

SMMML newsletter

March 2024

Based on data from January and February 2024

Monthly updates around multiple myeloma

MMsyndiTrack™



The goal of this newsletter is to give an overview of what is happening around multiple myeloma in terms of medical developments. This is achieved by monitoring news articles, PR releases and scientific reports on one hand. Conversations from HCPs, digital opinion leaders and other influencers attending congresses, offering their opinion on treatments and commenting on new developments on the other hand.

Who will benefit from this newsletter?

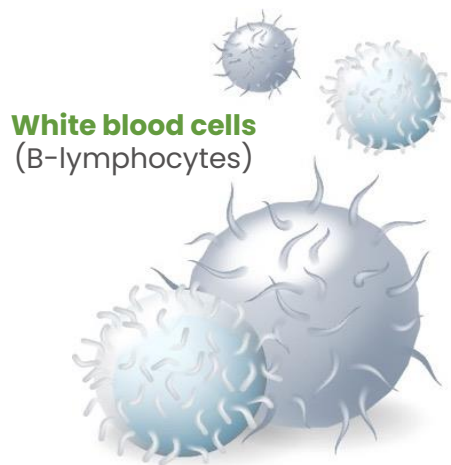
Any professionals interested in keeping up with developments around multiple myeloma:

- Marketers
- Business Analysts
- But also HCPs who want to anticipate the future landscape of MM management



Introduction on Multiple Myeloma

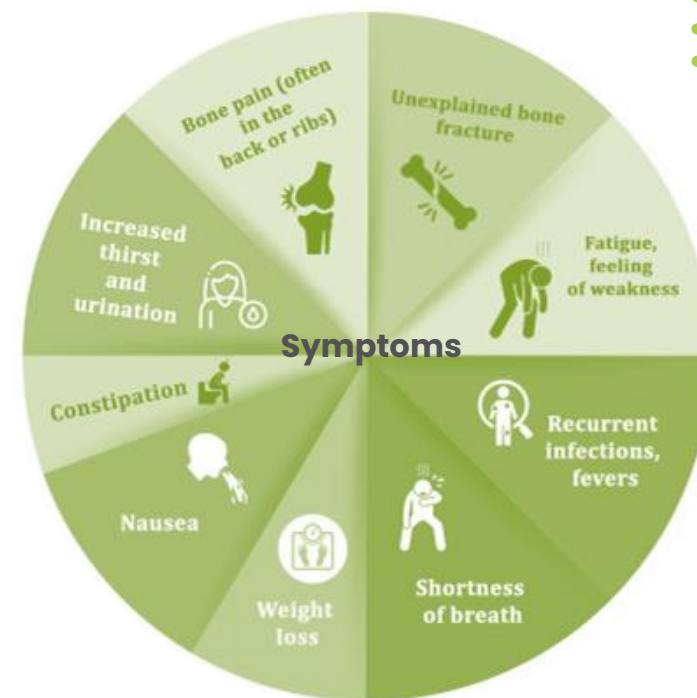
What is Multiple Myeloma?



70
YEARS



■ 5 year survival rate ~50%



Read more on Multiple Myeloma:



→ [Professional version in English](#)

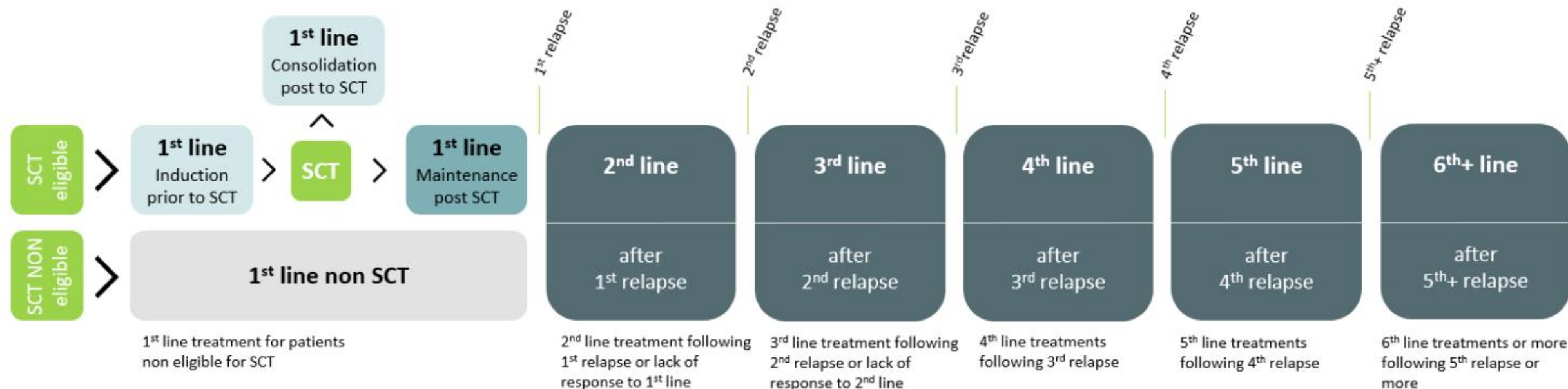
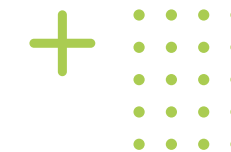
→ [Professional version in French](#)



→ [Consumer version in English](#)

→ [Consumer version in French](#)

MM lines of therapy based on to the following definitions



1st line Induction prior SCT

For stem cell candidates, the first step to gain a response to reduce the tumor burden before SCT. Please note that patients who received more than one SCT are considered to be in "1st line prior to stem cell transplant" for the latest SCT procedure planned. For instance, should a patient receive an induction treatment prior to a 2nd SCT, he should be considered as a 1st line transplant patient.

1st line Consolidation post SCT

1st line therapy **after** stem cell transplant to **deepen the response** achieved by adding a **short course** of full dose therapy.

