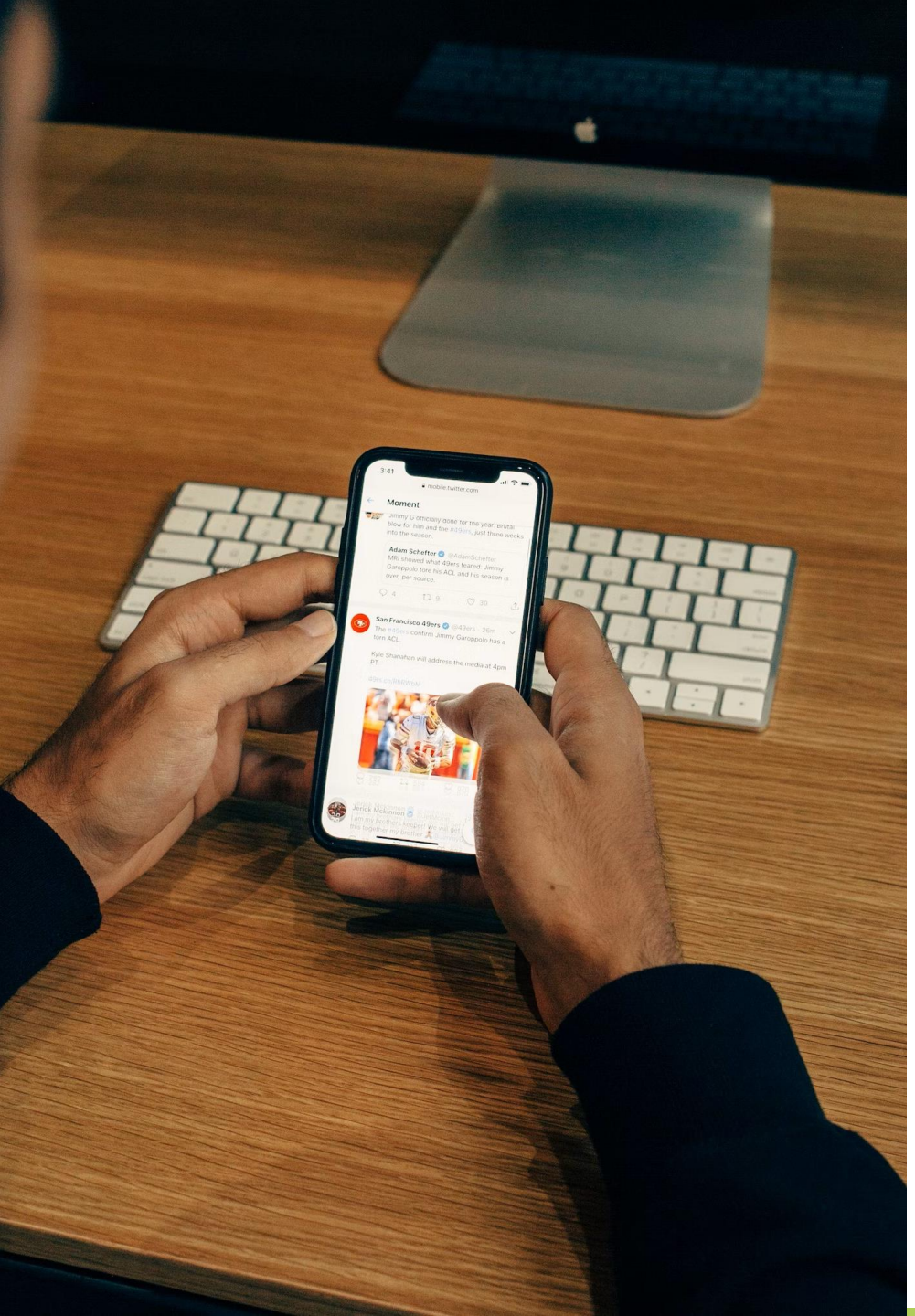


SMML newsletter

May 2024

Based on data from March/April 2024

Monthly updates around multiple myeloma

MMsyndiTrack™

Objectives

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.

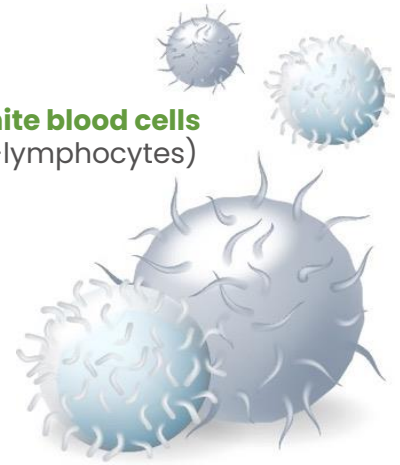
Who will benefit from this newsletter?

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?



White blood cells
(B-lymphocytes)

70
YEARS

■ 5 year survival rate ~50%

Read more on Multiple Myeloma:

MSD MANUAL
Professional Version

→ Professional version in English

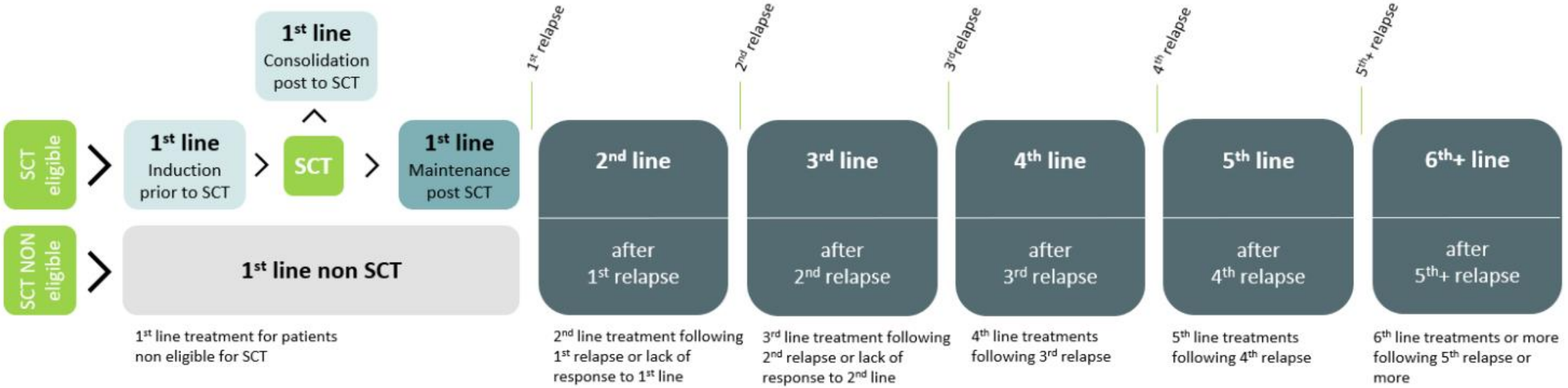
→ Professional version in French

MSD MANUAL
Consumer Version

→ 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
Tecvayli®	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
Elrexfio®	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

1844 — *"Rhubarb & orange peel, strengthening plaster to the chest, a pound of blood removed & leeches applied for maintenance therapy".*

1947 — Urethane

1958 — Melphalan

1962 — Corticosteroids

1983 — Autologous transplantation

1984 — Vincristine + Adriamycin + Dexamethasone

1999 — thalidomide

2002 — bortezomib (Velcade®)

2005 — lenalidomide (Revlimid®)

2010 — bendamustine (Levact®)

2012 — carfilzomib (Kyprolis® US)

2013 — pomalidomide (Imnovid®/Pomalyst®)

2015 — panabinostat (Farydak®); carfilzomib (Kyprolis® EU)

2016 — elotuzumab (Empliciti®); daratumumab (Darzalex®); ixazomib (Ninlaro®)

2020 — belantamab mafodotin (Blenrep® EU Belamaf ® US); selinexor (Nexpovio® EU Xpovio® US); isatuximab (Sarclisa®)

2021 — idecabtagene vicleucel (Abecma®)

2022 — ciltacabtagene autoleucel (Carvykti®); teclistamab (Tecvayli®)

2023 — melflufen (Pepaxti® EU Pepaxto® US); talquetamab (Talvey®); elranatamab (Elrexfio®)

20?? — marizomib, anetumab ravtansine, venetoclax, oprozomib

MM studies at APLUSA

16+ YEARS

17+ 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
- 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

March/April 2024

CONTENTS

SCOPE

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

There were a total of **81K** mentions from patients recorded during the listening period from **March 1st, 2024,** to **April 30th, 2024**.

