; Rodriguez ASH 2020, abs 293; Madduri ASH 2020, abs 291; Krishnan ASCO 2021; Bahlis ASCO 2021; Costa ASH 2019, abs 142; Berdeja ASCO 2021, abs 8008; Cohen ASH 2020

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CEVOSTAMAB: FCRH5 BISPECIFIC ANTIBODY PHASE I STUDY

- FcRH5: Fc receptor homolog 5
- 100% expression on MM cells
- Humanized IgG
- Prior CART, bispecific ab, and ADC allowed
- IV q3 weeks, for 17 cycles
- Cycle 1 step wise dosing

N (%) unless stated	N=53
Any CRS event*	40 (76)
Grade 1	18 (34)
Grade 2	21 (40)
Grade 3	1 (2) [†]
Median time to onset, hours (range)	6–12 (0–6, >48) [‡]
Any neurological event	15 (28)
Grade 1	10 (19)
Grade 2	5 (9)
Median time to onset, hours (range)	12–24 (0–6, >48) [‡]

All CRS events resolved with standard of care, tocilizumab (13 pts, 25%) or steroids (9 pts, 17%)

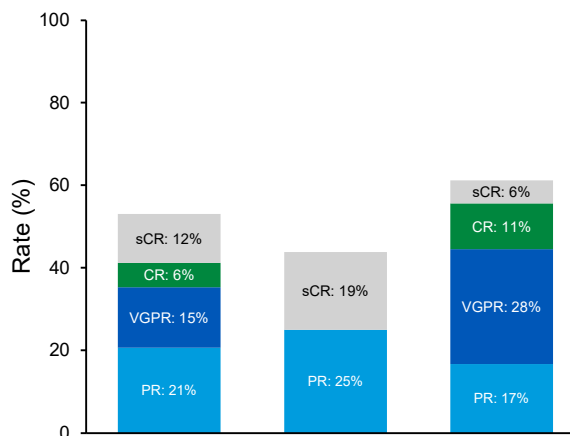
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CEVOSTAMAB: FCRH5 BISPECIFIC ANTIBODY PHASE I STUDY

- 51/53 pts efficacy evaluable; no response in $\leq 3.6/10.8$ mg cohorts
- ORR* in ≥ 3.6 mg/20mg cohorts
 - 53% (18/34) in all pts
 - 41% (7/17) in penta-drug refractory pts
 - 63% (5/8) in pts with prior anti-BCMA
- Median time to first response/best response: 29.5 days (range: 21–105)/57.5 days (range: 21–272)
- Response irrespective of target expression level in patients assessed to date
- MRD negativity by NGS ($<10^{-5}$) detected in 6/7 evaluable pts with \geq VGPR

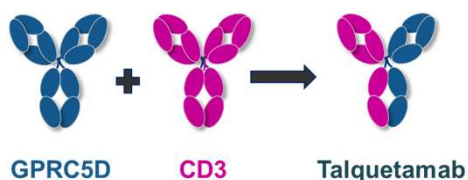
Response Rate (%)
in $\geq 3.6/20$ mg cohorts



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TALQUETAMAB: G PROTEIN-COUPLED RECEPTOR CLASS C GROUP 5 MEMBER D (GPC5D) BISPECIFIC ANTIBODY PHASE I STUDY



- GPRC5D – function unknown
- High expression in MM cells and limited expression in normal human tissue
- Expr in MM cells associated with poor prognosis
- Given subcutaneously

- Eligible patient's intolerant to standard therapies, prior BCMA directed treatments allowed
- Data as of July 2021 – 95 patients received SC talquetamab
- Two doses studied 405 μ g/kg weekly, and 800 μ g/kg biweekly
- No discontinuations due to AE's at either dose
- Common AE's at 405 μ g/kg weekly
 - CRS 73%, neutropenia 67%, Dysgeusia 60%, skin changes 77% and infections in 37%
- Common AE's at 800 μ g/kg biweekly
 - CRS 78%, dry mouth 44%, neutropenia 44%, skin changes 65% and 17% infections