1st line Maintenance post SCT

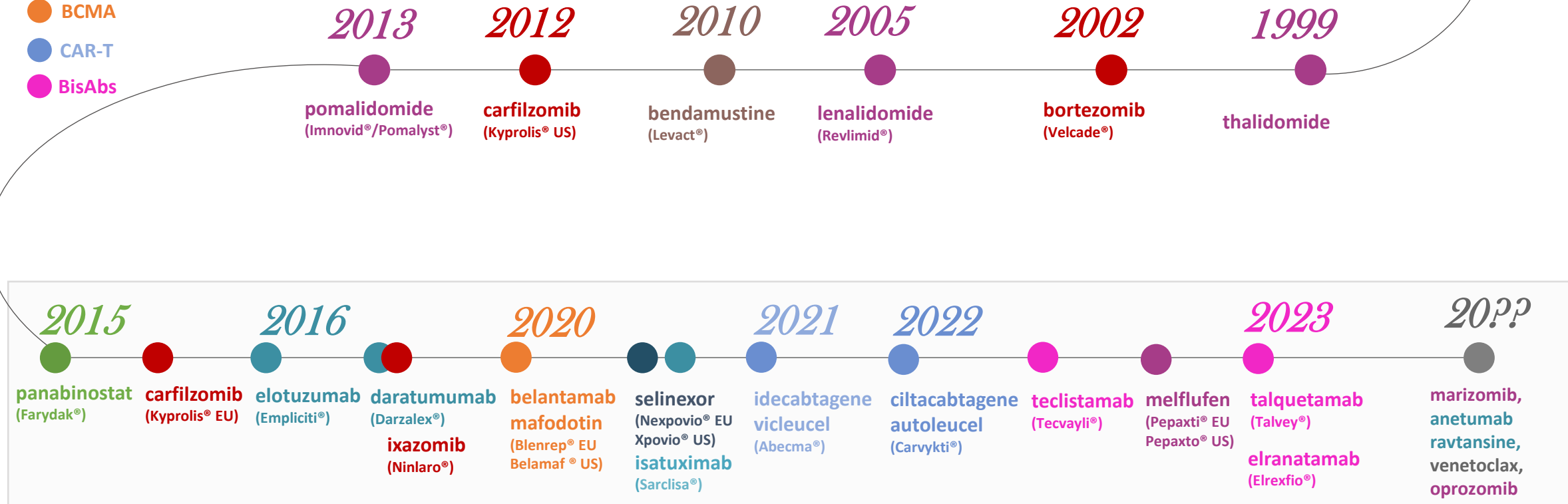
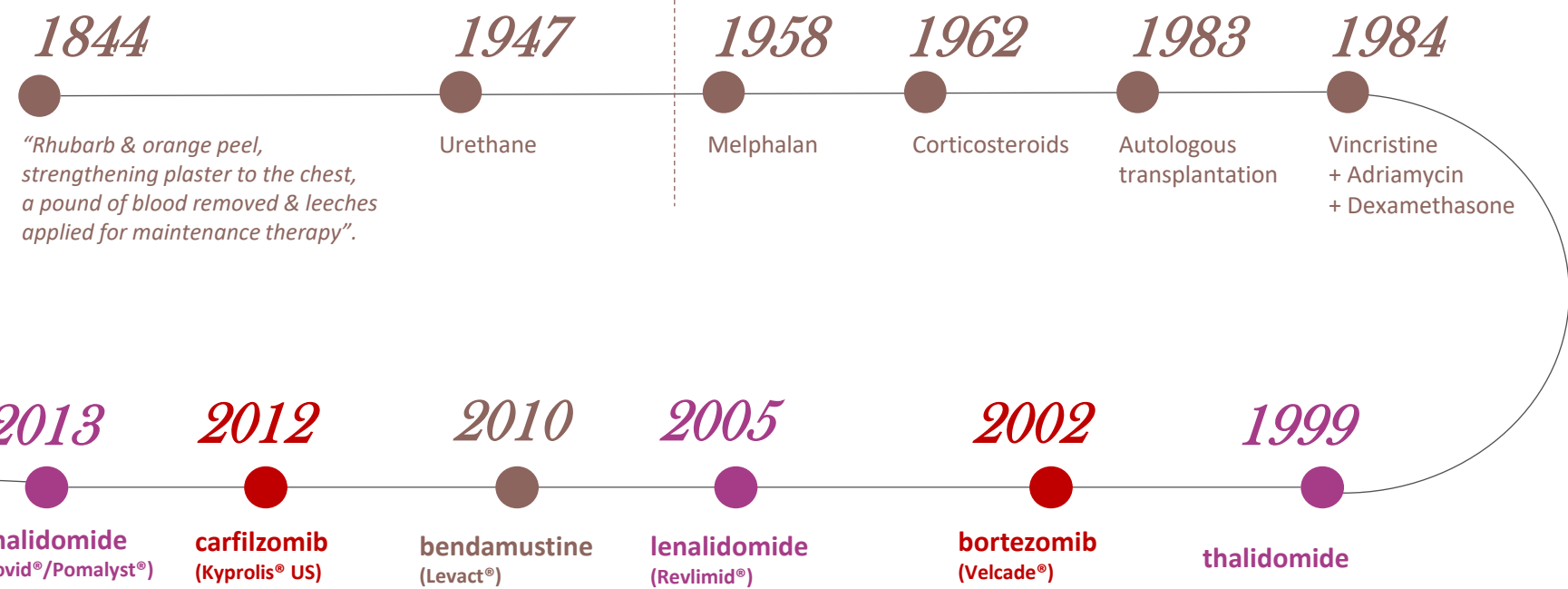
1st line therapy **after** stem cell transplant to **sustain the quality of the response** achieved by adding a long course – from several months up to disease progression – of reduced dose therapy.

Drugs approved by European Medicines Agency (EMA)						
Brand name	Active substance	Manufacturer	Class of therapy	EMA Date of authorisation	Line of treatment	Product Monograph
Revlimid®	lenalidomide	BMS	Immunomodulating agents (IMiDs)	14/06/2007	All lines	Click here
Thalidomide® / Thalomid® (US)	thalidomide	BMS	Immunomodulating agents (IMiDs)	16/04/2008	All lines	Click here
Imnovid® / Pomalyst® (US)	pomalidomide	BMS	Immunomodulating agents (IMiDs)	05/08/2013	2L+ (after Revlimid and Velcade)	Click here
Pepaxti® / Pepaxto® (US)	melflufen	Oncopeptides AB	Peptide conjugated alkylator	17/08/2022	Triple class exposed / 3L+ / 4L+ / 5L+	Click here
Velcade®	bortezomib	Janssen	Proteasome inhibitors (PIs)	26/04/2004	1LSCT / 1LNSCT	Click here
Kyprolis®	carfilzomib	Amgen	Proteasome inhibitors (PIs)	19/11/2015	2L+ / 3L+	Click here
Ninlaro®	ixazomib	Takeda	Proteasome inhibitors (PIs)	21/11/2016	2L+	Click here
Farydak®	panobinostat	Novartis + (Secura Bio)	Histone deacetylase inhibitors (HDACis)	28/08/2015	2L+ Relapsed / Refractory	Click here
Darzalex®	daratumumab	Janssen	Monoclonal antibody against CD38 (Mabs)	20/05/2016	All lines	Click here
Empliciti®	elotuzumab	BMS + (AbbVie)	Monoclonal antibody against SLAMF7 (Mabs)	11/05/2016	2L+ / 3L+	Click here
Sarclisa®	isatuximab	Sanofi	Monoclonal antibody against CD38 (Mabs)	30/05/2020	2L+ / 3L+	Click here
Tecvyli®	teclistamab-cqyv	Janssen	Bispecific B-cell maturation antigen (BCMA)-directed CD3 T-cell engager	21/07/2022	4L+ (1Pi + 1 IMiDs + 1anti-CD38 Mabs)	Click here
Talvey®	talquetamab-tgvs	Janssen	Bispecific antibody targeting GPRC5D receptor	09/08/2023 (FDA)	4L+ (1Pi + 1 IMiDs + 1anti-CD38 Mabs)	Click here
Elrexio®	elranatamab-bcmm	Pfizer	Bispecific B-cell maturation antigen (BCMA)-directed CD3 T-cell engager	14/08/2023 (FDA)	4L+ (1Pi + 1 IMiDs + 1anti-CD38 Mabs)	Click here
Blenrep® / Belamaf® (US)	belantamab mafodotin-blmf	GSK	Antibody-drug conjugates (BCMA)	25/08/2020	2L+ (4L+ after P, IMiD and MAB (L5+ in Italy)	Click here
Nexpovio® / Xpovio® (US)	selinexor	Karyopharm Therapeutics	Nuclear export inhibitor (SINE)	26/03/2021	Penta-refractory (2xPI + 2xIMiDs + 1 Mab)	Click here
Venclyxto® / Venclexta® (US)	venetoclax	AbbVie	B-cell lymphoma 2 (BCL-2)	04/12/2016	2L+ (already used in CLL / AML treatments)	Click here
Abecma®	idecabtagene vicleucel	BMS	Cell-based gene therapy (CAR-T)	18/08/2021	Triple class exposed / 3L+ / 4L+ / 5L+	Click here
Carvykti®	ciltacabtagene autoleucel	Janssen	Cell-based gene therapy (CAR-T)	25/05/2022	L3 / L4+ / L5+	Click here
Aredia®	pamidronate	Novartis	Bisphosphonates for bone disease	31/10/1991	Supportive care / Long-term use (5+ years)	Click here
Zometa®	zoledronate	Novartis	Bisphosphonates for bone disease	20/03/2001	Supportive care / Long-term use (5+ years)	Click here
Prolia® + Xgeva®	denosumab	Amgen	Bisphosphonates for bone disease	26/05/2010 - 13/07/2011	Supportive care	Prolia® / Xgeva®
Mozobil®	plerixafor	Genzyme	Stem cell mobilazor	30/07/2009	Supportive care	Click here