A majority of mentions came from **News (66%), X (formerly Twitter) (27%), Instagram (3%), Reddit (2%), blogs (1%) and Forums (1%).**

A total of **15K** unique authors were identified.

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

Social media listening period :March/April 2024
Scope: worldwide in English

Methodology

WEB

*Extraction**

81 370 Mentions

Filtering

Also includes:
- patient testimonies
- Post from associations
- financial/market news
- Articles/press release not focusing solely on multiple myeloma

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

- **Phase II and III clinical trials**
  - Phase II: 4 444 articles
  - Phase III: 3 040 articles
  - *Exclude:*
    - *Financial/market news*
    - *Phase I/II clinical trials*
    - *Articles non-focusing solely on phase II or III developments*
- **HCPs**
  - 2 665 Mentions
  - *X (formerly Twitter), Reddit, or forums users self-referencing as healthcare professionals in their bio/flags*
- **Press releases**
  - 7 027 Mentions
  - *Articles flagged as being press releases*
- **Market watch**
  - 1 619 Mentions
  - *Articles mentioning drug approval by a national healthcare authority.*
  - *Can also include non-approvals as well as additional authorizations and recommendations (e.g., medical reimbursements, etc.)*

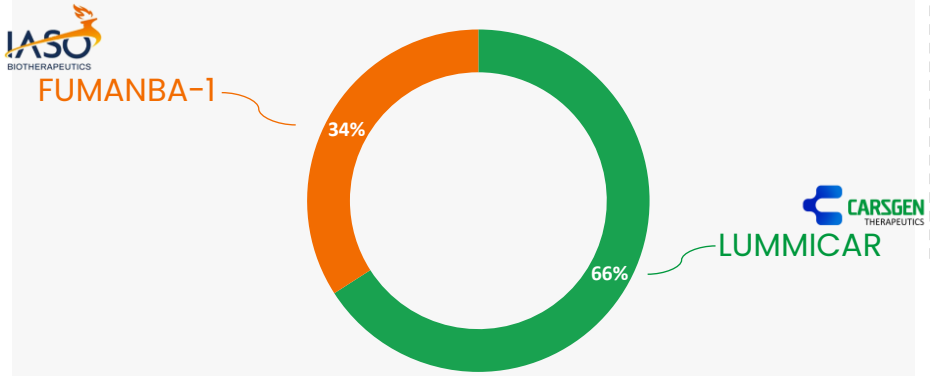
Social media listening period :March/April 2024
Scope: worldwide in English

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 autoleucel	
Celgene	KarMMa-2	RR	Monotherapy (one arm with lenalidomide) ; BMTCTN1902: Monotherapy: Idecabtagene vicleucel	
	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 autoleucel	
	CARTITUDE-2	RR	Monotherapy: ciltacabtagene autoleucel	
	GRIFFIN	1L	daratumumab, lenalidomide, bortezomib, and dexamethasone (D-RVd)	
	MajesTEC-1	RR	Monotherapy: teclistamab	
	MonumenTAL-1	RR	Monotherapy: talquetamab	
	RedirecTT-1	RR	teclistamab, talquetamab, daratumumab	
Nanjing IASO Biotechnology	FUMANBA-1	RR	Monotherapy: equecabtagene autoleucel	
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: Linvoseltamab (also known as 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 autoleucel (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 CAR-T: NMPA Approves the NDA for CARsgen's BCMA CAR-T Therapy Zevorcabtagene Autoleucel for Relapsed or Refractory Multiple Myeloma

Clinical trial mentioned/Sponsor



LUMMICAR-1
Ctrl + click to access clinical trial : NCT03975907

"Clinical Trial to Evaluate Zevor-cel (CT053) in Patients With Relapsed and/or Refractory Multiple Myeloma"

FUMANBA-1
Ctrl + click to access clinical trial : NCT05066646

"A Phase 1/2 Study of a Fully Human BCMA-targeting CAR (CT103A) in Patients With Relapsed/Refractory Multiple Myeloma"

Headlines/Hot off the press

NMPA Approves the NDA for CARsgen's BCMA CAR-T Therapy Zevorcabtagene Autoleucel for Relapsed or Refractory Multiple Myeloma

"CARsgen Therapeutics Holdings Limited (…) a company focused on innovative CAR T-cell therapies for the treatment of hematologic malignancies and solid tumors, announces that today the National Medical Products Administration ("NMPA") of China has approved the New Drug Application ("NDA") for zevorcabtagene autoleucel, for the treatment of adult patients with relapsed or refractory multiple myeloma who have previously progressed after at least 3 lines of therapy" Click here to read the full article

IASO Bio Announces NMPA's IND Approval for Equecabtagene Autoleucel in Second- and Third-Line Treatment of Multiple Myeloma

"IASO Bio, (…), today announced that China National Medical Products Administration (NMPA) has approved the Investigational New Drug (IND) application for Equecabtagene Autoleucel, a self-developed fully-human anti-B cell maturation antigen (BCMA) chimeric antigen receptor (CAR) autologous T-cell injection, for an expanded indication in treating relapsed and/or refractory multiple myeloma (R/RMM) patients who have undergone 1-2 lines of prior therapies and are refractory to lenalidomide. " Click here to read the full article

Molecules

zevorcabtagene autoleucel

equecabtagene autoleucel

Phase II N= 2 337 mentions
Social media listening period: March 2024
Scope: worldwide in English

Phase II Relapse/Refractory Bispecific Antibodies: Linvoseltamab Pivotal Data Presented at AACR Reinforce High Response Rate that Deepens Over Time in Patients with Heavily Pre-Treated Multiple Myeloma

Headlines/Hot off the press

Linvoseltamab Pivotal Data Presented at AACR Reinforce High Response Rate that Deepens Over Time in Patients with Heavily Pre-Treated Multiple Myeloma

"Regeneron Pharmaceuticals, Inc. today announced the oral plenary session presentation of positive pivotal data from the Phase 1/2 LINKER-MM1 trial of linvoseltamab in patients with relapsed/refractory (R/R) multiple myeloma (MM) at the American Association for Cancer Research (AACR) Annual Meeting 2024 in San Diego." Click here to read the full article

Sponsor

REGENERON

LINKER-MM1
Ctrl + click to access clinical trial : NCT03761108

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

Molecule

linvoseltamab

Phase II N= 2 107 mentions
Social media listening period: April 2024
Scope: worldwide in English

Phase II Relapse/Refractory CAR-T: Immix Biopharma Awarded European Union Orphan Drug Designation for NXC-201 in Multiple Myeloma

Headlines/Hot off the press

Immix Biopharma Awarded European Union Orphan Drug Designation for NXC-201 in Multiple Myeloma

"Immix Biopharma, Inc. (…), a clinical-stage biopharmaceutical company trailblazing cell therapies in autoimmune disease, today announced that the European Commission (EC) has granted orphan drug designation to NXC-201 for the treatment of multiple myeloma.." Click here to read the full article

Sponsor

HADASSAH UNIVERSITY MEDICAL CENTER

NEXICART-1

Ctrl + click to access clinical trial:

NCT04720313

In the ongoing phase 2 trial, NXC-201 is being evaluated for overall response rate (ORR), portion of patients with complete response (CR), and duration of response (DOR).

