2 December 2025
EMA/CAT/380337/2025
Human Medicines Division

CAT quarterly highlights and approved ATMPs

December 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: June – November 2025.

Advanced therapy medicinal products approvals

During its plenary meeting of June 2025, CAT adopted a positive draft opinion for **Zemcelpro** (dorocubicel / unexpanded umbilical cord cells) to treat adults with haematological malignancies. Zemcelpro can be used in patients requiring an allogeneic haematopoietic stem cell transplantation following myeloablative conditioning (chemotherapy and/or radiotherapy) for whom no other type of suitable donor cells is available. 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 Zemcelpro. The European Commission issued the marketing authorisation to Zemcelpro on 25 August 2025.

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

During its plenary meeting of November 2025, CAT adopted a positive draft opinion for **Waskyra** (genetically modified autologous CD34+ haematopoietic stem cell enriched population transduced *ex vivo* with a lentiviral vector encoding the human WAS gene) for the intended for the treatment of patients aged 6 months and older with Wiskott-Aldrich Syndrome (WAS). 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 marketing authorisation for the medicinal product Waskyra.

Waskyra was supported through an EMA pilot offering enhanced support to academic and non-profit developers of ATMPs addressing unmet medical needs.

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

Extension of indication of authorised ATMPs

During its plenary meeting of October 2025, CAT adopted an extension of indication for **Breyanzi** to include treatment of adult patients with relapsed or refractory mantle cell lymphoma (FL) after two or more lines of systemic therapy including a Bruton's tyrosine kinase inhibitor. Based on the assessment

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

of the CAT, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending a change to the terms of the marketing authorisation for Breyanzi.

More information can be found in the Summary of opinion.

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	4	32[#]
Negative draft opinions	4 [i,ii,iii]	0	0	0	3[vii]	7
Withdrawals	8 [ii, iv]	1[v]	1[vi]	0	3[viii]	13
Ongoing MAAs						3

 # 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] Sitoiganap
[vi] Lumevoq
[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***	**Total**
Positive opinion	110	47	49	33	55	294

Scientific recommendation on advanced therapy classification[1]						
	2009-2021	**2022**	**2023**	**2024**	**2025***	**Total**
Submitted	555	51	43	40	25	714
Adopted	544	46	52	39	30	711

Scientific advice procedure for ATMPs						
	2009-2021	**2022**	**2023**	**2024**	**2025***	**Total**

[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.

Scientific advice procedure for ATMPs						
Number of procedures	506	53	57	61	62	739

PRIME[2] Eligibility for ATMPs						
	2016-2021	**2022**	**2023**	**2024**	**2025***	**Total**
Discussed	105	10	13	17	19	164
Granted	46	4	9	6	4	69

* Period: January – November 2025

List of authorised ATMPs

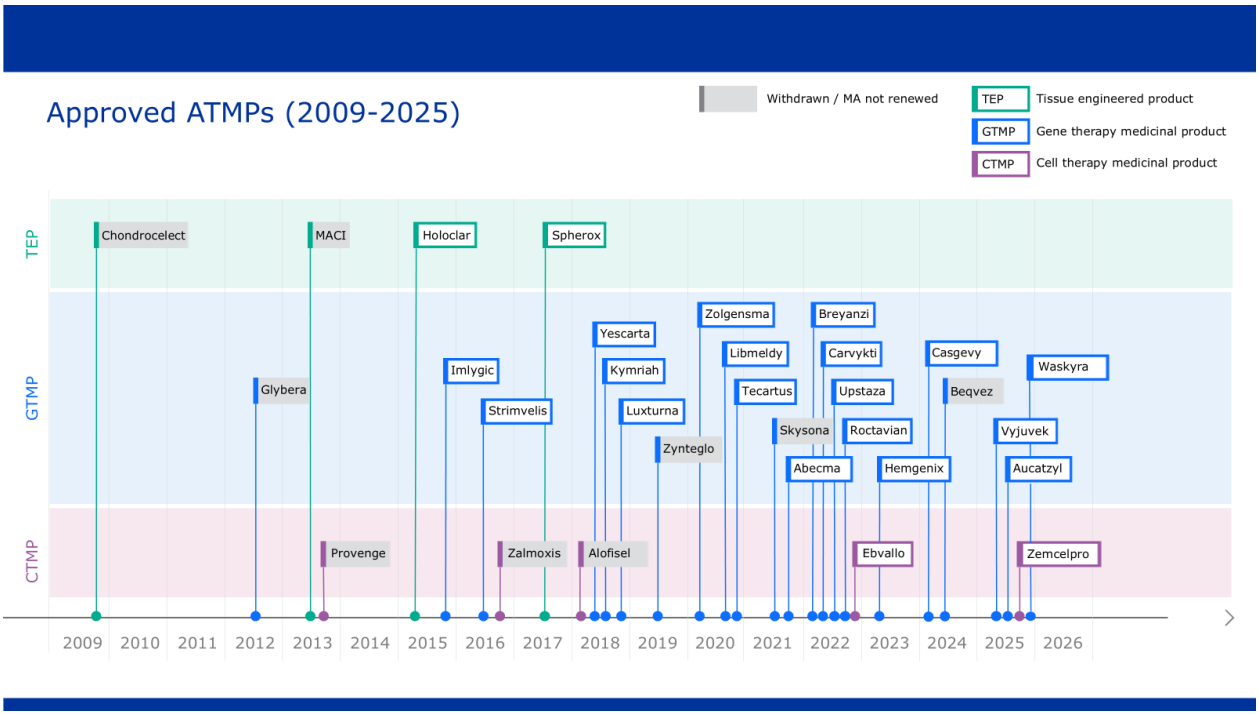
NAME	Type of ATMP	Authorisation Date	Orphan	PRIME	Comment
Chondrocelect	TEP	5/10/2009	No	No	MA withdrawn July 2016
Glybera	GTMP	25/10/2012	Yes	No	MA not renewed (MA ended Oct. 2017)
MACI	TEP, combined ATMP	27/06/2013	No	No	MA not renewed (MA ended June 2018)
Provenge	CTMP	6/09/2013	No	No	MA withdrawn 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	

[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.

NAME	Type of ATMP	Authorisation Date	Orphan	PRIME	Comment
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	
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	Opinion Nov. 2025	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


Approved ATMPs (2009-2025)
Withdrawn / MA not renewed
TEP
Tissue engineered product
GTMP
Gene therapy medicinal product
CTMP
Cell therapy medicinal product
TEP
GTMP
CTMP
Chondrocelect
MACI
Holoclar
Spherox
Glybera
Imlygic
Strimvelis
Yescarta
Kymriah
Luxturna
Zynteglo
Zolgensma
Libmeldy
Tecartus
Skysona
Abecma
Breyanzi
Carvykti
Upstaza
Roctavian
Hemgenix
Ebvallo
Casgevy
Beqvez
Waskyra
Vyjuvek
Aucatzyl
Zemcelpro
Provenge
Zalmoxis
Alofisel
2009
2010
2011
2012
2013
2014
2015
2016
2017
2018
2019
2020
2021
2022
2023
2024
2025
2026