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Inspections, Human Medicines Pharmacovigilance and Committees Division

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

November 2016 meeting

The Committee for Advanced Therapies (CAT) held its 87th CAT meeting on 3 – 4 November 2016.

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 gene therapy medicinal products:

- Anti-BCMA (B-cell maturation antigen) chimeric antigen receptor T-cells, intended for the treatment of multiple myeloma and B cell lymphoma.
- Modified vaccinia virus Ankara encoding human mucin-1 and interleukin-2, intended for the treatment of advanced non-squamous non-small cell lung cancer.
- Rilimogene galvacirepved and rilimogene glafolivec, intended for the treatment of metastatic, castrate-resistant prostate cancer.

The following products were classified as tissue engineered products:

- Autologous bone marrow-derived non-haematopoetic stem cells, intended for the treatment of multiple sclerosis.
- Wharton's jelly derived mesenchymal stem cells, intended for the treatment of acute myocardial infarction, chronic ishemic heart failure and no-option critical limb ischemia.
- Autologous adipose derived mesenchymal stem cells, intended for cardiac repair after myocardial infarction.
- Autologous skin cell suspension, intended for the treatment of burns, donor sites and other wounds.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

CAT workshop on cell-based cancer immunotherapies

The CAT workshop on cell-based cancer immunotherapies that will take place at EMA on 15 – 16 November 2016 can be followed via live broadcast. No registration is required for the broadcast. To watch the broadcast, click on the 'Multimedia' tab on the event webpage.

Organisational matters

- CAT discussed the outcome of the 'CAT Strategic Review & Learning meeting' that took place in Dublin, Ireland on 24 – 25 October 2016 under the auspices of the Slovak Presidency of the Council of the European Union.
- CAT initiated the discussion on their Work Plan for 2017.
- CAT discussed the progress of the development of the Guideline on requirements for investigational ATMPs and the Question and Answer document on minimally manipulated ATMPs.

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**	**Total**
Submitted MAAs	3	1	2	3	2	2	1	1	15
Positive draft Opinion	1	0	1[ii]	1[ii]	2	1	1	2	9 Corresponding to 8 ATMPs
Negative draft opinions	1[i]	0	1[ii]	0	0	0	2[*]	0	4
Withdrawals	1	1[i]	0	0	2	0	0	0	4
Ongoing MAAs									2

[i] Same product (Cerepro)
[ii] Same product (Glybera)
[*] CAT adopted two negative draft opinions for the same product (Heparesc)

Variations (Type II) for authorised ATMP									
	2009	**2010**	**2011**	**2012**	**2013**	**2014**	**2015**	**2016**	**Total**
Positive draft Opinion	0	0	1	1	9	4	3	6	24

Scientific recommendation on advanced therapy classification									
	2009	2010	2011	2012	2013	2014	2015	2016	Total
Submitted	22	19	12	22	20	28	61	55	239
Adopted	12	27	12	16	23	29	31	86	236

Certification of quality and non-clinical data for small and medium-sized enterprises developing ATMPs									
	2009	2010	2011	2012	2013	2014	2015	2016	Total
Submitted	1	0	0	1	3	1	1	2	9
Adopted	0	1	0	1	1	2	1	1	7

Scientific advice procedure for ATMPs									
	2009	2010	2011	2012	2013	2014	2015	2016	Total
Discussed*	25	30	36	31	36	48	63	60	329
Number of procedures	17	19	21	19	23	33	39	44	215

* Scientific advices for ATMPs are discussed by the CAT once or twice during the procedure

Paediatric Investigation Plans (PIP) for ATMPs									
	2009	2010	2011	2012	2013	2014	2015	2016	Total
Discussed*	4	7	6	9	7	7	3	4	47

* PIPs for ATMPs are discussed by the CAT once or twice during the procedure

Prime Eligibility for ATMPs									
	2016								Total
Discussed	21								21
Granted	7								7

Upcoming meetings following the November 2016 CAT meeting

The CAT Workshop on scientific and regulatory challenges of genetically modified cell-based cancer immunotherapy products will he held on 15 – 16 November 2016.

The 87th meeting of the CAT will be held on 8 – 9 December 2016.

NOTE:

1. 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

2. 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)

Nikolaus Križ
Head of Committees Secretariat Service
Tel.: (+44-20) 3660 7016
Fax: (+44-20) 3660 5520
AdvancedTherapies@ema.europa.eu