Molecule

NXC-201

Phase II N= 2 107 mentions
Social media listening period: April 2024
Scope: worldwide in English

Drugs in clinical trials (Phase III) monitored during the listening period

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 application to the European Medicines Agency for DARZALEX® (daratumumab)-based quadruplet therapy for the treatment of patients with transplant-eligible, newly diagnosed multiple myeloma

Headlines/Hot off the press

“Johnson & Johnson submits application to the European Medicines Agency for DARZALEX® (daratumumab)-based quadruplet therapy for the treatment of patients with transplant-eligible, newly diagnosed multiple myeloma”

“Janssen-Cilag International NV, a Johnson & Johnson company, today announced the submission of a Type II variation application to the European Medicines Agency. The submission is seeking approval for an indication extension of DARZALEX® subcutaneous formulation in combination with bortezomib, lenalidomide, and dexamethasone (D-VRd) for the treatment of adult patients with newly diagnosed multiple myeloma who are eligible for autologous stem cell transplant. ”
Click here to read the full article

Sponsor

EMN RESEARCH ITALY

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”

Combinations

daratumumab + lenalidomide + dexamethasone + bortezomib

Phase III N= 1 475 mentions
Social media listening period: March 2024
Scope: worldwide in English

Phase III Relapse/Refractory Triplet Therapies: GSK's blood cancer drug meets main goal in late-stage trial; analysts tout comeback

Headlines/Hot off the press

"GSK's blood cancer drug meets main goal in late-stage trial; analysts tout comeback"

"GSK said on Thursday a study showed its experimental drug Blenrep helped extend survival in patients with a type of blood cancer without symptoms worsening, marking a potential comeback for the drug after several setbacks."
Click here to read the full article

Sponsor

GSK

DREAMM-8
Ctrl + click to access clinical trial:
NCT04484623

"This study will evaluate the efficacy and safety of belantamab mafodotin in combination with pomalidomide and dexamethasone (Arm A) compared with that of combination of pomalidomide, bortezomib and dexamethasone (Arm B) in participants with relapsed/refractory multiple myeloma (RRMM)."

Combinations

pomalidomide + belantamab mafodotin + dexamethasone

Phase III N= 1 475 mentions
Social media listening period: March 2024
Scope: worldwide in English

Phase III Relapse/Refractory CAR-T: Bristol Myers Squibb's Abecma (idecabtagene vicleucel) Becomes First CAR T Cell Therapy Approved in the European Union in Earlier Lines for Triple-Class Exposed Relapsed and Refractory Multiple Myeloma

Headlines/Hot off the press

Bristol Myers Squibb's Abecma (idecabtagene vicleucel) Becomes First CAR T Cell Therapy Approved in the European Union in Earlier Lines for Triple-Class Exposed Relapsed and Refractory Multiple Myeloma

"Abecma demonstrated superiority over standard regimens in the Phase 3 KarMMa-3 trial, with a 51% reduction in risk of disease progression or death and a well-established safety profile with mostly low-grade and transient occurrences of cytokine release syndrome and neurotoxicity " Click here to read the full article

Sponsor

Celgene

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)"

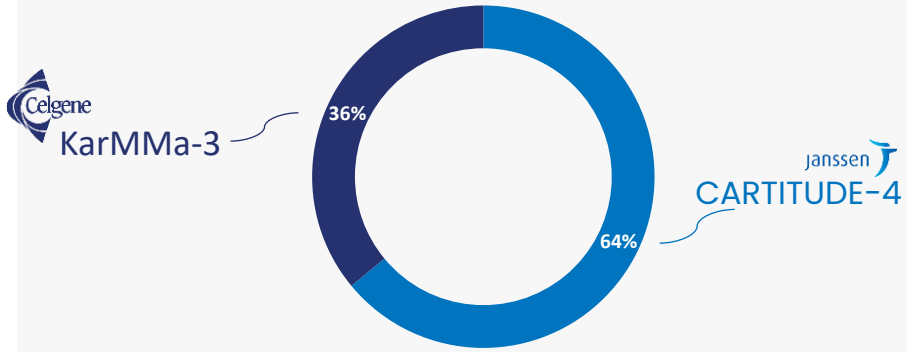
Molecule

idecabtagene vicleucel

Phase III N= 1 475 mentions
Social media listening period: March 2024
Scope: worldwide in English

Phase III Relapse/Refractory CAR-T: FDA Approves Carvykti for Patients with Relapsed or Refractory Multiple Myeloma Who Have Received at Least One Prior Line of Therapy

Clinical trial mentioned/Sponsor



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"

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)"

Molecules

ciltacabtagene autoleucel

idecabtagene vicleucel

Headlines/Hot off the press

FDA Approves Carvykti for Patients with Relapsed or Refractory Multiple Myeloma Who Have Received at Least One Prior Line of Therapy

"Johnson & Johnson announced today that the U.S. Food and Drug Administration has approved Carvykti® for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least one prior line of therapy, including a proteasome inhibitor and an immunomodulatory agent, and are refractory to lenalidomide." Click here to read the full article

CARVYKTI® (ciltacabtagene autoleucel) Approved by the European Commission for Second-line Treatment of Patients with Relapsed and Refractory Multiple Myeloma

"Legend Biotech Corporation, a global leader in cell therapy, announced today that the European Commission has granted approval of CARVYKTI® for the treatment of adult patients with relapsed and refractory multiple myeloma who have received at least one prior line of therapy" Click here to read the full article

Cranial Nerve Palsy May Be Present After Cilta-Cel for Multiple Myeloma

A subgroup of patients from the 3 CARTITUDE trials experienced cranial nerve palsy after treatment, most of whom were men. Click here to read the full article

Cilta-cel Shows High Responses for Lenalidomide-Refractory Myeloma in First Relapse

The latest CARTITUDE-4 data examine the efficacy and safety of ciltacabtagene autoleucel in lenalidomide-refractory multiple myeloma. Click here to read the full article

U.S. FDA Approves Bristol Myers Squibb and 2seventy bio's Abecma for Triple-Class Exposed Relapsed or Refractory Multiple Myeloma After Two Prior Lines of Therapy

"Bristol Myers Squibb and 2seventy bio, Inc. have announced that on April 4, 2024, the U.S. Food and Drug Administration approved Abecma® for the treatment of adult patients with relapsed or refractory multiple myeloma after two or more prior lines of therapy including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody, based on results from the KarMMa-3 trial. This approval expands Abecma's indication, making it available in earlier lines to patients who have relapsed or become refractory after exposure to these three main classes of treatment (triple-class exposed), after two prior lines of therapy.
Click here to read the full article

Phase III N= 1 565 mentions
Social media listening period: April 2024
Scope: worldwide in English

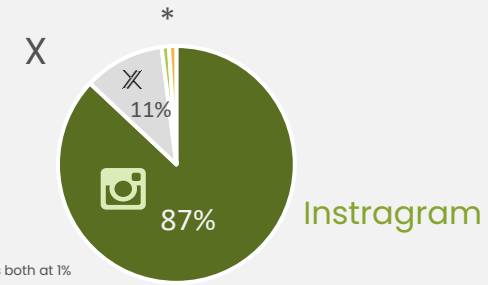
Multiple Myeloma Awareness Month: Focus On Patients

