



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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Inspections, Human Medicines Pharmacovigilance and Committees Division

## CAT monthly report of application procedures, guidelines and related documents on advanced therapies

### October 2019 meeting

The Committee for Advanced Therapies (CAT) held its 119<sup>th</sup> meeting on 9 – 11 October 2019.

The CAT Monthly Report includes statistical data on CAT scientific recommendations on Advanced Therapy Medicinal Product (ATMP) classification, certifications, initial evaluations, CAT contributions to Scientific Advice and Paediatric Investigation Plans, as well as variations, line extensions, renewals.

### **Scientific recommendation on advanced therapy product classification**

Further to consultation with the European Commission, the CAT finalised 7 scientific recommendations on the classification of advanced therapy medicinal products.

The following products were classified as a tissue engineered products:

- Adipose tissue derived mesenchymal stem cells, intended for the treatment of diabetic foot ulcers;
- Adipose tissue derived mesenchymal stem / stromal cells, intended for the treatment of bone and cartilage defects including osteoarthritis;
- Combination of platelet-rich plasma and stromal vascular fraction, intended for wound healing as additional therapy to fistula surgery in patients with complex and therapy refractory perianal fistula.

The following products were classified as gene therapy medicinal products:

- Human allogenic melanoma cells Mich1H6 and Mich2H6, intended for the treatment of advanced melanoma;
- Recombinant oncolytic adenovirus, intended for the treatment of treatment-naïve patients with localised prostate cancer;
- In vitro transcribed mRNA encoding human insulin-like growth factor 1, intended for the treatment of skeletal muscle injury.

The following product was classified as not an advanced therapy medicinal product:

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- CD1c(BDCA-1)+/CD141(BDCA-3)+ myeloid dendritic cells, intended for the treatment of patients with advanced, pre-treated solid tumours with injectable metastases.

## Organisation matters

- CAT discussed the agenda of the upcoming joint CAT-COMP-PDCO Strategic Review and Learning meeting that will be held in Helsinki (Finland) on 21 – 22 November 2019 under the auspices of the Finnish presidency of the European Union.
- CAT discussed the draft Questions and Answers on comparability for ATMPs, which is scheduled for adoption by the end of 2019.

## 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	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	Total
Submitted MAAs	3	1	2	3	2	2	1	1	4	3	0	22
Positive draft Opinion	1	0	1 <sup>ii</sup>	1 <sup>ii</sup>	2	1	1	2	2	3	1	15*
Negative draft opinions	1 <sup>i</sup>	0	1 <sup>ii</sup>	0	0	0	2 <sup>iii</sup>	0	0	0	0	4
Withdrawals	1	1 <sup>i</sup>	0	0	2	0	0	0	0	1	0	5
Ongoing MAAs												2

\* Corresponding to 14 ATMPs

<sup>i</sup> Same product (Cerepro)

<sup>ii</sup> Same product (Glybera)

<sup>iii</sup> Same product (Heparesc)

Variations (Type II) for authorised ATMP												
	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	Total
Positive opinion	0	0	1	1	9	4	3	6	3	8	16	51

Scientific recommendation on advanced therapy classification												
	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	Total
Submitted	22	19	12	22	20	28	61	60	46	55	51	396
Adopted	12	27	12	16	23	29	31	87	49	43	50	379

### Certification of quality and non-clinical data for small and medium-sized enterprises developing ATMPs

	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	Total
Submitted	1	0	0	1	3	1	1	2	2	1	1	13
Adopted	0	1	0	1	1	2	1	1	3	1	1	12

### Scientific advice procedure for ATMPs

	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	Total
Number of procedures	17	19	21	19	23	33	39	46	55	53	48	373

### Paediatric Investigation Plans (PIP) for ATMPs

	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	Total
Number of procedures	3	4	4	8	5	4	3	5	3	3	2	44

### Prime Eligibility for ATMPs

	2016	2017	2018	2019						Total
Discussed	22	16	14	13						65
Granted	8	6	6	5						25

## Upcoming meetings following the September 2019 CAT meeting

- The 120<sup>th</sup> meeting of the CAT will be held on 6 – 8 November 2019.

#### NOTE:

This Monthly Report, the Agenda of this meeting, the Minutes of the previous CAT meeting and other documents can be found on the internet at the following location: [European Medicines Agency - Committee meeting reports - CAT: Committee meeting reports](#)

Specific information related to ATMPs and the activities of the CAT (role, responsibilities and composition) can be found at: [European Medicines Agency - CAT - Committee for Advanced Therapies \(CAT\)](#)

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