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Procedure Management and Business Support Division

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

July 2014 meeting

The Committee for Advanced Therapies (CAT) held its 62nd CAT meeting on 17-18 July 2014.

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 three scientific recommendations on the following classification of advanced therapy medicinal products (ATMP).

The following products were classified as gene therapy medicinal products:

- Plasmid encoding a mutation-inactivated E7-E6 fusion protein from Human Papillomavirus 16 linked to the human chemokine hMIP-1α via a dimerization module derived from human IgG3, intended for the prevention and treatment of HPV16 induced pre-malignancies and malignancies.
- Plasmid encoding an inactive human telomerase reverse transcriptase protein fused to ubiquitin, intended for the treatment of various malignancies and for the prevention of tumour relapse.
- Oncolytic virus derived from a genetically modified type 1 herpes simplex virus (HSV-1), intended for the treatment of advanced pancreatic cancer and / or unresectable hepatocellular carcinoma.

Further information on the ATMP classification procedure can be found at:

European Medicines Agency - ATMP classification

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7523 7051
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

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**	**Total**
Submitted MAAs	3	1	2	3	2	1	12
Positive draft Opinion	1	0	1[i]	1[i]	2	0	5 Corresponding to 4 ATMPs
Withdrawals	1	1	0	0	2	0	4
Ongoing MAAs							4

[i] Same product (Glybera)

Variations (Type II) for authorised ATMP							
	2009	**2010**	**2011**	**2012**	**2013**	**2014**	**Total**
Positive draft Opinion	0	0	1	1	9	3	14

Scientific recommendation on advanced therapy classification							
	2009	**2010**	**2011**	**2012**	**2013**	**2014**	**Total**
Submitted	22	19	12	17	20	13	108
Adopted	12	27	12	14	23	13	103

Certification of quality and non-clinical data for small and medium-sized enterprises developing ATMPs							
	2009	**2010**	**2011**	**2012**	**2013**	**2014**	**Total**
Submitted	1	0	0	1	3	0	5
Adopted	0	1	0	1	1	2	5

Scientific advice procedures on ATMPs							
	2009	**2010**	**2011**	**2012**	**2013**	**2014**	**Total**
Discussed*	25	30	36	31	36	27	185

* Most scientific advices for ATMPs are discussed by the CAT at 2 time points during the SA procedure

Paediatric Investigation Plans (PIP) for ATMPs							
	2009	**2010**	**2011**	**2012**	**2013**	**2014**	**Total**
Discussed*	4	7	6	9	7	3	36

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

Upcoming meetings following the July 2014 CAT meeting

The 63rd meeting of the CAT will be held at the Agency on 18-19 September 2014.

On 11 September 2014, CAT is organising a workshop on ATMPs in collaboration with the German Society for Transfusion medicines and Immunohematology (DGTI) and the German Stem Cell Network (GSCN). For more information and registration, see here.

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)

Tony Humphreys
Head of Scientific Committee Support
Tel.: (+44-20) 3660 8583
Fax: (+44-20) 3660 5520
AdvancedTherapies@ema.europa.eu