Patients' online conversation analyzed: **225**

* 3026 mentions in total during MM awareness month

Mostly coming mostly from the **United states** and The **United kingdom.**

Source of content



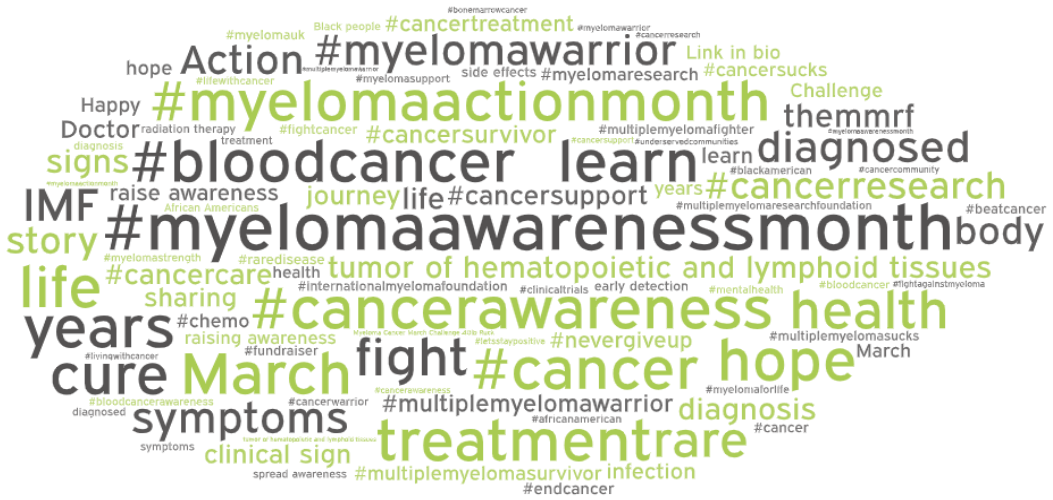
* Tumblr and forums both at 1%

SOV Patient/caregiver

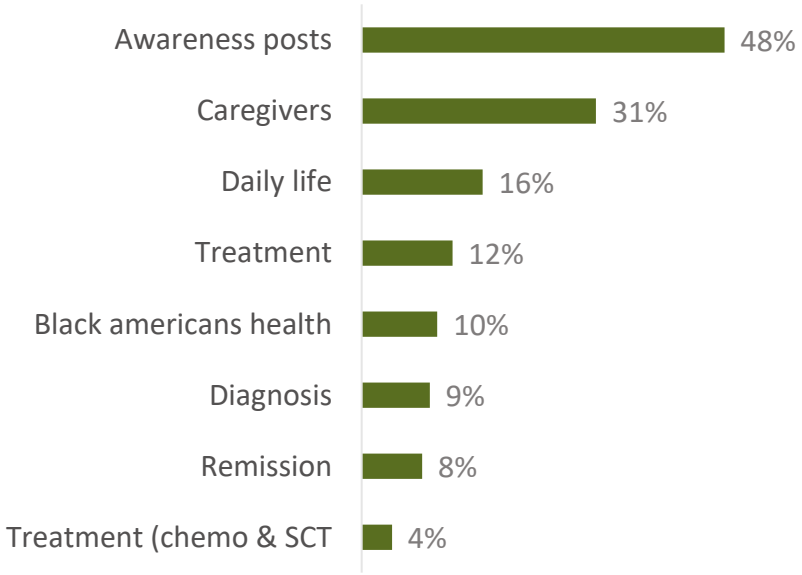
91%

9%

Social media listening period: March 2024
Scope: worldwide in English



Topic of discussions



Top posts per engagement

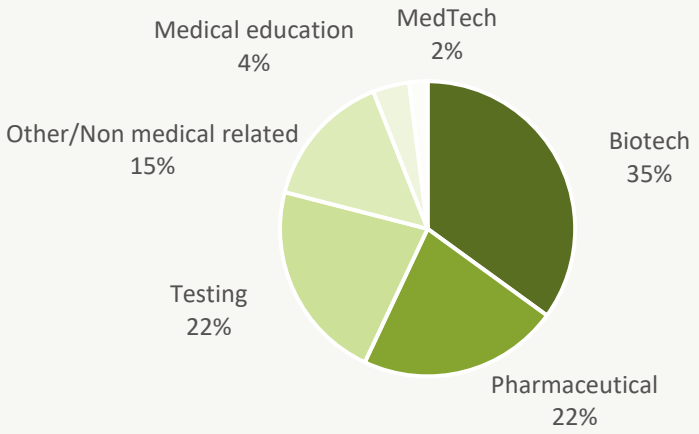
"GM Everyone 😊 March is Multiple Myeloma awareness month. When I received my diagnosis, I went off the grid to work out what to do next, welcomed by this wonderous scene just before being snowed in for a couple of days. Big Sky Country was the perfect environment to clear my head, develop acceptance, and find Purpose for the next chapter 🙏
My pinned is a wide format photograph of a landscape I came to love. I hope you enjoy this 2 minute flight ☮️ Best Seen Fullscreen
- Bilitis, Francis Lai 🎵 #montana #snow #winter #MentalWellness #cancerwarrior #drones @andre_tfw#FridayFeeling

"March is #MyelomaActionMonth! These pictures were taken 7 years ago during induction chemo. I wish people knew that #myeloma often presents as fatigue and back pain - common for a busy working mom. It was several months & some compression fractures before diagnosis. #mmsm"

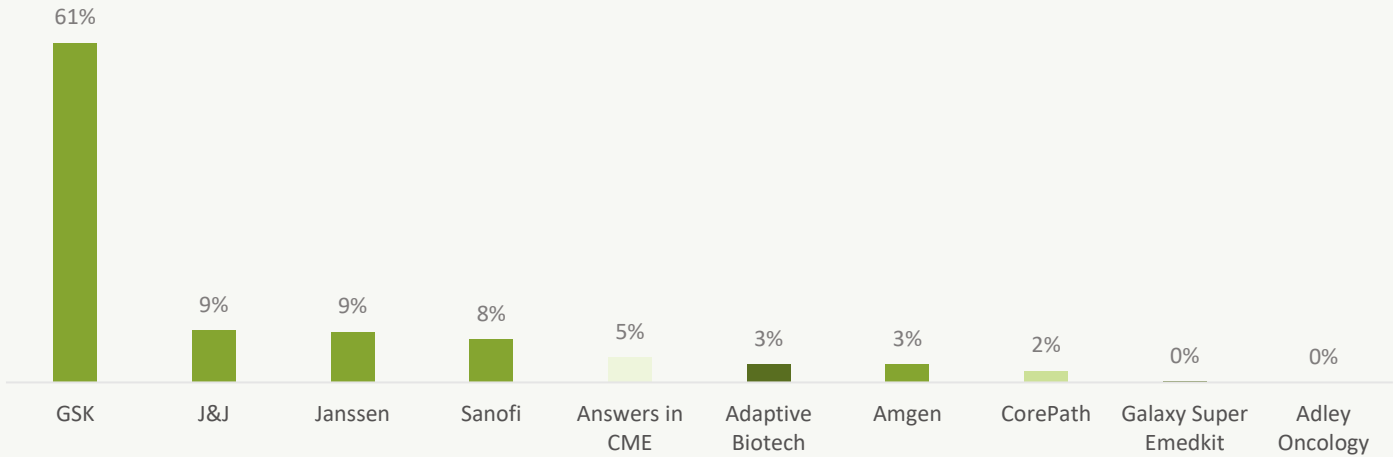
Word cloud emojis

GSK leads content about multiple myeloma awareness in terms of engagement. Overall, content about patient testimonies in the form of videos was the most successful type of post.

