



EUROPEAN MEDICINES AGENCY  
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Human Medicines Division

## CAT quarterly highlights and approved ATMPs

June 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: March – May 2026.

### Advanced therapy medicinal products approvals

During its plenary meeting of March 2026, CAT adopted a positive draft opinion **Adstiladrin** (nadofaragene firadenovec) that is intended for the treatment of adult patients with Bacillus Calmette-Guérin (BCG)-unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumours. Based on the assessment of the CAT, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of the conditional marketing authorisation for the medicinal product Adstiladrin. The European Commission issues the marketing authorisation for Adstiladrin on 28 May 2026.

More information on Adstiladrin can be found in the published [Summary of Opinion](#).

During its plenary meeting of April 2026, CAT adopted a positive draft opinion for **Itvisma** (onasemnogene abeparvovec) that is intended for the treatment of spinal muscular atrophy (SMA) in patients 2 years of age and older. Based on the assessment of the CAT, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of the marketing authorisation for the medicinal product Itvisma.

More information on Itvisma can be found in the published [Summary of Opinion](#).

### 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	51
Positive draft Opinion	20 <sup>i</sup>	6	1	1	4	2	34 <sup>#</sup>
Negative draft opinions	4 <sup>i,ii,iii</sup>	0	0	0	3 <sup>vii</sup>	0	7
Withdrawals	8 <sup>ii,iv</sup>	1 <sup>v</sup>	1 <sup>vi</sup>	0	3 <sup>viii</sup>	0	13
Ongoing MAAs							4

### # Corresponding to 33 ATMPs (see List of authorised ATMPs)

<sup>i</sup> One negative draft opinion and two positive draft opinions for the Glybera

<sup>ii</sup> Negative draft opinion and withdrawal for the Cerepro

<sup>iii</sup> Two negative draft opinions for Heparesc

<sup>iv</sup> Luxceptar, Roctavian, Artobend

<sup>v</sup> [Siteoiganap](#)

<sup>vi</sup> [Lumevog](#)

<sup>vii</sup> [Elevidys](#), [Jelrix](#) (two negative draft opinions)

<sup>viii</sup> [Amtaqvi](#), [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	15	313

Scientific recommendation on advanced therapy classification <sup>1</sup>							
	2009-2021	2022	2023	2024	2025	2026*	Total
Submitted	555	51	43	40	28	20	737
Adopted	544	46	52	39	32	14	727

<sup>1</sup> 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.

Scientific advice procedure for ATMPs							
	2009-2021	2022	2023	2024	2025	2026*	Total
Number of procedures	506	53	57	61	76	29	782

PRIME <sup>2</sup> Eligibility for ATMPs							
	2016-2021	2022	2023	2024	2025	2026*	Total
Discussed	105	10	13	17	21	18	184
Granted	46	4	9	6	6	7	78

\* Period: January – May 2026

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<sup>2</sup> 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	No	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	No	No	
Imlygic	GTMP	16/12/2015	No	No	
Strimvelis	GTMP	26/05/2016	Yes	No	
Zalmoxis	CTMP	18/08/2016	No	No	MA withdrawn Oct. 2019
Spherox	TEP	10/07/2017	No	No	
Alofisel	CTMP	23/03/2018	No	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	No*	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	No	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	
Casgevly	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	
Adstiladrin	GTMP	28/5/2026	No	No	
Itvisma	GTMP	Awaited	Yes	No	Opinion in April 2026

More information on authorised products can be found on: [www.ema.europa.eu](http://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

° Orphan designation withdrawn after withdrawal or expiry of the marketing authorisation