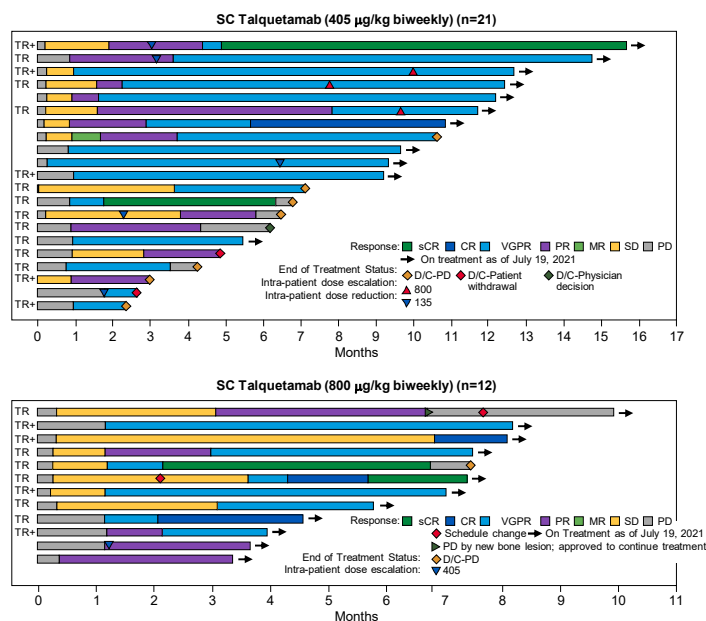
Redrawn from: Krishnan A et.al. ASH 2021 abstract 158

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TALQUETAMAB

- 30 evaluable patients at 405 mg/kg weekly dose ORR was 70% (\geq VGPR 57%)
- 17 evaluable patients at 800mg/kg biweekly, ORR 71% (\geq VGPR 53%)



+, penta-drug refractory; CR, complete response; D/C, discontinued; MR, minimal response; PD, progressive disease; PR, partial response; SC, subcutaneous; sCR, stringent complete response; SD, stable disease; TR, triple-class refractory; VGPR, very good partial response

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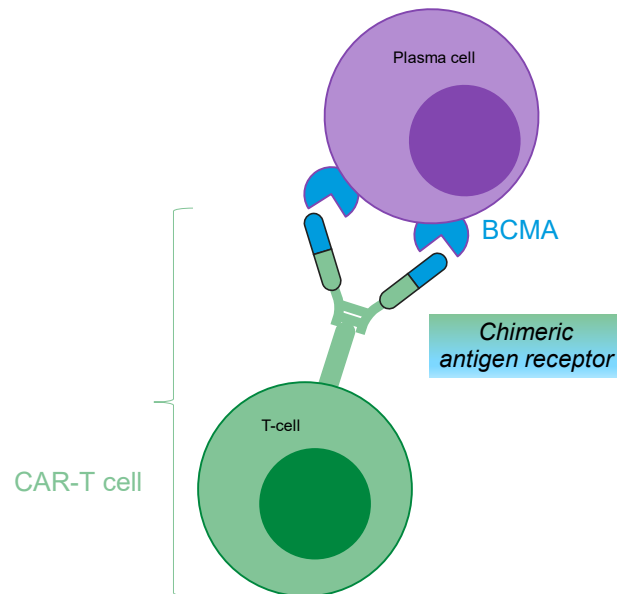
OVERVIEW OF BISPECIFIC ANTIBODIES

- Several targeting BCMA in clinical trials
- Non-BCMA directed antibodies are encouraging
- CRS and neurotoxicity less grade 3, than CAR T cells
- Maximum response and duration of response yet to be determined
- More likely to be an option to combine with other agents