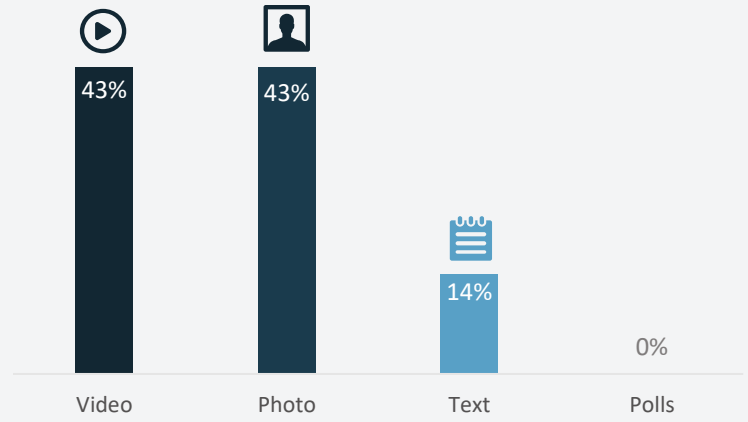
Type of companies posting



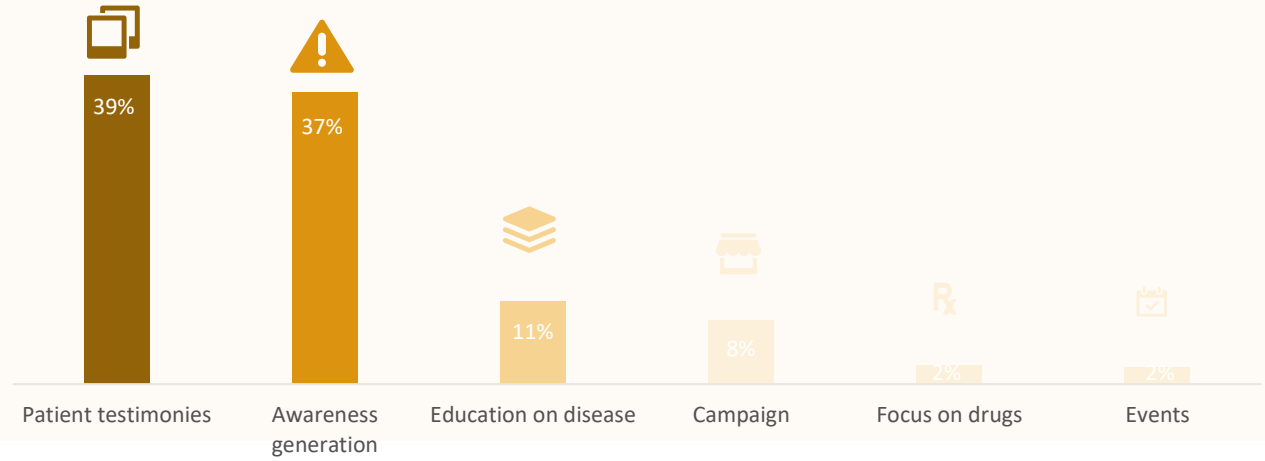
Companies with the most engagement during MM awareness month



Engagement per type of content



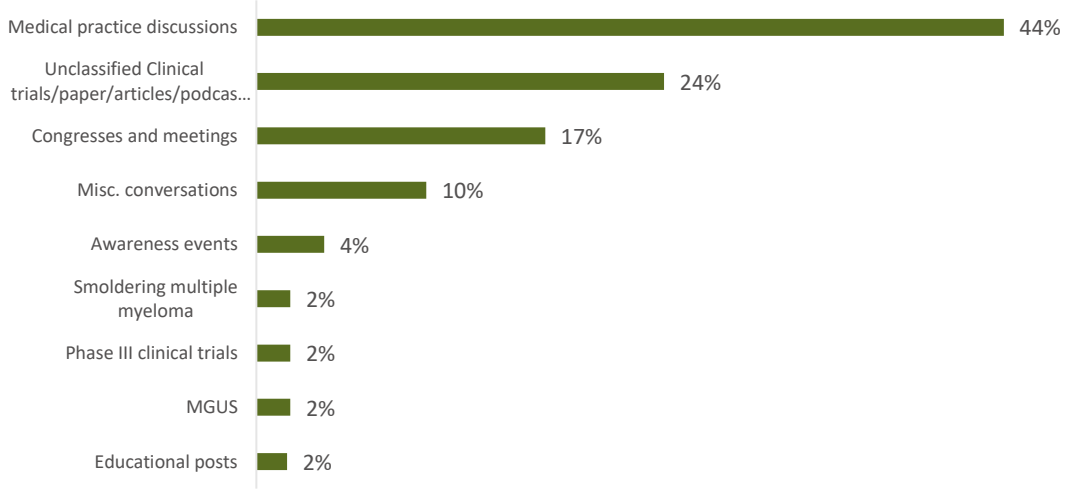
Engagement per type of topics



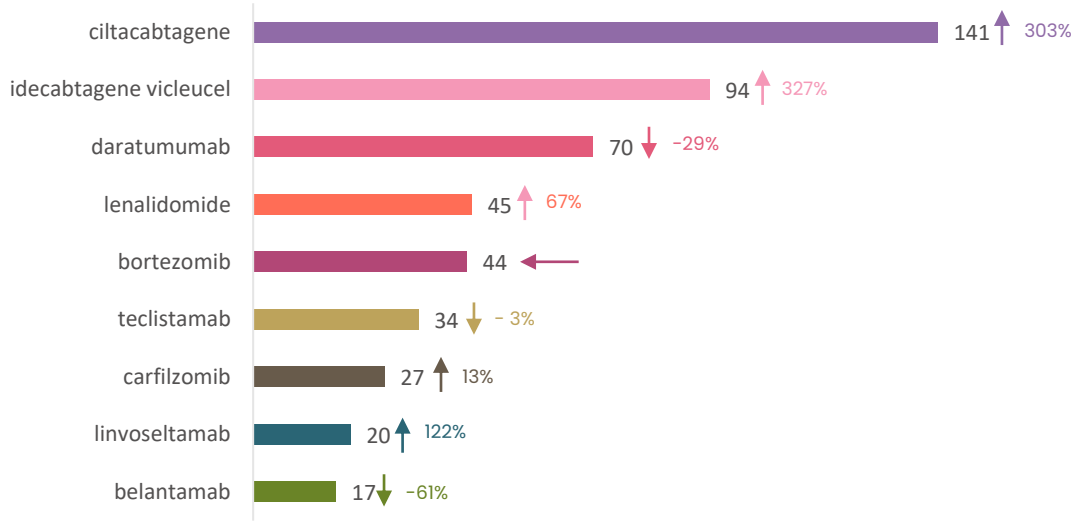
MM awarness month top ten companies N= 53 mentions
Social media listening period: March 2024
Scope: worldwide in English

