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Human Medicines Division

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

January 2021 meeting

The Committee for Advanced Therapies (CAT) held its 133rd meeting on 20 – 22 January 2021.

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[1]

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

The following products were classified as gene therapy medicinal products:

- Autologous anti-CD19 chimeric antigen receptor T cells, intended for the treatment of B- cell malignancies;
- Messenger ribonucleic acid (mRNA) encoding the human glucose debranching enzyme, intended for the treatment of glycogen storage disease III;
- Messenger ribonucleic acid (mRNA) encoding human interleukin 2 (IL-2), linked to interfering RNA targeting vascular endothelial growth factor A, intended for the treatment of solid tumours.

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

- Autologous omental adipose tissue and biodegradable fibrin glue, intended for the treatment of renal traumatic/disease conditions.

[1] 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.

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Organisational matters

- CAT adopted its work plan for 2021.
- CAT received detailed feedback on the development of the Questions and Answers document on principles of GMP for the manufacturing of starting materials of biological origin for the manufacturing of genetically modified cells.

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								
	2009-2015	**2016**	**2017**	**2018**	**2019**	**2020**	**2021**	**Total**
Submitted MAAs	14	1	4	3	2	8	0	31
Positive draft Opinion	7 [i]	2	2	3	1	3	0	18*
Negative draft opinions	4 [i,ii,iii]	0	0	0	0	0	0	4
Withdrawals	4 [ii]	0	0	1	1[iv]	2[v]	0	8
Ongoing MAAs								6

*** Corresponding to 17 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
[v] Roctavian; Artobend

Variations (Type II) for authorised ATMP								
	2009-2015	**2016**	**2017**	**2018**	**2019**	**2020**	**2021**	**Total**
Positive opinion	18	6	3	8	16	27	4	82

Scientific recommendation on advanced therapy classification								
	2009-2015	**2016**	**2017**	**2018**	**2019**	**2020**	**2021**	**Total**
Submitted	184	60	46	55	70	74	15	504
Adopted	150	87	49	43	67	87	4	487

Certification of quality and non-clinical data for small and medium-sized enterprises developing ATMPs								
	2009-2015	**2016**	**2017**	**2018**	**2019**	**2020**	**2021**	**Total**
Submitted	7	2	2	1	1	0	0	14
Adopted	6	1	3	1	1	2	0	14

Scientific advice procedure for ATMPs								
	2009-2015	**2016**	**2017**	**2018**	**2019**	**2020**	**2021**	**Total**
Number of procedures	171	46	55	53	56	61	0	442

Paediatric Investigation Plans (PIP) for ATMPs								
	2009-2015	**2016**	**2017**	**2018**	**2019**	**2020**	**2021**	**Total**
Number of procedures	31	5	3	3	2	1	0	45

Prime Eligibility for ATMPs							
	2016	**2017**	**2018**	**2019**	**2020**	**2021**	**Total**
Discussed	22	16	14	16	23	3	94
Granted	8	6	6	10	8	1	39

Upcoming meetings following the January 2021 CAT meeting

- The 134th meeting of the CAT will be held on 17 – 19 February 2021.

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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