MM treatment history timeline



- IMiDs
- PIs
- IMS
- Mabs
- HDACi
- SINE
- BCMA
- CAR-T
- BisAbs





17+

YEARS



18+

COUNTRIES OVER TIME

UP
TO 90

HCPs
per wave
per country

UP
TO 4

WAVES
per year

4,5k

PATIENTS CHARTS
per wave

18k

PATIENTS CHARTS
per year (in EU5)

What's new

MMsyndiTrack™

Launching of a US pilot wave, Why ?

- Needs from clients for MM US data
- Back data for EU5 for 15 years
- MM US market changing fast
- Different needs in the US market for labs (patients' ethnicity treatments gap as an example)

Japan wave available

China data soon available!

APLUSA's added value

- Quarterly + month to month data collection (our competitors → only quarterly data)
- Market adaptability: adjusting our questionnaires and updating the list of treatments by including market trends on a monthly basis → **new CAR-Ts + BisAbs**
- Patient's full treatment history
- Deliverables with Power BI DID



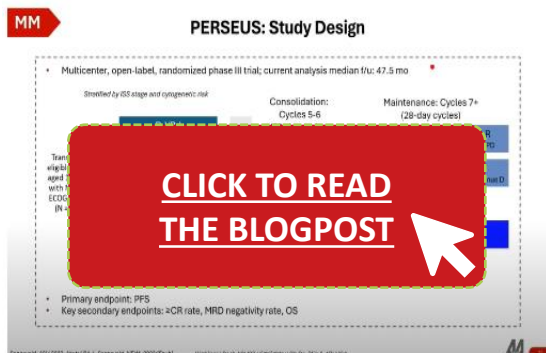
"MM at APLUSA"... it also means many exclusive content to share with you:



Explore the exclusive content meticulously curated by our team specifically for you on MM, including blog posts, videos of webinars, and other engaging content formats.

BLOGPOST: POST ASH 23 WEBINAR WITH DR. BLIN | FOCUS ON MM SESSION

Discover the transcription of our [Post-ASH 2023 webinar with Dr. BLIN](#), provides comprehensive coverage of several pivotal studies related to Multiple Myeloma (MM) from the [ASH23 congress](#). Dr. BLIN delves into the specifics of each study, discussing their design, patient characteristics, main findings, and implications for the treatment of MM. Below is a condensed transcript covering the essence of each study discussed in the video!

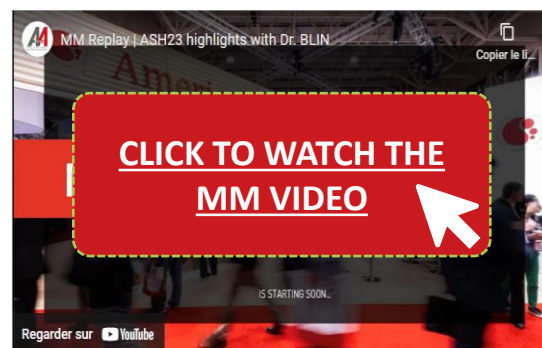


WEBINAR: POST ASH 23 WEBINAR WITH DR. BLIN | MM ABSTRACTS SELECTION

Last December took place the [65th ASH Annual Meeting and Exposition](#) in San Diego, California.

Dr. Nicolas Blin, hematologist at Nantes University Hospital, with whom we regularly collaborate, took part in this latest edition of the ASH congress.

Co-moderated by one of our APLUSA experts, Dr. Blin held a webinar on Thursday February 8 to update you on the hot topics and abstracts issues following the 65th ASH annual meeting.

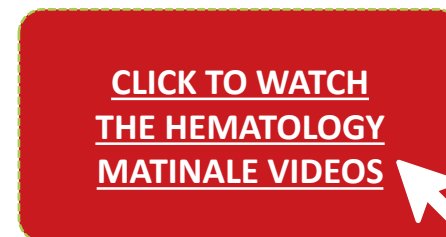


EVENT & REPLAYS: LA MATINALE APLUSA HEMATOLOGY EDITION

La Matinale APLUSA: your exclusive opportunity to join experts in discussing the latest advancements in various medical indications, providing you with unique perspectives and networking opportunities in a collaborative setting.

La Matinale APLUSA - hematology edition took place on November 17, 2023. This Matinale was an opportunity for healthcare professionals to keep up to date with the latest advances in hematology (MM, DLBCL, AML, MDS and CLL), and to interact with leading professionals in the field of hematology. Our guests discovered syndicated data selected by our APLUSA experts, analyzed and commented by Dr. Blin live.

Did you miss La Matinale APLUSA - Hematology edition? Discover the video contents, replays and read the full transcript of the discussions by clicking the button below:





March 2024



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News around clinical trials in Phase III

- Phase III Line 1 Quadruplet therapy
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- Phase III Relapse/Refractory Triplet Therapies
- Phase III Relapse/Refractory CAR T therapy

03.

Themes of discussion : HCPs

- SOV Themes of discussion
- Posts driving most engagement

04.

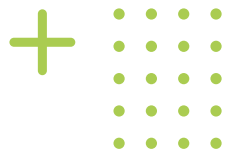
News articles overtime

- Volume of articles per volume of mentions
- Articles per themes

05.

Market watch

- Market watch



SCOPE



The scope of the analysis is focused on mentions coming **worldwide**.*



There were a total of **68K** mentions from patients recorded during the listening period from **January 1st, 2024**, to **February 29th, 2024**.