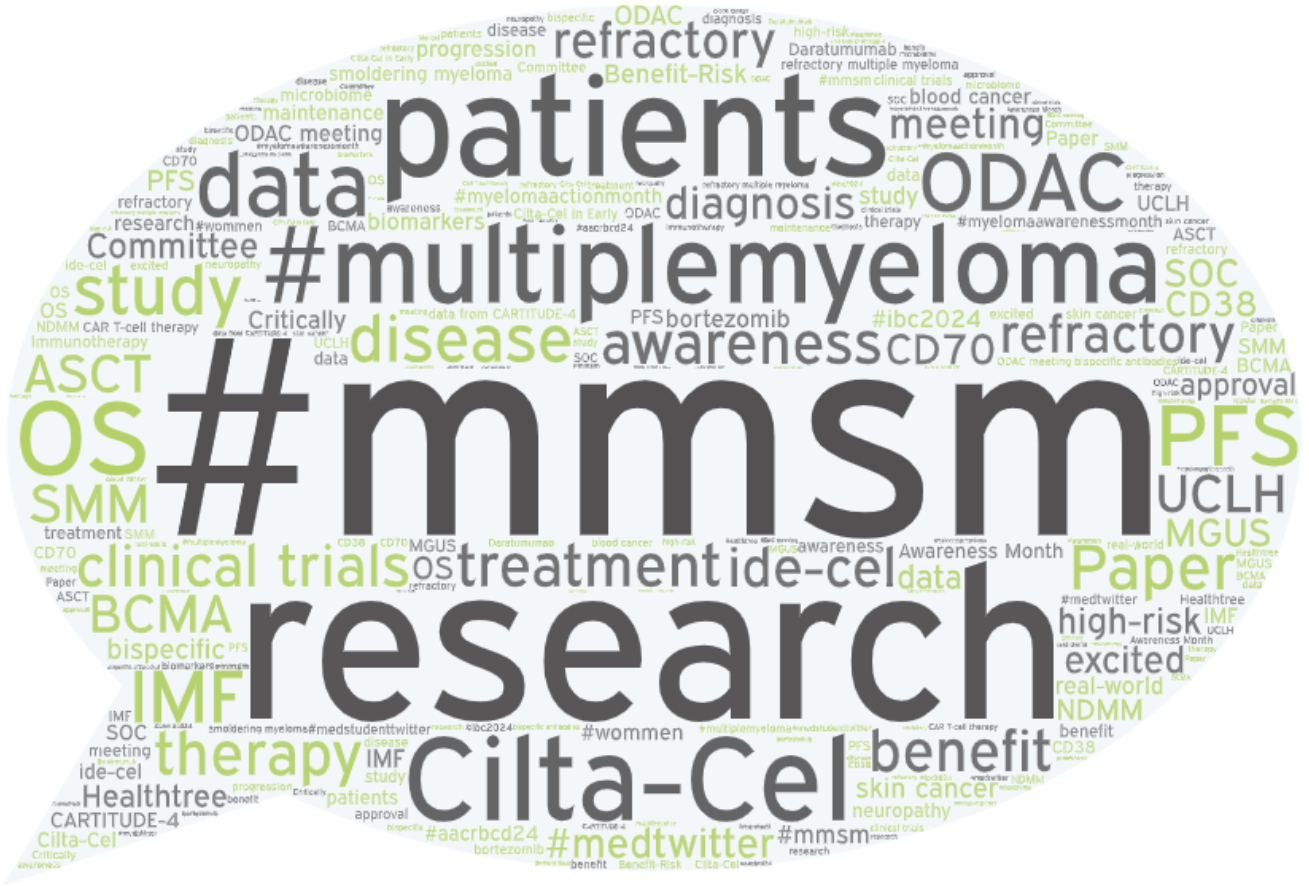
Online discussions focused heavily on Carvykti both in March and in April, first with the ODAC decision to allow its use in earlier relapsed/refractory multiple myeloma patients. A decision that was later confirmed in April when Carvykti was authorised by the FDA for said patients.

SOV topics of conversations



SOV molecules





HCPs conversation N= 2 665 mentions
Social media listening period: March/April 2024
Scope: worldwide in English

**Variation of volume compared to previous month*

**emerging*

April and March was a time of guidance and reflection on treatment options and modalities for online HCPs this month.

Dr Rajkumar shared the IMWG committee consensus guidelines for the optimal use of bispecific antibodies, accessible here (a subscription to the lancet oncology is required).

Dr Rajkumar also enthusiastically mused about the number of molecules that have been approved since the 2000's. He then shared some resources to facilitate the treatment journey in an ensuing thread.

Dr Tembhare promoted a study for which he was the principal investigator. The study is available here.

Most engagement

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

Vincent Rajkumar
@VincentRK

Just out: International Myeloma Working Group guidelines for bispecific antibodies myeloma.

Limited time: Free copy link in the thread. @TheLancetOncol @paurotero @JKaufmanMD @szusmani @YiLinMDPhD @TomBmt133 @mvmateos @bdermanmd @MinnemaMonique et al

Traduire le post

thelancet.com
International Myeloma Working Group immunotherapy comr
Multiple myeloma remains an incurable disease, despite the development of numerous drug classes and combinations...

Vincent Rajkumar
@VincentRK

Here are all the drug approvals for relapsed multiple myeloma in 20 years. Bookmark it! Amazing! #MedTwitter

Traduire le post

Drug /Combination	Approval	Indication
Bortezomib	AA (2003)	RRMM/>2L,
Bortezomib	Regular (2005)	RRMM/, 1-3L
Liposomal doxorubicin HCl	Regular (2007)	RRMM/, ≥1L
Lenalidomide with dex	Regular (2005)	RRMM/≥1L
Carfilzomib	AA (2012)	RRMM/,≥1L
Carfilzomib with Rd	Regular (2015)	RRMM/>1-3 prior lines
Carfilzomib with dex	Regular (2016)	MM, 1-3 prior lines
Pomalidomide with dex	AA (2013)	RRMM/≥2L, including lenalidomide and PI

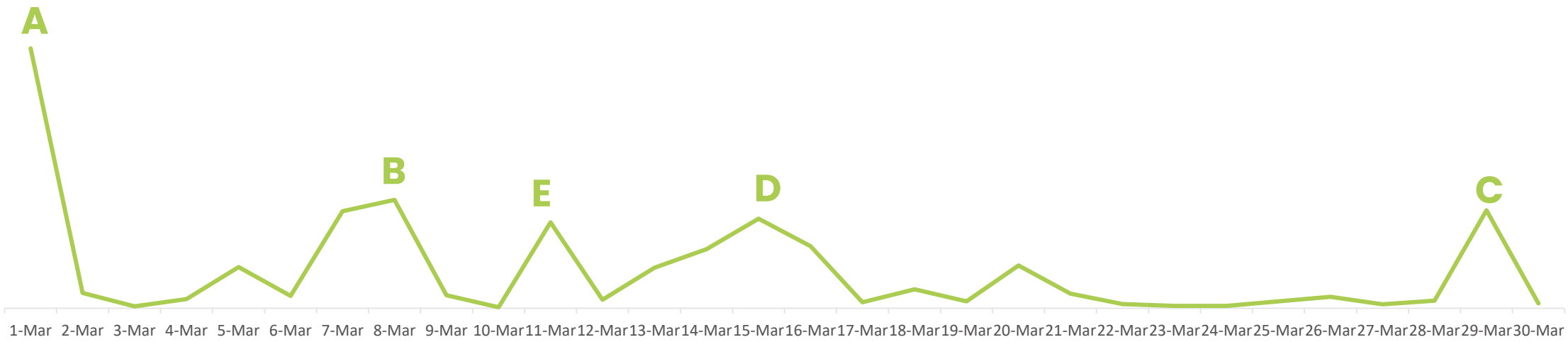
Prashant Tembhare
@PrashantTembha1

Happy to share a recent publication from our lab on CTC and Peripheral blood MRD in myeloma using highly sensitive flow cytometry @Hemasphere_EHA @BrunoPaiva_UNAV @LabOrfao @AmeetRKin @EHA_Hematology @HoratiuOlteanu @sindhucherian @DrOlaLandgren @NikhilMunshiMD @NoopurRajeMD

HCPs conversation N= 2 665 mentions
Social media listening period: March/April 2024
Scope: worldwide in English

Media (press releases): volume and articles per peak (March 2024)

Volume of articles overtime



A

"HealthTree Foundation Announces Launch of **HealthTree Research Hub** in Multiple Myeloma" Link

"**NMPA Approves** the NDA for CARsgen's BCMA CAR-T Therapy **Zevorcabtagene Autoleucel** for Relapsed or Refractory Multiple Myeloma" Link

"**Cullinan Oncology** Announces U.S**. FDA Clearance** of Investigational New Drug Application for Novel MICA/B Antibody, **CLN-619**, for Relapsed/Refractory Multiple Myeloma" Link

"**Boosting Minority Enrollment in Clinical Trials**" Link

"Multiple Myeloma in **Black and Hispanic Communities**" Link

B "More multiple myeloma patients eligible for stem cell transplantation" Link

"**Johnson & Johnson submits application to the European Medicines Agency for DARZALEX®** (daratumumab)-based quadruplet therapy for the treatment of patients with transplant-eligible, newly diagnosed multiple myeloma" Link