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CAR-T CELLS



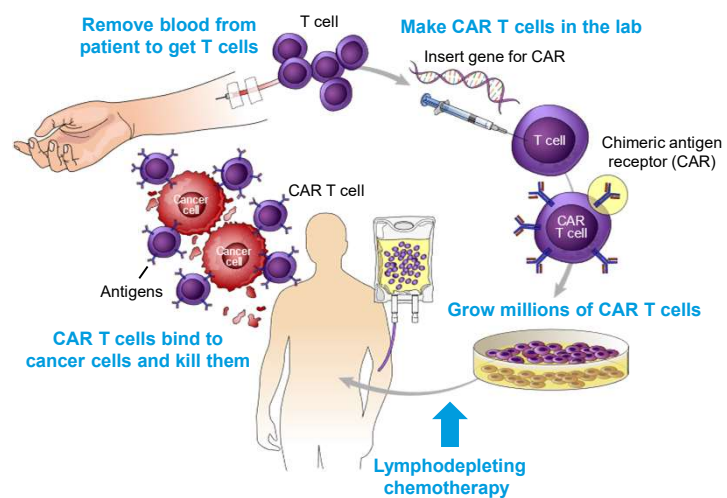
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CAR T-CELL THERAPY

Benefits

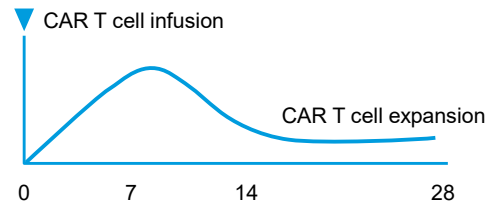
- High response rates (~ 75% of patients)
- No maintenance
- No steroids
- Effective even in heavily pretreated or previously refractory patients



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CAR T CELLS – RISKS



May occur within minutes or hours but generally appears within days or weeks
Coincides with maximal T-cell expansion
May need hospital/ICU care

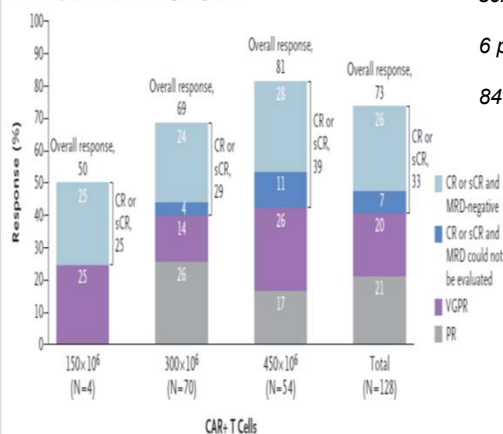
- Cytokine release syndrome (CRS)
 - Fevers, chills
 - Low blood pressure
 - Low oxygen levels
 - Multi-system organ damage
- Neurotoxicity
 - Delirium
 - Loss of ability to speak
 - Inability to write
 - Decreased alertness (obtundation)
 - seizures
- Prolonged cytopenias

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IDE-CEL REGISTRATION STUDY (KARMMA-1) RESULTS

A Tumor Response, Overall and According to Target Dose

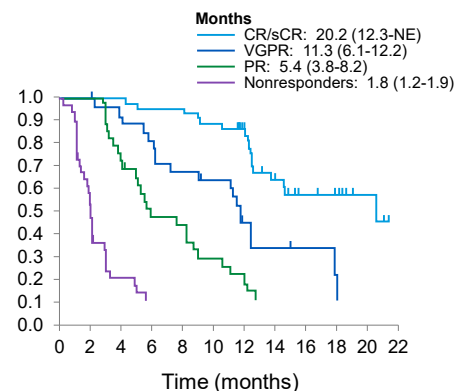


Time from Dx to CART screen: 6 yr (1-17)

6 prior lines of therapy

84% triple refractory

PFS by Response



- Single dose CAR-T with no maintenance therapy
- ORR of 73% and CRR of 33%
- mOS 19.4 mo (95% CI 18.2 – NE)

Redrawn from: Munshi NC et al: N Engl J Med 2021;384:705-716.

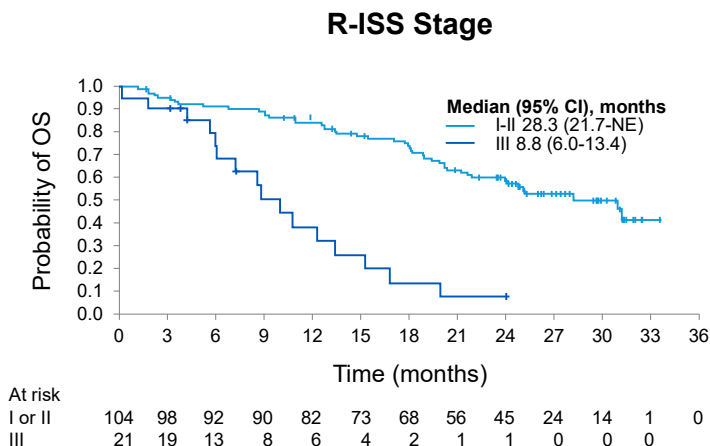
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KARMMA-1 STUDY (IDE-CEL) LONG TERM FOLLOW UP