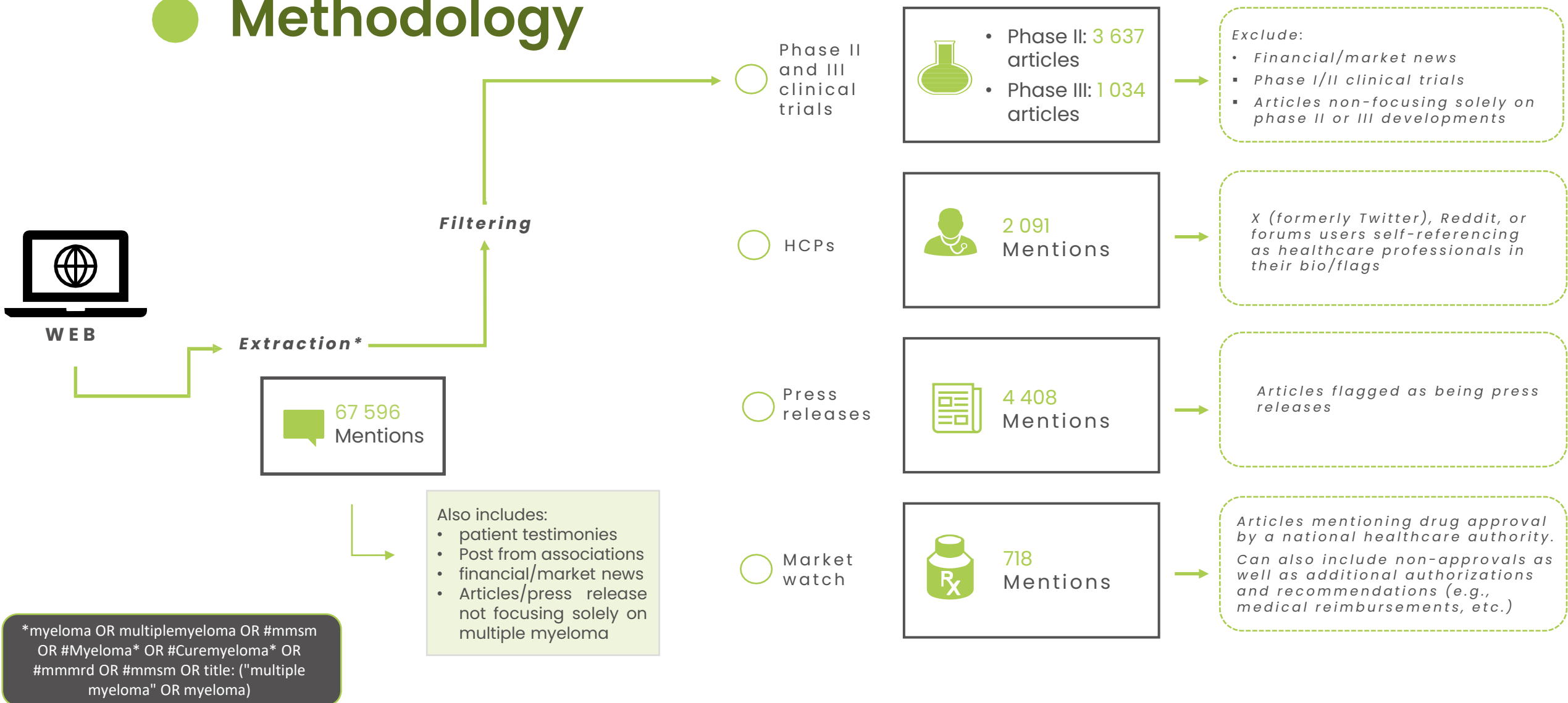
A majority of mentions came from **News (61%)**, **X (formerly Twitter) (32%)**, **Instagram (2%)**, **Reddit (2%)**, **Forums (2%)** and **Blogs (1%)**.



A total of **16K** unique authors were identified.

*myeloma OR multiplemyeloma OR #mmsm
OR #Myeloma* OR #Curemyeloma* OR
#mmmr OR #mmsm OR title: ("multiple
myeloma" OR myeloma)

Methodology

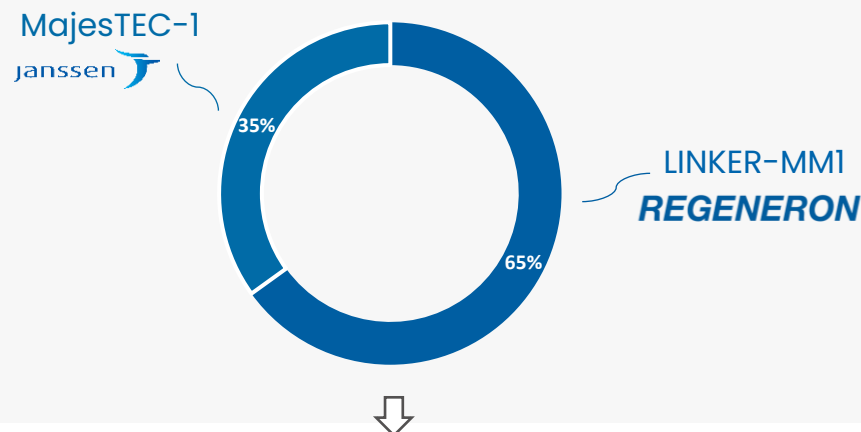


Drugs in clinical trials (Phase II) monitored during the listening period				
Sponsor	Trial name + link (ctrl + right click)	Line of treatment	Combination/Monotherapy being studied	Note
AbbVie	NCT03314181	RR	venetoclax, daratumumab and dexamethasone (With and Without Bortezomib)	
Bristol-Myers Squibb	ELOQUENT-3	RR	Elotuzumab, pomalidomide, dexamethasone	
CARsgen Therapeutics	LUMMICAR-2	RR	Monotherapy: zevorcabtagene autoleucl	
Celgene	KarMMa-2	RR	Monotherapy (one arm with lenalidomide) ; BMTCTN1902: Monotherapy: Idecabtagene vicleucl	
	NCT03374085	RR	Monotherapy: mezigdomide or in combination with dexamethasone	
	NCT03989414	1L/RR	bortezomb, dexamethasone, daratumumab, elotuzumab, isatuximab, carfilzomib	
	NCT03989414	IL/RR	mezigdomide, bortezomib, dexamethasone, daratumumab, carfilzomib, elotuzumab, isatuximab	
Cellular Biomedicine Group	NCT05521802	RR	Monotherapy: C-CAR088	
Gilead	NCT05396885	RR	Monotherapy: CART-ddBMCA	
GSK	DREAMM-2	RR	Monotherapy: blenrep	
Janssen	CARTITUDE-1	RR	Monotherapy: ciltacabtagene autoleucl	
	CARTITUDE-2	RR	Monotherapy: ciltacabtagene autoleucl	
	GRIFFIN	1L	daratumumab, lenalidomide, bortezomib, and dexamethasone (D-RVd)	
	MajesTEC-1	RR	Monotherapy: teclistamab	
	MonumenTAL-1	RR	Monotherapy: talquetamab	
	RedirectTT-1	RR	teclistamab, talquetamab, daratumumab	
Nanjing IASO Biotechnology	FUMANBA-1	RR	Monotherapy: equecabtagene autoleucl	
Nexcella	NCT04720313	RR	Monotherapy: NXC-201	
Pfizer	MagnetisMM-3	RR	Monotherapy: elranatamab	
	MagnetisMM-9	RR	Monotherapy: elranatamab or in combination with dexamethasone	
Regeneron	LINKER-MM1	RR	Monotherapy: REGN5458	
Other	Cardamon	/	cyclophosphamide, dexamethasone, carfilzomib	Sponsor: University College, London
	FORTE	1L	carfilzomib, lenalidomide, daratumumab, dexamethasone	Sponsor: Mario Boccadoro, University of Turin, Italy
	MASTER	/	dexamethasone, lenalidomide, daratumumab, carfilzomib	Sponsor: University of Alabama at Birmingham
	NCT02969837	1L	elotuzumab, carfilzomib, lenalidomide, dexamethasone	Sponsor: University of Chicago
	NCT03590652	RR	daratumumab, ixazomib, pomalidomide, dexamethasone	Sponsor: University of California, San Diego
	NCT04309981	RR	Monotherapy: cesnicabtagene autoleucl (ARI0002h)	Sponsor: Sara V. Latorre
	NCT05123131	1L	isatuximab, bortezomib, lenalidomide, dexamethasone	Sponsor: Cancer Trials Ireland
	REBUILD	RR	Monotherapy: daratumumab	Sponsor: Hellenic Society of Hematology
	NCT06105554	RR	belumosudil mesylate with or without dexamethasone	Sponsor: M.D. Anderson Cancer Center