"**GSK** announces **positive results from DREAMM-8** phase III trial for Blenrep versus standard of care combination in relapsed/refractory multiple myeloma" Link

C "**IASO Bio** Announces **NMPA's IND Approval for Equecabtagene Autoleucel** in Second- and Third-Line Treatment of Multiple Myeloma" Link

D "CARVYKTI® (**ciltacabtagene autoleucel**) Receives **Recommendation from the U.S. FDA Oncologic Drugs Advisory Committee** for Earlier Treatment of Patients with Relapsed/Refractory Multiple Myeloma" Link

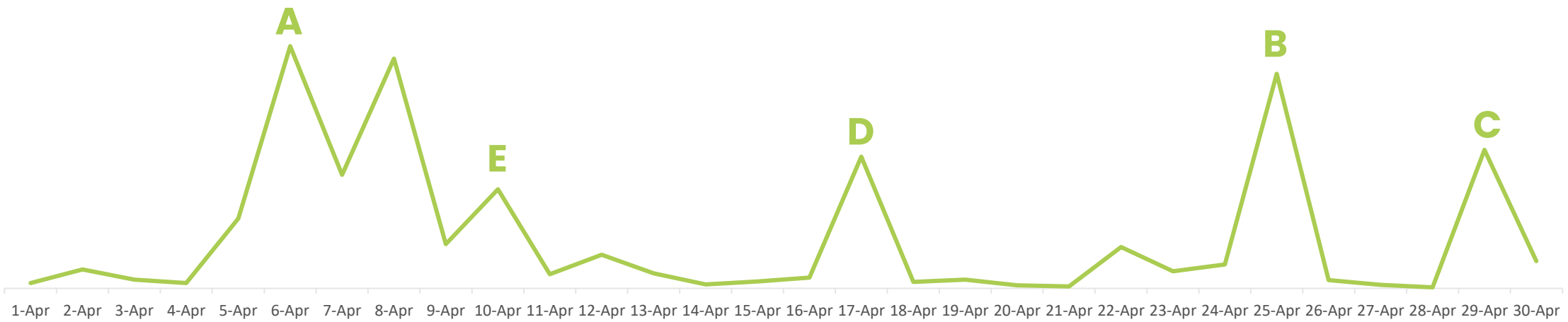
"**FDA Advisory Committee** Votes in Favor of Bristol Myers Squibb's and 2seventy bio's **Abecma** for Triple-Class Exposed Multiple Myeloma in Earlier Lines of Therapy" Link

"Mayo Clinic Minute: Advances in multiple myeloma treatment" Link

Media (press release, excluding financial news) N= 3 725 mentions
Social media listening period: March 2024
Scope: worldwide in English

Media (press releases): volume and articles per peak (April 2024)

Volume of articles overtime



A

"**CARVYKTI®** is the First and Only BCMA-Targeted Treatment **Approved by the U.S. FDA** for Patients with Relapsed or Refractory Multiple Myeloma Who Have Received at Least One Prior Line of Therapy" Link

"**FDA approves** earlier use of **Abecma** for triple-class exposed multiple myeloma" Link

B

"Lucio N. Gordan, MD Discusses Findings of Phase 3 Clinical Trial Supporting Advanced Treatments for Multiple Myeloma in National Broadcast" Link

"**Starton Therapeutics** Announces Enrollment Completion for STAR-LLD **Phase 1b Clinical Trial** in Multiple Myeloma" Link

C

"**Immix Biopharma** Awarded European Union Orphan Drug Designation for **NXC-201** in Multiple Myeloma" Link

D

"**BioLineRx** Announces Poster Presentation on Apheresis Center Efficiency and CXCR4 Antagonists including **APHEXDA®** (motixafortide) in Patients with Multiple Myeloma at the ASFA 2024 Annual Meeting" Link

"New Agent Shows Early Promise in Triple-Class Refractory Multiple Myeloma" Link

E

"**ASTCT** Supports the FDA's Approval of **Earlier Use of CAR T-Cell Therapy** for Multiple Myeloma" Link

"**Opna Bio** Presents Promising Preclinical Data in Multiple Myeloma with **OPN-6602** (...) at the American Association of Cancer Research Annual Meeting" Link

"**FDA** appears receptive to **surrogate endpoint supporting accelerated approval of multiple myeloma drugs**" Link

Media (press release, excluding financial news) N= 3 302 mentions
Social media listening period: April 2024
Scope: worldwide in English

Articles per theme (March 2024)

APROVAL AND CLEARANCES

- "**NMPA Approves** the NDA for CARsgen's BCMA CAR-T Therapy **Zevorcabtagene Autoleucel** for Relapsed or Refractory Multiple Myeloma" Link
- "**Cullinan Oncology** Announces U.S**. FDA Clearance** of Investigational New Drug Application for Novel MICA/B Antibody, **CLN-619**, for Relapsed/Refractory Multiple Myeloma" Link
- "**Johnson & Johnson submits application to the European Medicines Agency for DARZALEX®** (daratumumab)-based quadruplet therapy for the treatment of patients with transplant-eligible, newly diagnosed multiple myeloma" Link
- "**IASO Bio** Announces **NMPA's IND Approval for Equecabtagene Autoleucel** in Second- and Third-Line Treatment of Multiple Myeloma" Link
- "CARVYKTI® (**ciltacabtagene autoleucel**) Receives **Recommendation from the U.S. FDA Oncologic Drugs Advisory Committee** for Earlier Treatment of Patients with Relapsed/Refractory Multiple Myeloma" Link
- "**FDA Advisory Committee** Votes in Favor of Bristol Myers Squibb's and 2seventy bio's **Abecma** for Triple-Class Exposed Multiple Myeloma in Earlier Lines of Therapy" Link

Antibody-drug conjugates (BCMA)

- "**GSK** announces **positive results from DREAMM-8** phase III trial for Blenrep versus standard of care combination in relapsed/refractory multiple myeloma" Link

PATIENT LIFE

- "**Boosting Minority Enrollment in Clinical Trials**" Link
- "Multiple Myeloma in **Black and Hispanic Communities**" Link
- "More multiple myeloma patients eligible for stem cell transplantation" Link

RESEARCH

- "HealthTree Foundation Announces Launch of **HealthTree Research Hub** in Multiple Myeloma" Link
- "Mayo Clinic Minute: Advances in multiple myeloma treatment" Link

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Scope: worldwide in English

Articles per theme (April 2024)

BISPECIFIC ANTIBODIES

- "New Agent Shows Early Promise in Triple-Class Refractory Multiple Myeloma" Link

CAR-T

- "**CARVYKTI®** is the First and Only BCMA-Targeted Treatment **Approved by the U.S. FDA** for Patients with Relapsed or Refractory Multiple Myeloma Who Have Received at Least One Prior Line of Therapy" Link
- "**FDA approves** earlier use of **Abecma** for triple-class exposed multiple myeloma" Link
- "**Immix Biopharma** Awarded European Union Orphan Drug Designation for **NXC-201** in Multiple Myeloma" Link

CLINICAL TRIAL

- "**Starton Therapeutics** Announces Enrollment Completion for STAR-LLD **Phase 1b Clinical Trial** in Multiple Myeloma" Link

CONGRESSES AND PRESENTATIONS

- "Lucio N. Gordan, MD Discusses Findings of Phase 3 Clinical Trial Supporting Advanced Treatments for Multiple Myeloma in National Broadcast" Link
- "**BioLineRx** Announces Poster Presentation on Apheresis Center Efficiency and CXCR4 Antagonists including **APHEXDA®** (motixafortide) in Patients with Multiple Myeloma at the ASFA 2024 Annual Meeting" Link

EP300/CBP bromodomain inhibitors

- "**Opna Bio** Presents Promising Preclinical Data in Multiple Myeloma with **OPN-6602** (…) at the American Association of Cancer Research Annual Meeting" Link

MISC.

