



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

11 October 2023
EMA/CAT/247792/2023
Human Medicines Division

CAT quarterly highlights and approved ATMPs October 2023

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: August – October 2023.

Advanced therapy medicinal products approvals

No approvals of ATMPs in the period covered by this report

Extension of indication of authorised ATMPs

No extensions of indications in the period covered by this report

Overview of product-related activities

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

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



Initial Evaluation of Marketing Authorisation Applications (MAA) for ATMP					
	2009-2020	2021	2022	2023*	Total
Submitted MAAs	32	3	1	2	38
Positive draft Opinion	18 ⁱ	2	6	0	26 [#]
Negative draft opinions	4 ^{i,ii,iii}	0	0	0	4
Withdrawals	8 ^{ii, iv}	0	1 ^v	1 ^{vi}	10
Ongoing MAAs					2

Corresponding to 25 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					
	2009-2020	2021	2022	2023*	Total
Positive opinion	78	32	47	40	197

Scientific recommendation on advanced therapy classification ¹					
	2009-2020	2021	2022	2023*	Total
Submitted	489	66	51	39	645
Adopted	483	61	46	45	635

Scientific advice procedure for ATMPs					
	2009-2020	2021	2022	2023*	Total
Number of procedures	442	64	53	46	605

PRIME ² Eligibility for ATMPs					
	2016-2020	2021	2022	2023 ⁺	Total
Discussed	91	14	10	11	126
Granted	39	7	4	8	58

* Period: January-October 2023 + Period: January-September 2023

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	
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	No	
Ebvallo	CTMP	16/12/2022	Yes	Yes	
Hemgenix	GTMP	20/02/2023	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

