23 October 2015
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Procedure Management and Business Support Division

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

October 2015 meeting

The Committee for Advanced Therapies (CAT) held its 75th CAT meeting on 15 – 16 October 2015.

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 recommends the granting of the marketing authorisation for Imlygic

Imlygic (talimogene laherparepvec) is a gene therapy medical product, based on a genetically modified herpes simplex virus producing the protein GM-CSF. Imlygic is indicated for the treatment of adults with melanoma that cannot be removed by surgery and that has spread either to the surrounding area or to other areas of the body (regionally or distantly metastatic) without affecting the bones, brain, lung or other internal organs. Imlygic is recommended to be injected directly into the melanoma lesions.

Following an in-depth review of the dossier submitted by the applicant, Amgen Europe B.V., CAT concluded during its October meeting that a positive benefit risk profile has been demonstrated for Imlygic. CAT adopted the positive draft opinion recommending the granting of the marketing authorisation for Imlygic. The CHMP adopted the positive opinion for Imlygic during its October 2015 meeting

Further information can be found in the press release.

CAT refuses the granting of the marketing authorisation for Heparesc

In June 2015, CAT and CHMP adopted a negative opinion, recommending the refusal of the marketing authorisation for Heparesc, a somatic cell therapy medicinal product containing living human liver cells, intended for the treatment of urea cycle disorders. The applicant, Cytonet GmbH & Ci KG, requested a re-examination of the opinion. After considering the grounds for this request, CAT re-examined the initial opinion and confirmed its original negative draft opinion. The CHMP adopted meeting the negative opinion for Heparesc during its October 2015.

Further information can be found in the Questions and Answers document on this negative opinion.

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Scientific recommendation on advanced therapy product classification

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

The following product was classified as gene therapy medicinal product:

- Live-attenuated, double-deleted *Listeria monocytogenes* expressing human mesothelin, intended for the treatment of malignant pleural mesothelioma.

The following product was classified as a gene therapy medicinal product, combined ATMP:

- Encapsulated allogeneic cells secreting GM-CSF and irradiated autologous tumour cells, intended for the treatment of solid tumours.

CAT received 4 new ATMP classification requests for which a scientific recommendation will be delivered within 60 days (active review time).

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

European Medicines Agency - ATMP classification

Organisational, regulatory and methodological matters

- CAT adopted the scientific guideline on post-authorisation efficacy studies for release for public consultation. The guideline will be published after adoption by the other concerned Committees.
- Guideline on quality, non-clinical and clinical aspects of gene therapy medicinal products: CAT appointed drafting group members to review the comments received during the external consultation and finalise the revision of this guideline.
- CAT discussed the outcome of an analysis of the European Clinical trial database for trials with ATMPs. The completed analysis and a discussion of the trends in trials with ATMPs will be published next year.
- CAT agreed the topics for their Work Plan for 2016. The CAT Work Plan will be published in the beginning of 2016.

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**	**Total**
Submitted MAAs	3	1	2	3	2	2	1	14
Positive draft Opinion	1	0	1[ii]	1[ii]	2	1	1	7 Corresponding to 6 ATMPs
Negative draft opinions	1[i]	0	1[ii]	0	0	0	2[iii]	4
Withdrawals	1	1[i]	0	0	2	0	0	4
Ongoing MAAs								3

[i] Same product (Cerepro)
[ii] Same product (Glybera)
[iii] Same product (Heparesc)

Variations (Type II) for authorised ATMP								
	2009	**2010**	**2011**	**2012**	**2013**	**2014**	**2015**	**Total**
Positive draft Opinion	0	0	1	1	9	4	3	18

Scientific recommendation on advanced therapy classification								
	2009	**2010**	**2011**	**2012**	**2013**	**2014**	**2015**	**Total**
Submitted	22	19	12	22	20	28	28	151
Adopted	12	27	12	16	23	29	19	138

Certification of quality and non-clinical data for small and medium-sized enterprises developing ATMPs								
	2009	**2010**	**2011**	**2012**	**2013**	**2014**	**2015**	**Total**
Submitted	1	0	0	1	3	1	1	7
Adopted	0	1	0	1	1	2	1	6

Scientific advice procedures on ATMPs								
	2009	**2010**	**2011**	**2012**	**2013**	**2014**	**2015**	**Total**
Discussed*	25	30	36	31	36	48	53	259
Number of procedures	17	19	21	19	23	33	36	168

* 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**	**2015**	**Total**
Discussed*	4	7	6	9	7	7	2	42

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

Upcoming meetings following the October 2015 CAT meeting

The 76th meeting of the CAT will be held on 12 – 13 November 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)

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