Phase II Relapse/Refractory Bispecific antibodies: Linvoseltamab BLA for Treatment of Relapsed/Refractory Multiple Myeloma Accepted for FDA Priority Review



Clinical trial mentioned/Sponsor



Headlines/Hot off the press

“ Linvoseltamab BLA for Treatment of Relapsed/Refractory Multiple Myeloma Accepted for FDA Priority Review ”

“Regeneron Pharmaceuticals, Inc. today announced that the U.S. Food and Drug Administration (FDA) has accepted for Priority Review the Biologics License Application (BLA) for linvoseltamab to treat adult patients with relapsed/refractory (R/R) multiple myeloma (MM) that has progressed after at least three prior therapies. The target action date for the FDA decision is August 22, 2024. Linvoseltamab is an investigational bispecific antibody designed to bridge B-cell maturation antigen on multiple myeloma cells with CD3-expressing T cells to facilitate T-cell activation and cancer-cell killing.”

Click [here](#) to read the full article

“ TECVAYLI® (teclistamab-cqyv) biweekly dosing approved by the US FDA for the treatment of patients with relapsed or refractory multiple myeloma ”

“Johnson & Johnson announced today that the US Food and Drug Administration (FDA) has approved the supplemental Biologics License Application (sBLA) for TECVAYLI® (teclistamab-cqyv) for a reduced dosing frequency of 1.5 mg/kg every two weeks (Q2W) in patients with relapsed or refractory multiple myeloma (RRMM) who have achieved and maintained a complete response (CR) or better for a minimum of six months. 1 There is a continued unmet need for patients with multiple myeloma and this approval allows increased flexibility in dosing schedule for appropriate patients with a weight-based regimen.”

Click [here](#) to read the full article

LINKER-MM1

Ctrl + click to access clinical trial: [NCT03761108](#)

“Phase 1/2 Study of REGN5458 in Patients With Relapsed or Refractory Multiple Myeloma”

MajesTEC-1

Ctrl + click to access clinical trial: [NCT04557098](#)

“A Study of Teclistamab in Participants With Relapsed or Refractory Multiple Myeloma”

Molecules

linvoseltamab

teclistamab

relapsed or refractory multiple myeloma
treat adult patients with relapsed
Marketing Authorization Application
multiple myeloma cells
accepted for review the Marketing Authorization
B-cell maturation antigen
Regeneron Pharmaceuticals Priority Review
treatment of adult patients with relapsed
Food and Drug Administration
bispecific antibody designed
approved the supplemental Biologics License Application
MajesTEC-1 sBLA

linvoseltamab for the treatment



Sponsor	Trial name + link (ctrl + right click)	Line of treatment	Combination/Monotherapy being studied	Note
AbbVie	Bellini	RR	venetoclax, bortezomib, dexamethasone	
	CANOVA	RR	venetoclax, dexamethasone	
Celgene	DETERMINATION	RR	lenalidomide, bortezomib, dexamethasone	
	KarMMa-3	RR	Monotherapy: Idecabtagene vicleucel	
GSK	DREAMM-3	RR	Monotherapy: belantamab mafodotin	
	DREAMM-7	RR	belantamab mafodotin, bortezomib and dexamethasone	
	DREAMM-8	RR	belantamab mafodotin Plus pomalidomide and dexamethasone	
Janssen	AURIGA	Maintenance	daratumumab, lenalidomide	
	CARTITUDE-4	RR	Monotherapy: ciltacabtagene autoleucel	
	CASTOR	RR	daratumumab, bortezomib, dexamethasone	
	MAIA	1L	daratumumab, lenalidomide, dexamethasone	
	MajesTEC-3	RR	teclistamab, daratumumab Subcutaneously (SC) (Tec-Dara)	
	POLLUX	RR	daratumumab, lenalidomide, and dexamethasone	
Karyopharm	BOSTON	RR	selinexor, bortezomib,, dexamethasone	
Oncopeptides	OCEAN	RR	Monotherapy: melphalan flufenamide	
Pfizer	MagnetisMM-5	RR	Monotherapy: elranatamab or doublet therapy with daratumumab	
Sanofi	ICARIA-MM	RR	isatuximab, pomalidomide, dexamethasone	
	IKEMA	RR	isatuximab, carfilzomib And dexamethasone	
Takeda	TOURMALINE-MM1	RR	ixazomib, lenalidomide, dexamethasone	
	TOURMALINE-MM2	1L	ixazomib, lenalidomide, dexamethasone	
Other	ATLAS	Maintenance	lenalidomide, carfilzomib, dexamethasone	Sponsor: University of Chicago
	DRAMMATIC	/	lenalidomide, daratumumab	Sponsor: SWOG Cancer Research Network
	EQUATE	1L	daratumumab, bortezomib, lenalidomide and dexamethasone	Sponsor: ECOG-ACRIN Cancer Research Group
	Myeloma XI	1L	cyclophosphamide, dexamethasone plus lenalidomide with or without carfilzomib	Sponsor: University of Leeds
	IsKia	1L	isatuximab, lenalidomide, carfilzomib, dexamethasone	Sponsor: European Myeloma Network
	PERSEUS	1L	daratumumab, bortezomib, dexamethasone, lenalidomide	Sponsor: European Myeloma Network



Phase III Line 1 Quadruplet therapy: Johnson & Johnson submits supplemental Biologics License Application to U.S. FDA seeking approval of DARZALEX Faspro® (daratumumab and hyaluronidase-fihj)-based regimen for the treatment of patients with transplant-eligible, newly diagnosed multiple myeloma



Headlines/Hot off the press

“Johnson & Johnson submits supplemental Biologics License Application to U.S. FDA seeking approval of DARZALEX Faspro® (daratumumab and hyaluronidase-fihj)-based regimen for the treatment of patients with transplant-eligible, newly diagnosed multiple myeloma

“Data supporting the application showed the addition of DARZALEX Faspro® to lenalidomide, bortezomib and dexamethasone (VRd) induction and consolidation and lenalidomide maintenance therapy reduced the risk of progression or death by 58 percent compared to standard of care” Click [here](#) to read the full article

PERSEUS
Ctrl + click to access clinical trial:
[NCT03710603](#)

“A Phase 3 Study Comparing Daratumumab, VELCADE (Bortezomib), Lenalidomide, and Dexamethasone (D-VRd) vs VELCADE, Lenalidomide, and Dexamethasone (VRd) in Subjects With Previously Untreated Multiple Myeloma Who Are Eligible for High-dose Therapy”

⇒

Sponsor



Combination

daratumumab + **lenalidomide**
+ **dexamethasone** + **bortezomib**



Headlines/Hot off the press

“ FDA Withdraws Approval of Pepaxto for Multiple Myeloma ”

“Pepaxto was withdrawn because the OCEAN study did not confirm clinical benefit and the available evidence showed the drug was not safe or effective.”