- Overall survival (OS) is not decreased with age, extramedullary disease or triple refractory disease
- OS is decreased by R-ISS stage

FDA approved
March 26, 2021



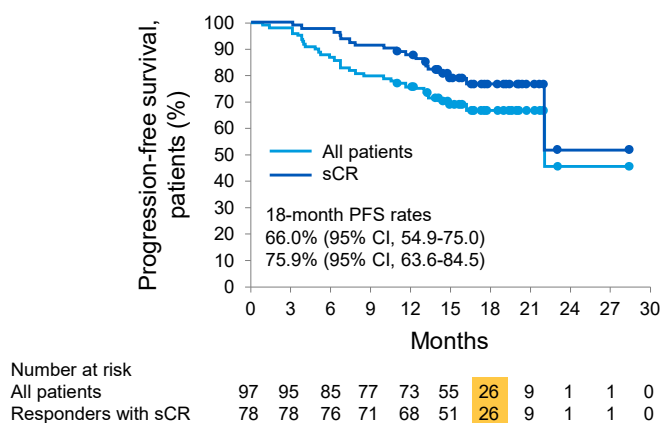
Redrawn from: Anderson L et al. ASCO 2021. Abstr 8016

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CILTA-CEL (Ciltacabtagene autoleucel; Carvykti) REGISTRATION STUDY CERTITUDE-1

- 3 or more prior lines of therapy
- Triple class exposed
- Median # lines of therapy 6 (4-8)
- Median Follow up 12.4 months
- ORR: 97%; sCR: 67%, MRD sCR: 34%
- 18-month PFS 66%
- 18-month OS 81%



Median duration of follow-up: 18 months (range, 1.5-30.5)

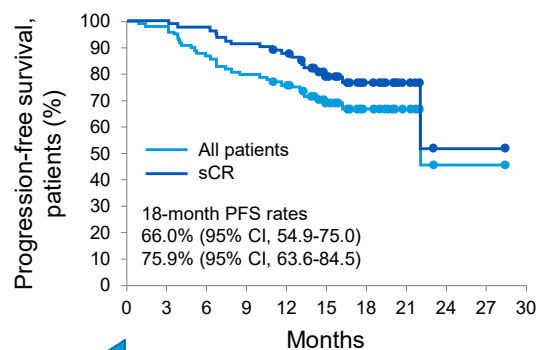
Berdeja, JG. *Lancet*. July 2021

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CILTA-CEL (Ciltacabtagene autoleucel; Carvykti) REGISTRATION STUDY CERTITUDE-1

- 3 or more prior lines of therapy
- Triple class exposed
- Median # lines of therapy 6 (4-8)
- Median Follow up 12.4 months
- ORR: 97%; sCR: 67%, MRD sCR: 34%
- 18-month PFS 66%
- 18-month OS 81%



FDA Approved
Feb. 28, 2022

7 95 85 77 73 55 26 9 1 1 0
8 78 76 71 68 51 26 9 1 1 0

Follow-up: 18 months (range, 1.5-30.5)

Berdeja, JG. *Lancet*. July 2021

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CAR T-CELL THERAPY DATA

	Ide-cel KarMMa-1 ¹ (N = 128)	Cilta-cel CARTITUDE -1 ² (N = 97)	P-BCMA- 101 PRIME ³ (N = 55)	Bb21217 CRB-402 ⁴ (N = 69)	CT053 LUMMICAR- 2 ⁵ (N = 20)	Allo-715 UNIVERSA L ⁶ (N = 31)
ORR	73%	97%	67%	73%	94%	60-67%
CR/sCR	33%	67%		29%	29%	
Durability	mPFS 8.8 mo	12 mo PFS 76%	NA	mDOR 17 mo	NA	NA

1. Munshi NC et al. *N Engl J Med* 2021;384:705-716. 2. Usmani et al. ASCO 2021, abstr 8005. 3. Costello et al ASH 2020, abstr 134. 4. Alsina et al ASH 2020, abstr 130. 5. Kumar et al. ASH 2020, abstr 133. 6. Mailankody et al. ASH 2020, abstr 129

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WHY DOES CAR T NOT ALWAYS WORK ?

