23 May 2025
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Human Medicines Division

CAT quarterly highlights and approved ATMPs

May 2025

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: February – May 2025.

Advanced therapy medicinal products approvals

During its plenary meeting of February 2025, CAT adopted a positive draft opinion for **Vyjuvek** (beremagene geperpavec) for the treatment of wounds in patients with dystrophic epidermolysis bullosa. 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 Vyjuvek. The European Commission issued the marketing authorisation to Vyjuvek on 23 April 2025.

More information on Vyjuvek can be found in the published EPAR.

During its plenary meeting of May 2025, CAT adopted a positive draft opinion for **Aucatzyl** (obecabtagene autoleucel) for the treatment of adults from 26 year of age with relapsed or refractory B-cell precursor acute lymphoblastic leukaemia. Based on the assessment of the CAT, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a conditional marketing authorisation for the medicinal product Aucatzyl.

More information on Aucatzyl can be found in the published Summary of opinion.

Extension of indication of authorised ATMPs

No extensions of indications during the reporting period.

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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***	**Total**
Submitted MAAs	35	1	4	7	2	49
Positive draft Opinion	20 [i]	6	1	1	2	30[#]
Negative draft opinions	4 [i,ii,iii]	0	0	0	0	4
Withdrawals	8 [ii, iv]	1[v]	1[vi]	0	0	10
Ongoing MAAs						9

 # Corresponding to 29 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] Sitoiganap
[vi] Lumevoq

Variations (Type II) for authorised ATMP						
	2009-2021	**2022**	**2023**	**2024**	**2025***	**Total**
Positive opinion	110	47	49	33	28	267

Scientific recommendation on advanced therapy classification[1]						
	2009-2021	**2022**	**2023**	**2024**	**2025***	**Total**
Submitted	555	51	43	40	16	705
Adopted	544	46	52	39	17	698

Scientific advice procedure for ATMPs						
	2009-2021	**2022**	**2023**	**2024**	**2025***	**Total**
Number of procedures	506	53	57	61	27	704

[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.

PRIME[2] Eligibility for ATMPs						
	2016-2021	**2022**	**2023**	**2024**	**2025***	**Total**
Discussed	105	10	13	17	9	154
Granted	46	4	9	6	2	67

* Period: January – May 2025

[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
Holoclar	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	

NAME	Type of ATMP	Authorisation Date	Orphan	PRIME	Comment
Upstaza	GTMP	18/07/2022	Yes	No	
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	
Vyjuvek	GTMP	23/4/2025	Yes	Yes	
Aucatzyl	GTMP	Pending; Opinion May 2025	Yes	Yes	

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