



08 September 2017
EMA/CAT/652287/2017
Procedure Management and Committees Support Division

Committee for Advanced Therapies (CAT)

Minutes of the Written Procedure – August 2017

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1. Written Procedure Related Documents

- 1.1. **Agenda (EMA/CAT/489514/2017) for the CAT Written Procedure August 2017**

2. Evaluation of ATMPs

2.1. Opinions

No items

2.2. Oral explanations

No items

2.3. Day 180 List of outstanding issues

No items

2.4. Day 120 Lists of questions

No items

2.5. Day 80 assessment reports

No items

2.6. Ongoing initial full application

- 2.6.1. Expanded human allogeneic mesenchymal adult stem cells extracted from adipose tissue – Orphan - EMEA/H/C/0004258

TiGenix S.A.U.; treatment of complex perianal fistula(s)

Scope: applicant's request to extend the clock-stop to respond to the D180 LoOI

Action: timetable for adoption

2.7. New applications

No items

2.8. Withdrawal of initial marketing authorisation application

No items

2.9. Re-examination of initial application procedures under Article 9(2) of Regulation no. 726/2004

No items

2.10. GMP and GCP inspections requests

2.11. Type II variations

No items

2.12. Other post-authorisation activities

No items

3. Certification of ATMPs

3.1. Opinions

No items

3.2. Day 60 evaluation reports

No items

3.3. Ongoing initial application

No items

3.4. New applications

4. Scientific Recommendation on Classification of ATMPs

4.1. New requests – appointment of CAT Co-ordinators

4.1.1. Allogeneic human glial-restricted precursors - H0004887/0001

Intended for the treatment of amyotrophic lateral sclerosis

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for information

4.1.2. Allogeneic human glial-restricted precursors - H0004898/0001

Intended for the treatment of spinal cord injuries

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

This is the same product as in 4.1.1 (second indication). CAT appointed the same CAT member as CAT Coordinator

4.1.3. Messenger RNA encoding immunostimulatory proteins caTLR4, CD40L and CD70 and tumour associated antigens (TAA) tyrosinase, gp100, MAGE A3, MAGE C2 and PRAME - H0004899/0001

Intended for the treatment of melanoma

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

- 4.1.4. Nominations were received. CAT member was appointed as CAT coordinator for this procedure Nuclease-resistant, synthetic double-stranded, siRNA designed to temporarily inhibit the expression of the collagen-specific chaperone, HSP47 - H0004900/0001
-

Intended for the treatment of hepatic fibrosis

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

- 4.1.5. Nominations were received. The CAT member was appointed as CAT coordinator for this procedure Cultured viable chondrocytes in a 3D Hydrogel - H0004901/0001
-

Intended for the treatment of articular cartilage defect of the knee

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

- 4.2. **Nominations were received The CAT member was appointed as CAT coordinator for this procedure Day 30 Co-ordinators' first reports**

No items

- 4.3. **Day 60 Co-ordinators' revised reports following List of Questions**

No items

- 4.4. **Finalisation of procedures**

- 4.4.1. **Autologous adipose tissue-derived mesenchymal stem cells - H0004813/0001**
-

Intended for the treatment of chronic wound

Scope: no comments raised by the European Commission. Final ATMP scientific recommendation

Action: for information

- 4.5. **Follow-ups and guidance**

No items

5. Scientific Advice

- 5.1. **New requests – appointment of CAT Co-ordinators**

- 5.2. **CAT Rapporteurs' reports**

No items

5.3. List of issues

No items

5.4. Finalisation of Scientific Advice procedures

No items

5.5. Follow-up of Scientific Advice procedures

No items

6. Pre-Authorisation Activities

6.1. Paediatric investigation plans

No items

6.2. ITF briefing meetings in the field of ATMPs

6.3. Priority Medicines (PRIME) – Eligibility requests

6.3.1. Month 0 - Start of the procedure

There are no procedures starting in August. New eligibility requests will appear in the September agenda.

6.3.2. Month 1 – Discussion of eligibility

6.3.3. Month 2 – Recommendation for eligibility

No items

7. Organisational, regulatory and methodological matters

7.1. Mandate and organisation of the CAT

No items

7.2. Coordination with EMA Scientific Committees

No items

7.3. Coordination with EMA Working Parties/Working Groups/Drafting Groups

No items

7.4. Co-operation within the EU regulatory network

No items

7.5. Co-operation with international regulators

No items

7.6. CAT Work Plan

No items

7.7. Planning and reporting

No items

7.8. Others

No items

8. Any other business

No items

Date of next CAT meeting:
Wednesday 6th to Friday 8th September 2017