Click [here](#) to read the full article

Sponsor



OCEAN

Ctrl + click to access
clinical trial:
[NCT03151811](#)

“A Study of Melphalan Flufenamide (Melflufen)-Dex or Pomalidomide-dex for RRMM Patients Refractory to Lenalidomide”



Combination

**Melphalan Flufenamide
+ dexamethasone**





Phase III Relapse/Refractory Triplet Therapies: Triplet Therapy Including Belamaf Prolongs Survival in Multiple Myeloma



Headlines/Hot off the press

“ Triplet Therapy Including Belamaf Prolongs Survival in Multiple Myeloma ”

“For patients with relapsed or refractory multiple myeloma (RRMM), triplet therapy of belantamab mafodotin (belamaf) plus bortezomib and dexamethasone (Bvd) improves outcomes, with an acceptable safety profile, according to a study presented during the February 2024 session of the American Society for Clinical Oncology Plenary Series.”

Click [here](#) to read the full article

Sponsor



DREAMM-7

Ctrl + click to access clinical trial:

[NCT04246047](#)

“A Multicenter, Open-Label, Randomized Phase III Study to Evaluate the Efficacy and Safety of the Combination of Belantamab Mafodotin, Bortezomib, and Dexamethasone (B-Vd) Compared With the Combination of Daratumumab, Bortezomib and Dexamethasone (D-Vd) in Participants With Relapsed/Refractory Multiple Myeloma”



Combination

**belantamab mafodotin + dexamethasone
+ bortezomib**

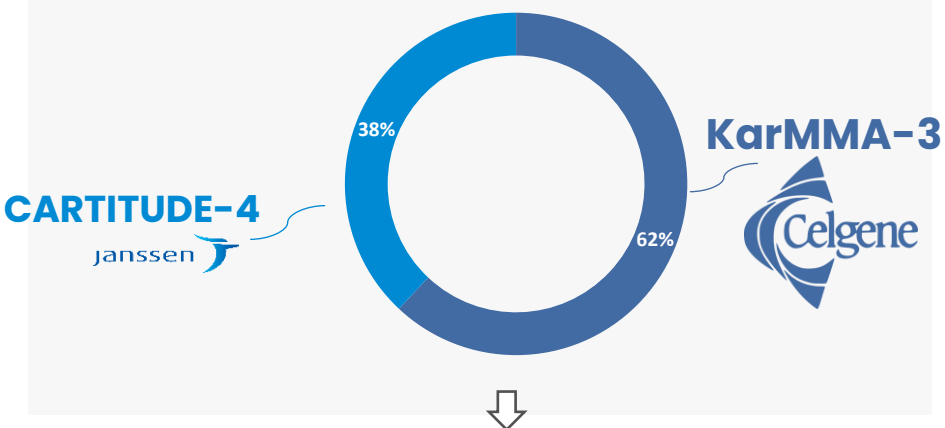




Phase III Relapse/Refractory CAR T therapy: Bristol Myers Squibb Receives Positive CHMP Opinion for CAR T Cell Therapy Abecma (idecabtagene vicleucel) in Earlier Lines of Therapy for Triple-Class Exposed Relapsed and Refractory Multiple Myeloma



Clinical trial mentioned/Sponsor



KarMMA-3

Ctrl + click to access the clinical trial: [NCT03651128](#)

"Efficacy and Safety Study of bb2121 Versus Standard Regimens in Subjects With Relapsed and Refractory Multiple Myeloma (RRMM) (KarMMA-3)"

CARTITUDE-4

Ctrl + click to access clinical trial: [NCT04181827](#)

"A Study Comparing JNJ-68284528, a CAR-T Therapy Directed Against B-cell Maturation Antigen (BCMA), Versus Pomalidomide, Bortezomib and Dexamethasone (Pvd) or Daratumumab, Pomalidomide and Dexamethasone (DPd) in Participants With Relapsed and Lenalidomide-Refractory Multiple Myeloma"

Headlines/Hot off the press

“ Bristol Myers Squibb Receives Positive CHMP Opinion for CAR T Cell Therapy Abecma (idecabtagene vicleucel) in Earlier Lines of Therapy for Triple-Class Exposed Relapsed and Refractory Multiple Myeloma ”

Click [here](#) to read the full article

“ Legend Biotech Announces Positive CHMP Opinion for CARVYKTI® (ciltacabtagene autoleucel) for the Treatment of Patients with Relapsed and Lenalidomide Refractory Multiple Myeloma in Earlier Lines of Therapy ”

Click [here](#) to read the full article

“ Bristol Myers Squibb and 2seventy bio Share Update on U.S. FDA Oncologic Drugs Advisory Committee Meeting for Abecma in Triple-Class Exposed Multiple Myeloma Based on KarMMA-3 Study ”

