



5 March 2026
EMA/53733/2026
Human Medicines Division

CAT quarterly highlights and approved ATMPs

March 2026

This report provides information on Advanced Therapy Medicinal Products (ATMPs) approvals and extension of indications of authorised ATMPs, as well as statistical data on product-related activities.

The period covered by this report is: December 2025 – February 2026.

Advanced therapy medicinal products approvals

None during the reporting period.

Extension of indication of authorised ATMPs

None during the reporting period.

Overview of product-related activities

The Committee discussed ongoing evaluation procedures for ATMPs and other related procedures as summarised in the following tables:

Initial Evaluation of Marketing Authorisation Applications (MAA) for ATMP							
	2009-2021	2022	2023	2024	2025	2026*	Total
Submitted MAAs	35	1	4	7	3	0	50
Positive draft Opinion	20 ⁱ	6	1	1	4	0	32 [#]
Negative draft opinions	4 ^{i,ii,iii}	0	0	0	3 ^{vii}	0	7
Withdrawals	8 ^{ii,iv}	1 ^v	1 ^{vi}	0	3 ^{viii}	0	13
Ongoing MAAs							4

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Corresponding to 31 ATMPs (see List of authorised ATMPs)

- i One negative draft opinion and two positive draft opinions for the Glybera
- ii Negative draft opinion and withdrawal for the Cerepro
- iii Two negative draft opinions for Heparesc
- iv Luxceptar, Roctavian, Artobend
- v [Sitoiqanap](#)
- vi [Lumevog](#)
- vii [Elevidys](#), [Jelrix](#) (two negative draft opinions)
- viii [Amtagvi](#), [Fanskya](#), [Jelrix](#) (after re-examination)

Variations (Type II) for authorised ATMP							
	2009-2021	2022	2023	2024	2025	2026*	Total
Positive opinion	110	47	49	33	59	8	306

Scientific recommendation on advanced therapy classification ¹							
	2009-2021	2022	2023	2024	2025	2026*	Total
Submitted	555	51	43	40	28	8	725
Adopted	544	46	52	39	32	3	716

Scientific advice procedure for ATMPs							
	2009-2021	2022	2023	2024	2025	2026*	Total
Number of procedures	506	53	57	61	76	13	766

PRIME ² Eligibility for ATMPs							
	2016-2021	2022	2023	2024	2025	2026*	Total
Discussed	105	10	13	17	21	6	172
Granted	46	4	9	6	6	2	73

* Period: January – February 2026

¹ More information on the scientific recommendation on advanced therapy classification and the summaries of ATMP classification can be found on the [ATMP classification webpage](#).

It is stressed that the scientific recommendation on advanced therapy classification does not amount to any endorsement of the plausibility of the product, including the mode of action or therapeutic indication(s) claimed by the applicant.

² PRIority MEdicines (PRIME) scheme. PRIME was set up in March 2016 to provide early and enhanced scientific and regulatory support to medicines that have the potential to significantly address patients' unmet medical needs. More information can be found at the [PRIME webpage](#).

List of authorised ATMPs

NAME	Type of ATMP	Authorisation Date	Orphan	PRIME	Comment
Chondrocelect	TEP	5/10/2009	No	No	MA withdrawn July 2016
Glybera	GTMP	25/10/2012	Yes	No	MA not renewed (MA ended Oct. 2017)
MACI	TEP, combined ATMP	27/06/2013	No	No	MA not renewed (MA ended June 2018)
Provenge	CTMP	6/09/2013	No	No	MA withdrawn May 2015
Holoclax	TEP	17/02/2015	Yes	No	
Imlygic	GTMP	16/12/2015	No	No	
Strimvelis	GTMP	26/05/2016	Yes	No	
Zalmoxis	CTMP	18/08/2016	Yes	No	MA withdrawn Oct. 2019
Spherox	TEP	10/07/2017	No	No	
Alofisel	CTMP	23/03/2018	Yes	No	MA withdrawn Dec. 2024
Yescarta	GTMP	23/08/2018	Yes	Yes	
Kymriah	GTMP	23/08/2018	Yes	Yes	
Luxturna	GTMP	22/11/2018	Yes	No	
Zynteglo	GTMP	29/05/2019	Yes	Yes	MA withdrawn March 2022
Zolgensma	GTMP	18/05/2020	Yes	Yes	
Libmeldy	GTMP	17/12/2020	Yes	No	
Tecartus	GTMP	14/12/2020	Yes	Yes	
Skysona	GTMP	16/07/2021	Yes	Yes	MA withdrawn Nov. 2021
Abecma	GTMP	18/08/2021	Yes	Yes	
Breyanzi	GTMP	4/04/2022	No	Yes	
Carvykti	GTMP	25/05/2022	Yes	Yes	
Upstaza	GTMP	18/07/2022	Yes	No	

NAME	Type of ATMP	Authorisation Date	Orphan	PRIME	Comment
Roctavian	GTMP	24/08/2022	Yes	Yes	
Ebvallo	CTMP	16/12/2022	Yes	Yes	
Hemgenix	GTMP	20/02/2023	Yes	Yes	
Casgevy	GTMP	9/02/2024	Yes	Yes	
Beqvez	GTMP	24/07/2024	No	Yes	MA withdrawn May 2025
Vyjuvek	GTMP	23/4/2025	Yes	Yes	
Aucatzyl	GTMP	17/7/2025	Yes	Yes	
Zemcelpro	CTMP	25/8/2025	Yes	Yes	
Waskyra	GTMP	9/01/2026	Yes	No	

More information on authorised products can be found on: www.ema.europa.eu (type in the product name in the search box)

Abbreviations: ATMP: advanced therapy medicinal product; GTMP: gene therapy medicinal product; CTMP: cell therapy medicinal product; TEP: tissue engineered product; MA: Marketing authorisation