- "**ASTCT** Supports the FDA's Approval of **Earlier Use of CAR T-Cell Therapy** for Multiple Myeloma" Link
- "**FDA** appears receptive to **surrogate endpoint supporting accelerated approval of multiple myeloma drugs**" Link

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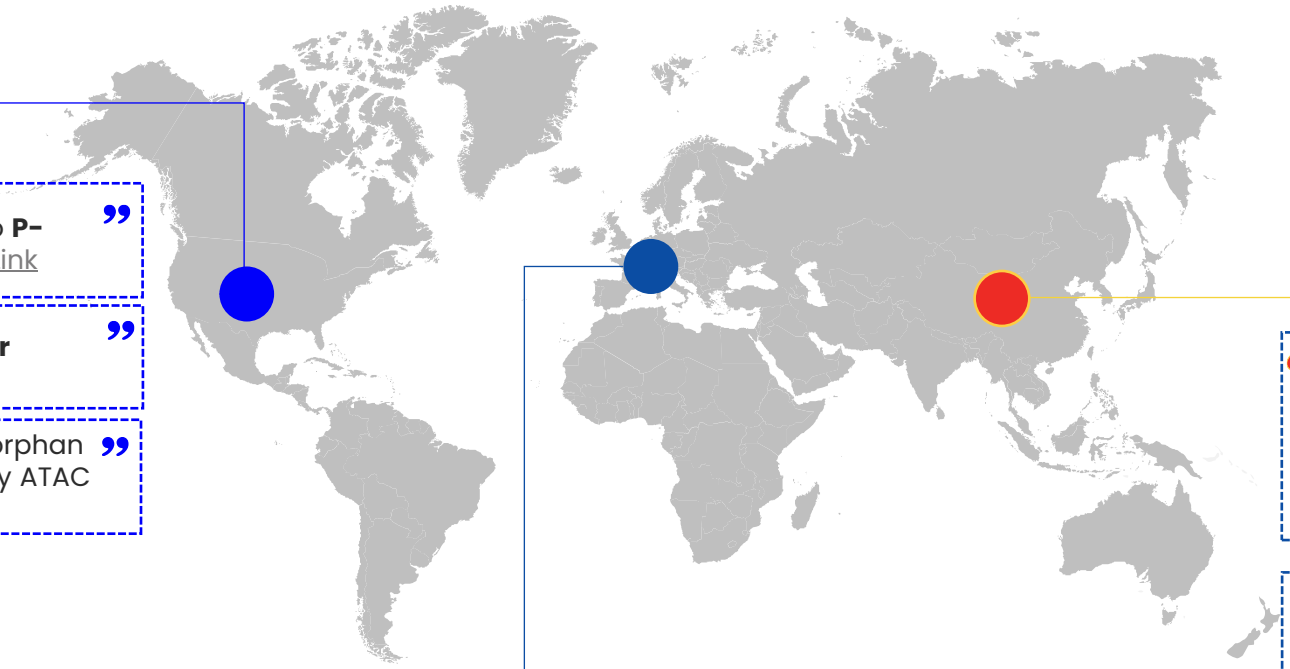
Drug Market Watch

March 2024



FDA

- FDA Grants Orphan Drug Designation to **P-BCMA-ALLO1** in R/R Multiple Myeloma Link
- FDA approves B.C. company's **cancer diagnostic device** Link
- EQS-News: Heidelberg Pharma granted orphan drug designation by FDA for its proprietary ATAC candidate **HDP-101** Link

国家药品监督管理局
National Medical Products Administration

- NMPA Approves the NDA for CARsgen's BCMA CAR-T Therapy **Zevorcabtagene Autoleucel** for Relapsed or Refractory Multiple Myeloma Link
- IASO Bio Announces NMPA's IND Approval for **Equecabtagene Autoleucel** in Second- and Third-Line Treatment of Multiple Myeloma Link

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

- Bristol Myers Squibb's Abecma (**idecabtagene vicleucel**) Becomes First CAR T Cell Therapy Approved in the European Union in Earlier Lines for Triple-Class Exposed Relapsed and Refractory Multiple Myeloma Link

European Commission

- J&J seeks EU approval for new **Darzalex** multiple myeloma indication Link

Drug Market Watch

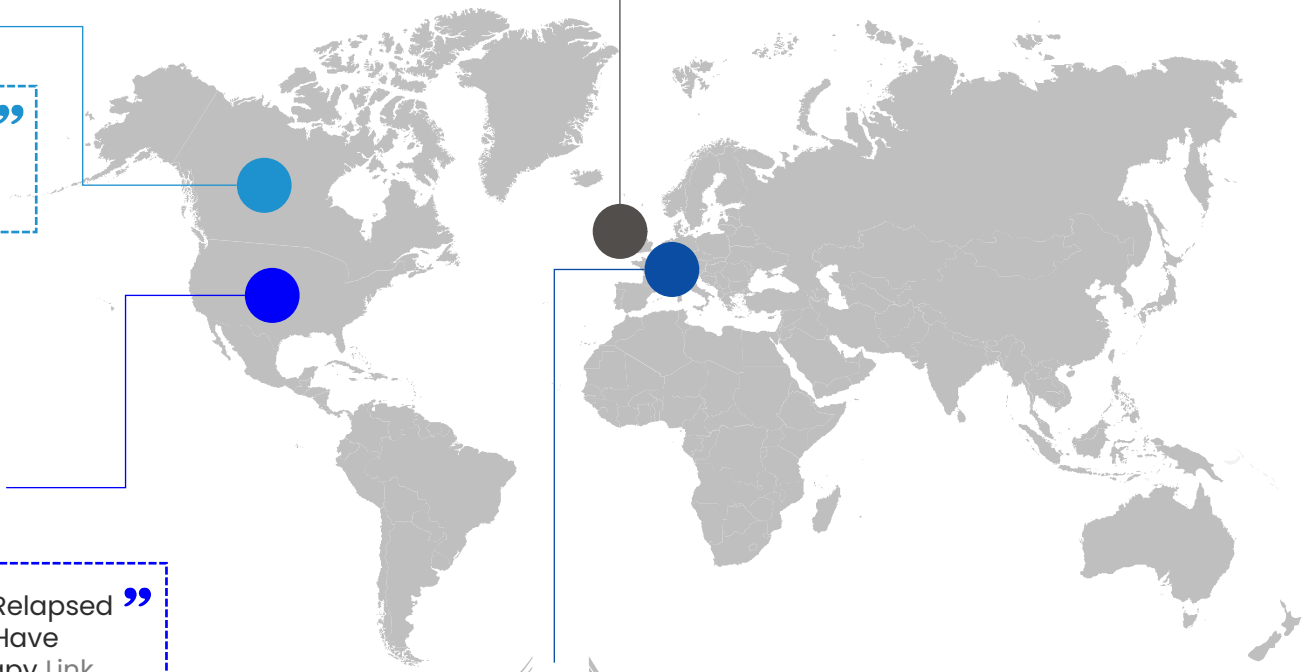
April 2024

INESSS
LE SAVOIR PREND FORME

> INESSS Recommendation to Deny Reimbursement for Multiple Myeloma Treatment is a Global Outlier Link

NICE
National Institute for Health and Care Excellence

> **NICE** recommends **Nexpovio** for multiple myeloma patients, addressing treatment gaps Link



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> **CARVYKTI®** (ciltacabtagene autoleucel) **Approved by the European Commission** for Second-line Treatment of Patients with Relapsed and Refractory Multiple Myeloma Link

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