MM is too aggressive (progresses before infusion)

Patient T cells are less effective

Do not persist long enough

Loss of target by MM cell

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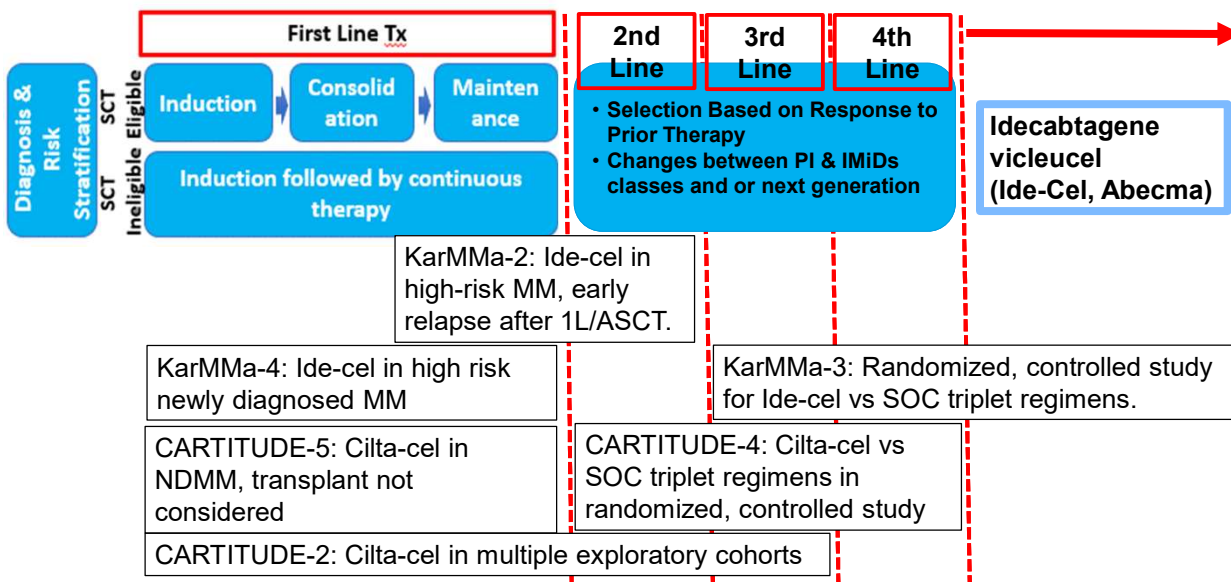
FUTURE OF CAR T-CELL THERAPY

- Obtaining T cells earlier in the disease
- Obtain T cells from healthy donors
- Use other targets other than BCMA
- Manufacturing differences, optimize to expedite manufacturing

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CAR-T INVESTIGATIONS IN EARLIER LINES OF THERAPY



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7. FUTURE IS BRIGHT



<https://www.dreamstime.com/stock-photos-golden-path-bright-future-eps-image5580023>

As of today, the FDA has approved for MM 3 naked t-mAb, 1 cargo loaded t-mAb, and 2 CAR-T

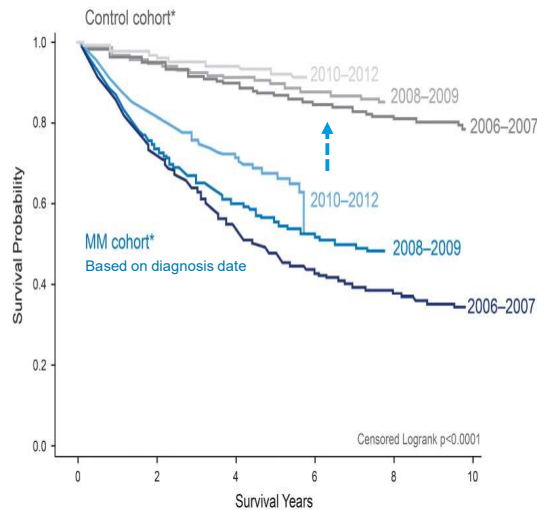
Within next year or two, more coming including bi-specific T-cell engagers