Click [here](#) to read the full article

Molecules

idecabtagene vicleucel

ciltacabtagene autoleucel

European Union

demonstrated disease progression

EMA has recommended chimeric antigen receptor

Drug Administration

CAR T cell therapy

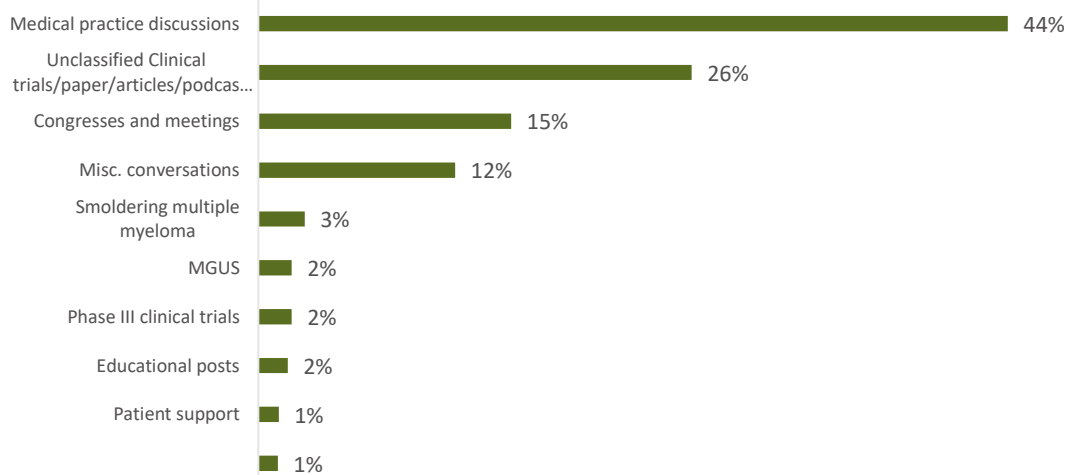
ciltacabtagene autoleucel

Treatment of Patients with Relapsed earlier lines of therapy

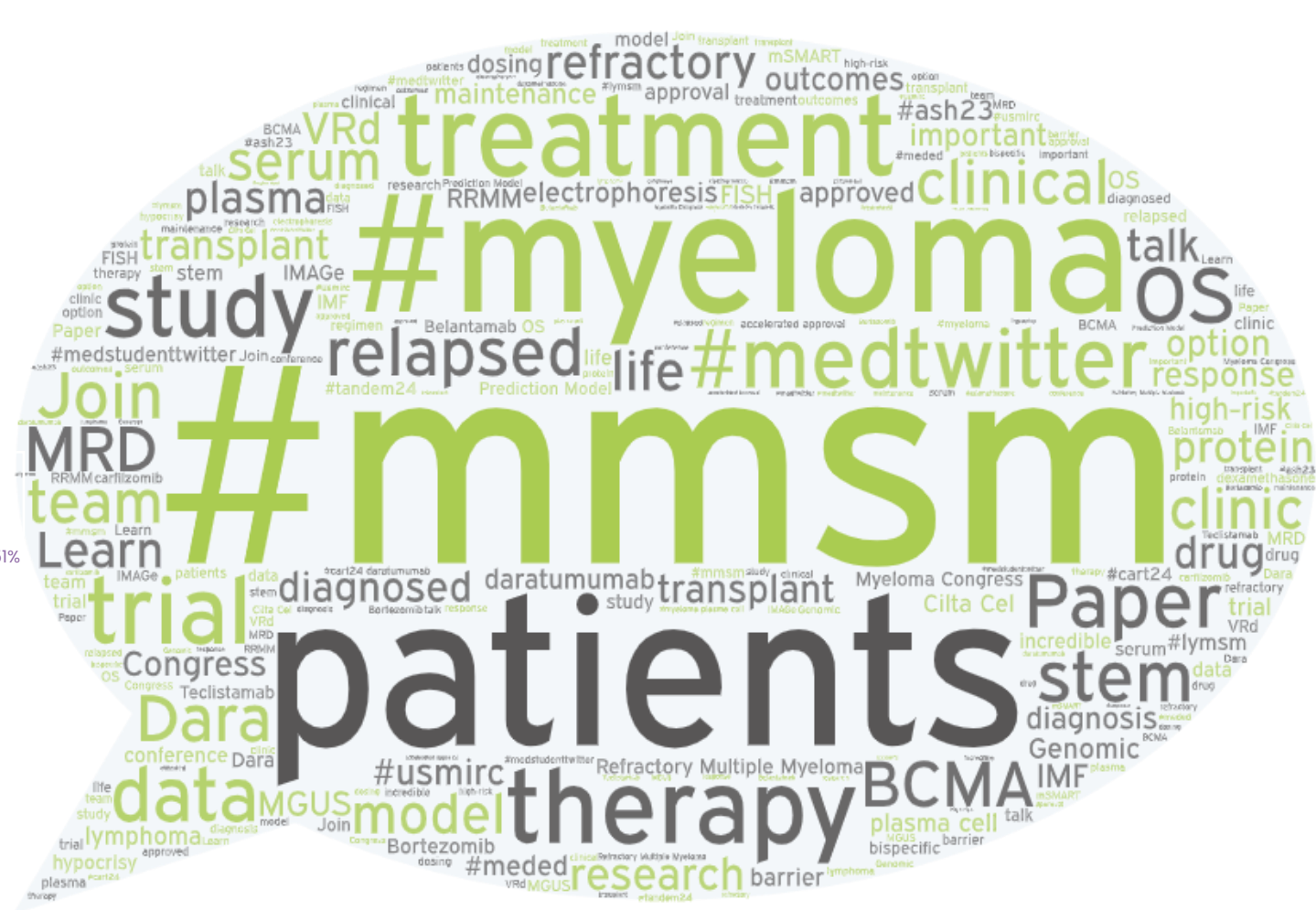
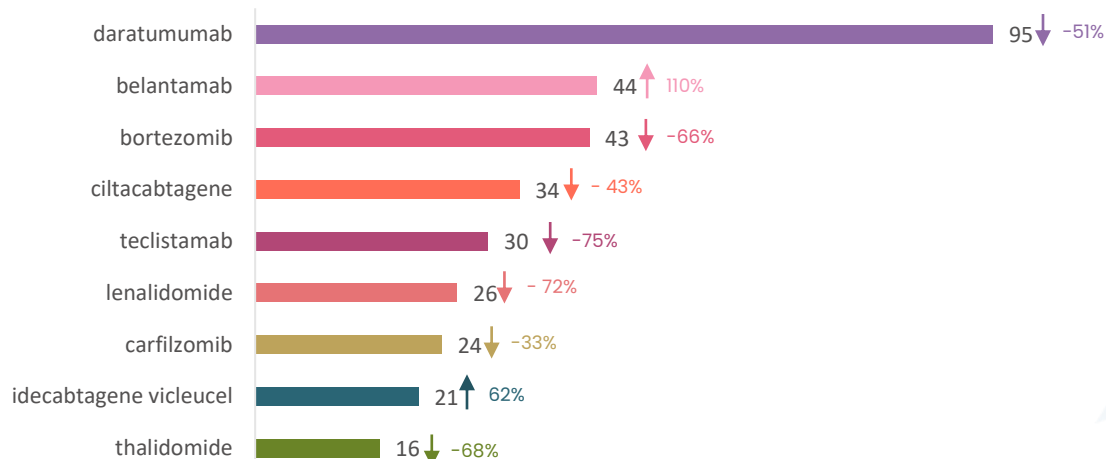
meeting of the Oncologic Drugs Advisory



SOV topics of conversations



SOV molecules



The posts receiving the most engagement this month were entirely educational in nature.

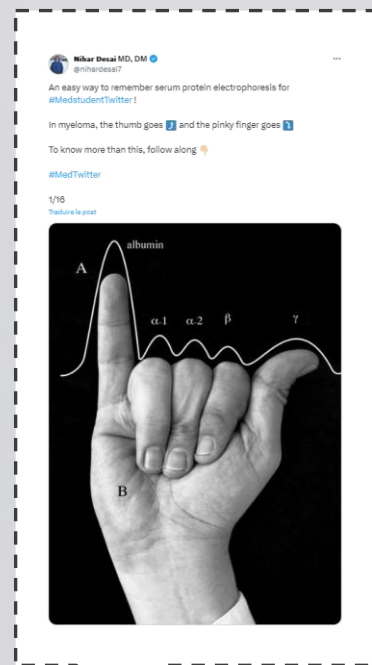
This month top posts are good examples of the kind of content HCPs share when they want to educate/share knowledge about multiple myeloma.

The posts go from the sharing of mnemonic techniques for the interpretation of diagnosis tools from Drs Desai and Gottfried, to a quiz launched by Dr Chaudhry where fellow doctors are invited to guess the disorder.

Those educational posts are usually well-liked and are an opportunity for doctors to spark more interactions and launch conversations around specific topics of concern.

Most engagement

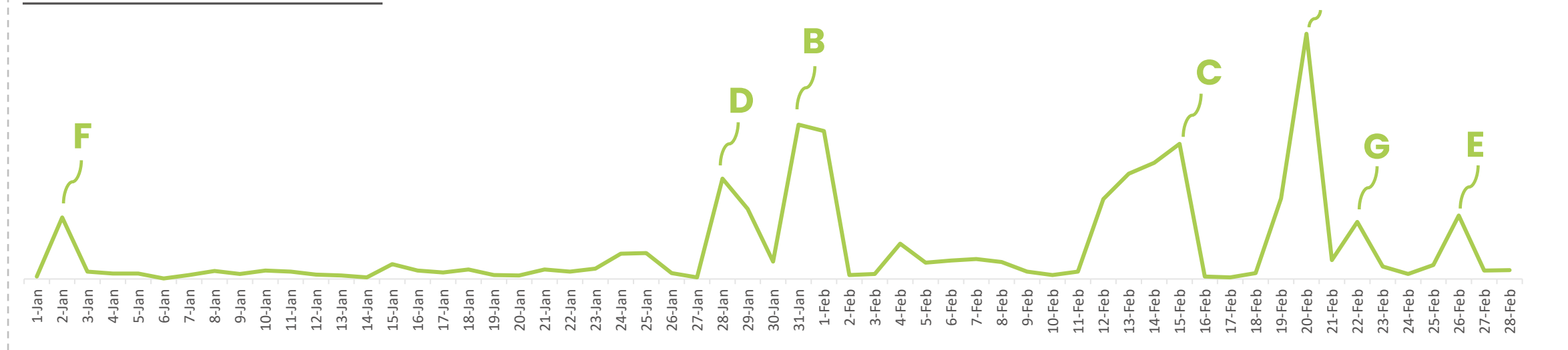
Most retweeted, liked and replied to (Ctrl + right click to access tweets)



