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Procedure Management and Business Support Division

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

December 2014 meeting

The Committee for Advanced Therapies (CAT) held its 66th CAT meeting on 11 – 12 December 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.

CAT adopts the draft opinion for the first stem-cell derived ATMP

At its December meeting, CAT adopted a draft opinion recommending the granting a marketing authorisation for the advanced therapy medicinal product Holoclar. The active substance of Holoclar is *ex-vivo* expanded autologous human corneal epithelial cells containing stem cells. It is intended to treat moderate to severe limbal stem cell deficiency (LSCD) due to physical or chemical burns to the eye(s) in adults, a rare condition that can result in blindness. More information on Holoclar can be found on the EMA website.

CAT meeting with Interested Parties

CAT organised a meeting with its Interested Parties on Thursday 11 December 2014. Fourteen interested parties to the CAT attended this meeting. The following items were discussed: the Reflection Paper on ATMP Classification (currently under revision); the application of the Risk Based Approach during ATMP development; CAT workplan 2015-2016; interactions with CAT interested parties; support to ATMP developers. A full report of the interested parties meeting will be published on the EMA website.

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 tissue engineered products:

- Allogeneic cord blood cells, *ex vivo* modulated with 16,16 dimethyl prostaglandin E2, intended for haematopoietic stem cell transplantation;

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

- Autologous differentiated adipocytes derived from the subcutaneous adipose tissue intended for the treatment of primary perianal fistula.

The following product was classified as not being an ATMP:

- *In vitro* derived platelets intended for the treatment of thrombocytopenia.

CAT received three new ATMP classification requests for which a scientific recommendation will be delivered within 60 days (active review time) after the receipt of the final request.

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

European Medicines Agency - ATMP classification

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	2	13
Positive draft Opinion	1	0	1[i]	1[i]	2	1	6 Corresponding to 5 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	4	15

Scientific recommendation on advanced therapy classification							
	2009	**2010**	**2011**	**2012**	**2013**	**2014**	**Total**
Submitted	22	19	12	17	20	28	123
Adopted	12	27	12	14	23	29	119

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	1	6
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	48	206

* 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	7	40

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

Upcoming meetings following the December 2014 CAT meeting

The 67th meeting of the CAT will be held on 15-16 January 2015.

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