Many more novel therapies on the horizon

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MULTIPLE MYELOMA



With each passing year, the **difference** between age and gender based expected survival

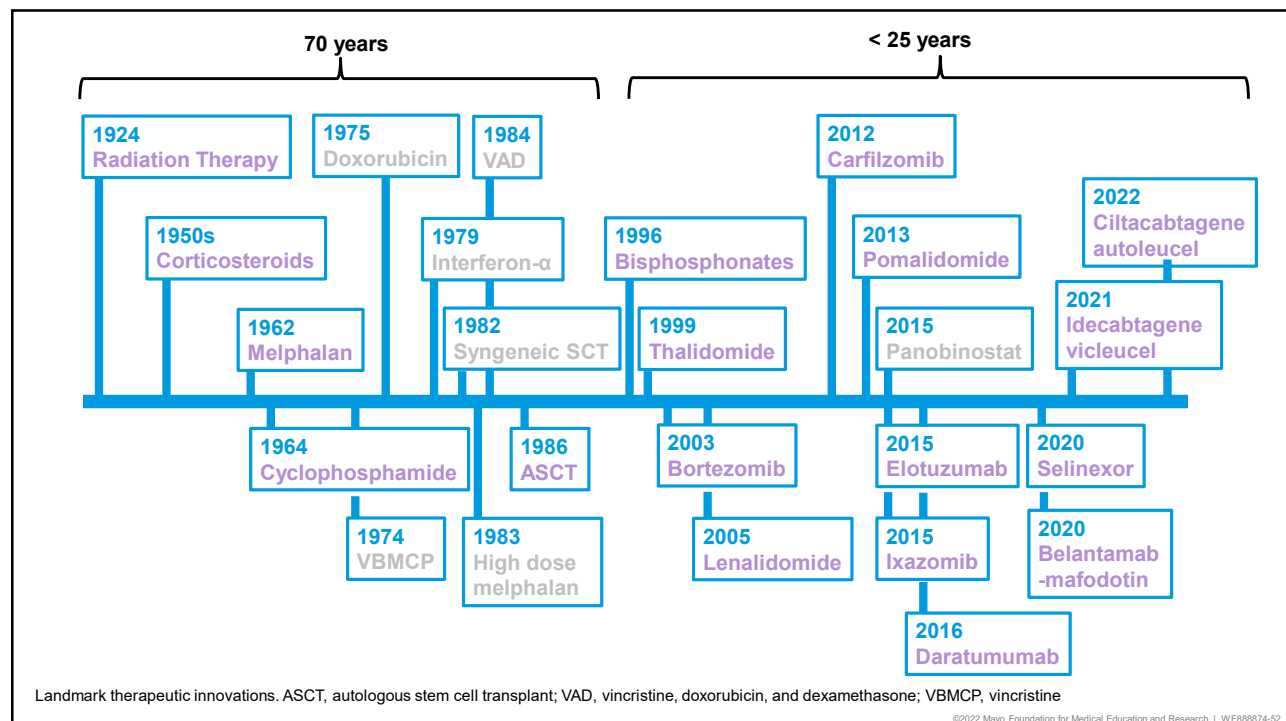
and survival for patients with multiple myeloma

SHRINKS

Fonseca et al. Leukemia (2017) 1915 – 1921

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ACKNOWLEDGEMENTS



Patients



Multiple Myeloma Awareness[®]



The Leukemia & Lymphoma Society[®]



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QUESTIONS & ANSWERS



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ASK A QUESTION

ADVANCES IN MULTIPLE MYELOMA

Ask a question by **phone**:

Press star (*) zero (0) on your keypad to ask a question
To remove your question press star (*) 2 on your keypad

Ask a question by **web**:

Click "Ask a question"
Type your question
Click "Submit"

Due to time constraints, we can only take one question per person.
Once you've asked your question, the operator will transfer you back into the audience line.