Media (press releases): volume and articles per peak



Volume of articles overtime



A “Regeneron Pharmaceuticals, Inc. today announced that the U.S. Food and Drug Administration (FDA) has accepted for Priority Review the **Biologics License Application (BLA)** for **linvoseltamab** to treat adult patients with relapsed/refractory (R/R) multiple myeloma (MM) that has progressed after at least three prior therapies. The target action date for the FDA decision is August 22, 2024. Linvoseltamab is an investigational bispecific antibody designed to bridge B-cell maturation antigen on multiple myeloma cells with CD3-expressing T cells to facilitate T-cell activation and cancer-cell killing.” [Link](#)

“Tecvayli (teclistamab-cqyv) Biweekly Dosing Approved by the U.S. FDA for the Treatment of Patients with Relapsed or Refractory Multiple Myeloma” [Link](#)

B “Renowned Actor and **Artist Ice-T** Works Alongside the International Myeloma Foundation to Raise **Awareness of Multiple Myeloma in the African American Community** During Black History Month” [Link](#)

C “**BioLineRx** Announces Acceptance of Two Poster Presentations on **APHExDA®** (motixafortide) for CD34+ Hematopoietic Stem Cell (HSC) Mobilization in Patients with Multiple Myeloma at the 2024 Tandem Meetings of ASTCT® and CIBMTR®” [Link](#)

D “**Oricell** Announces **FDA Clearance of IND Application for OriCAR-017**, a novel GPRC5D Targeted CAR-T Cell Therapy Utilizing the Company’s Proprietary Platform, for the Treatment of Relapsed/Refractory Multiple Myeloma.” [Link](#)

“**Gracell** Biotechnologies Announces **FDA Clearance of IND Application for Phase I Clinical Trial of FasTCAR-T GC012F** as Early-Line Treatment of Multiple Myeloma” [Link](#)

D (continued) “**BMS** announces **CHMP recommendation** for multiple myeloma therapy **Abecma**” [Link](#)

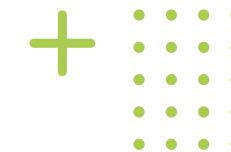
E “**EMN2024**: Turin hosts International **Multiple Myeloma Conference** spotlighting research importance & innovative treatments” [Link](#)

“**FDA Pulls** Multiple Myeloma Drug **Pepaxto** From Market After Failing Phase 3 Study” [Link](#)

F “**Starton Therapeutics** Announces **Initial Key Safety and Efficacy Signals with STAR-LLD** in Patients with Relapsed or Refractory Multiple Myeloma” [Link](#)

G “**Legend Biotech** Announces **Positive CHMP Opinion** for **CARVYKTI® (ciltacabtagene autoleucel)** for the Treatment of Patients with Relapsed and Lenalidomide Refractory Multiple Myeloma in Earlier Lines of Therapy” [Link](#)

Confidential



Awareness

- “Renowned Actor and **Artist Ice-T** Works Alongside the International Myeloma Foundation to Raise **Awareness of Multiple Myeloma in the African American Community** During Black History Month” [Link](#)

Bispecific antibody

- “**Regeneron** Pharmaceuticals, Inc. today announced that the U.S. Food and Drug Administration (FDA) has accepted for Priority Review the **Biologics License Application (BLA) for linvoseltamab** to treat adult patients with relapsed/refractory (R/R) multiple myeloma (MM) that has progressed after at least three prior therapies. The target action date for the FDA decision is August 22, 2024. Linvoseltamab is an investigational bispecific antibody designed to bridge B-cell maturation antigen on multiple myeloma cells with CD3-expressing T cells to facilitate T-cell activation and cancer-cell killing.” [Link](#)
- “**Tecvayli (teclistamab-cqyv)** Biweekly Dosing **Approved by the U.S. FDA** for the Treatment of Patients with Relapsed or Refractory Multiple Myeloma” [Link](#)

CAR T-cell therapy

- “**Oricell** Announces **FDA Clearance of IND Application for OriCAR-017**, a novel GPRC5D Targeted CAR-T Cell Therapy Utilizing the Company’s Proprietary Platform, for the Treatment of Relapsed/Refractory Multiple Myeloma.” [Link](#)
- “**Gracell** Biotechnologies Announces **FDA Clearance of IND Application for Phase I Clinical Trial of FasTCAR-T GC012F** as Early-Line Treatment of Multiple Myeloma” [Link](#)
- “**BMS** announces **CHMP recommendation** for multiple myeloma therapy **Abecma**” [Link](#)
- “**Legend Biotech** Announces **Positive CHMP Opinion** for **CARVYKTI® (ciltacabtagene autoleucel)** for the Treatment of Patients with Relapsed and Lenalidomide Refractory Multiple Myeloma in Earlier Lines of Therapy” [Link](#)

Conference

- “**EMN2024**: Turin hosts International **Multiple Myeloma Conference** spotlighting research importance & innovative treatments” [Link](#)

Hematopoietic stem cell mobilizer/CXCR4 antagonist.

- “**BioLineRx** Announces Acceptance of Two Poster Presentations on **APHEXDA®** (motixafortide) for CD34+ Hematopoietic Stem Cell (HSC) Mobilization in Patients with Multiple Myeloma at the 2024 Tandem Meetings of ASTCT® and CIBMTR®” [Link](#)

Peptide conjugated alkylator

- “**FDA Pulls** Multiple Myeloma Drug **Pepaxto** From Market After Failing Phase 3 Study” [Link](#)

Relapsed or Refractory Multiple Myeloma

- “**Starton Therapeutics** Announces **Initial Key Safety and Efficacy Signals with STAR-LLD** in Patients with Relapsed or Refractory Multiple Myeloma” [Link](#)

Drug Market Watch

January/February 2024



“ **ELREXFIO™** is authorized by Health Canada for adults with relapsed or refractory multiple myeloma in Canada [Link](#) ”



“ Johnson & Johnson submits supplemental Biologics License Application to U.S. FDA seeking approval of **DARZALEX FASPRO®** (daratumumab and hyaluronidase-fihj)-based regimen for the treatment of patients with transplant-eligible, newly diagnosed multiple myeloma [Link](#) ”

“ Regeneron: **Linvoseltamab** BLA To Treat RR/MM Accepted For FDA Priority Review [Link](#) ”

“ **TECVAYLI® (teclistamab-cqyv)** biweekly dosing approved by the US FDA for the treatment of patients with relapsed or refractory multiple myeloma [Link](#) ”

“ FDA withdraws approval for **Pepaxto** as a multiple myeloma treatment [Link](#) ”



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

“ EMA Accepts Marketing Authorization Application for **Linvoseltamab** in R/R Multiple Myeloma [Link](#) ”

“ Bristol Myers Squibb Receives Positive CHMP Opinion for CAR T Cell Therapy Abecma (**idecabtagene vicleucel**) in Earlier Lines of Therapy for Triple-Class Exposed Relapsed and Refractory Multiple Myeloma [Link](#) ”

“ CHMP Recommends Approval of **Cilta-Cel** for Early Relapsed/Refractory Multiple Myeloma [Link](#) ”