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LLS EDUCATION & SUPPORT RESOURCES



HOW TO CONTACT US:

To contact an **Information Specialist** about disease, treatment and support information, resources and clinical trials:

Call: (800) 955-4572

Monday to Friday, 9 a.m. to 9 p.m. ET

Chat live online: www.LLS.org/InformationSpecialists

Monday to Friday, 10 a.m. to 7 p.m. ET

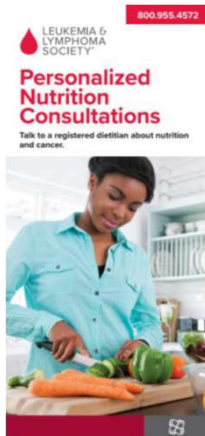
Email: www.LLS.org/ContactUs

All email messages are answered within one business day.

CLINICAL TRIAL SUPPORT CENTER

Work one-on-one with an LLS Clinical Trial Nurse Navigator who will help you find clinical trials and personally assist you throughout the entire clinical-trial process.

www.LLS.org/Navigation



LEUKEMIA & LYMPHOMA SOCIETY

800.955.4572

Personalized Nutrition Consultations

Talk to a registered dietitian about nutrition and cancer.

NUTRITION CONSULTATIONS
Our registered dietitian has expertise in oncology nutrition and provides free one-on-one consultations by phone or email.
www.LLS.org/Consult



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LLS EDUCATION & SUPPORT RESOURCES



Online Chats

Online Chats are free, live sessions, moderated by oncology social workers. To register for one of the chats below, or for more information, please visit www.LLS.org/Chat.



Education Videos

View our free education videos on disease, treatment, and survivorship. To view all patient videos, please visit www.LLS.org/EducationVideos.



Patient Podcast

The Bloodline with LLS is here to remind you that after a diagnosis comes hope. To listen to an episode, please visit www.TheBloodline.org.



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LLS EDUCATION & SUPPORT RESOURCES

877.557.2672

Help With Finances

The Leukemia & Lymphoma Society (LLS) offers financial assistance* to help individuals with blood cancer.

The **LLS Patient Aid** Program provides financial assistance to blood cancer patients in active treatment. Eligible patients will receive a \$100 stipend. Visit www.LLS.org/PatientAid

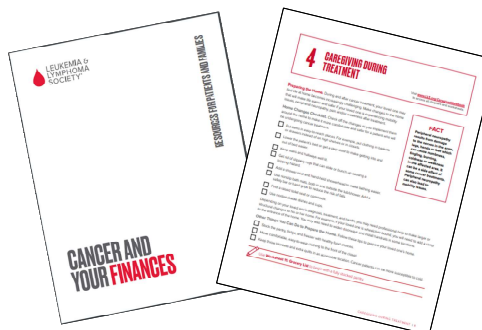
The **Urgent Need** Program, established in partnership with Mopple's Love, helps pediatric and young adult blood cancer patients, or adult blood cancer patients who are enrolled in clinical trials, with acute financial need. The program provides a \$500 grant to assist with non-medical expenses, including utilities, rent, mortgage, food, lodging, dental care, child care, elder care, and other essential needs. Visit www.LLS.org/UrgentNeed

The **Susan Lang Pay-It-Forward Patient Travel Assistance** Program provides blood cancer patients a \$500 grant to assist with transportation and lodging-related expenses. Visit www.LLS.org/Travel

The **Co-Pay Assistance** Program offers financial support toward the cost of insurance co-payments and/or insurance premiums for prescription drugs. Visit www.LLS.org/Copay

*Funding for LLS's Co-pay Assistance Program is provided by pharmaceutical companies. Funding for other LLS financial assistance programs is provided by donations from individual donors, companies, and LLS campaigns.

The Leukemia & Lymphoma Society (LLS) offers the following financial assistance programs to help individuals with blood cancers:
www.LLS.org/Finances



To order free materials: www.LLS.org/Booklets



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THANK YOU

This program is supported by



We have one goal: A world without blood cancers

