



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

18 May 2016  
EMA/CAT/315321/2016  
Procedure Management and Committees Support Division

## Committee for Advanced Therapies (CAT)

### Agenda for the meeting on 18-20 May 2016

Chair: Paula Salmikangas - Vice-chair: Martina Schübler-Lenz

18 May 2016, 14:00 – 18:00, room 03-E  
19 May 2016, 09:00 – 18:00, room 03-E  
20 May 2016, 09:00 – 12:00, room 03-E

#### Health and safety information

In accordance with the Agency's health and safety policy, delegates are to be briefed on health, safety and emergency information and procedures prior to the start of the meeting.

#### Disclaimers

Some of the information contained in this agenda is considered commercially confidential or sensitive and therefore not disclosed. With regard to intended therapeutic indications or procedure scopes listed against products, it must be noted that these may not reflect the full wording proposed by applicants and may also vary during the course of the review. Additional details on some of these procedures will be published in the CAT meeting reports once the procedures are finalised.

Of note, this agenda is a working document primarily designed for CAT members and the work the Committee undertakes.

#### Note on access to documents

Some documents mentioned in the agenda cannot be released at present following a request for access to documents within the framework of Regulation (EC) No 1049/2001 as they are subject to on-going procedures for which a final decision has not yet been adopted. They will become public when adopted or considered public according to the principles stated in the Agency policy on access to documents (EMA/127362/2006).



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## 1. Introduction

### 1.1. Welcome and declarations of interest of members, alternates and experts

Pre-meeting list of participants and restrictions in relation to declarations of interests applicable to the items of the agenda for the CAT plenary session to be held on 18 – 20 May 2016. See May 2016 CAT minutes (to be published post-June 2016 CAT meeting).

### 1.2. Adoption of agenda

CAT agenda for 18 - 20 May 2016

### 1.3. Adoption of the minutes

CAT minutes of 20 - 21 April 2016

### 1.4. Technical information

## 2. Evaluation of ATMPs

### 2.1. Opinions

No items

### 2.2. Oral explanations

#### 2.2.1. Characterised viable haploidentical Herpes Simplex virus thymidine kinase (HSV-Tk) and Human Low Affinity Nerve Growth Factor Receptor ( $\Delta$ LNGFR) transfected donor lymphocytes; *Orphan*; EMA/H/C/002801

MolMed SpA; treatment of adjunctive treatment in haploidentical haematopoietic stem cell transplantation of adult patients with high-risk haematological malignancies

Scope: Oral explanation

**Action:** Oral explanation to be held on 18.05.2016 at 15:00hrs

Documents:

- Updated Rapporteurs report
- PRAC AR on the RMP on the responses to the 3<sup>rd</sup> LoOIs
- BWP report

3<sup>rd</sup> List of Outstanding Issues adopted on 23.03.16. Eight-month clock-stop agreed on 17.04.15. 2<sup>nd</sup> List of Outstanding Issues adopted on 22.01.16. 1<sup>st</sup> List of Outstanding Issues adopted on 20.03.15. List of Questions adopted on 18.07.14.

### 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

No items

## 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

No items

## 2.11. Type II variations

### 2.11.1. ChondroCelect - Characterised viable autologous cartilage cells expanded *ex vivo* expressing specific marker proteins; EMEA/H/C/000878/II/0018/G

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MAH: TiGenix NV

Rapporteur: Egbert Flory; Co-rapporteur: Tiina Palomäki; CHMP Coordinator: Jan Müller-Berghaus

Scope: submission of a revised RMP version 10 in order to add information resulting from the assessment of MEA16 and MEA18 in relation to the confirmatory randomized controlled trial in small lesions. Two potential risks 'transmission of infective agents' and 'allergic/hypersensitivity reaction' (from the recommendation of PSUSA/273/201504) are also added together with updated information in the RMP.

**Action:** for silent adoption

Document:  
Opinion

## 2.12. Other post-authorisation activities

No items

### 3. Certification of ATMPs

Disclosure of information related to this section cannot be released at the present time as it is deemed to contain commercially confidential information.

#### 3.1. Opinions

No items

#### 3.2. Day 60 evaluation reports

No items

#### 3.3. Ongoing initial application

No items

#### 3.4. New applications

No items

### 4. Scientific Recommendation on Classification of ATMPs

#### 4.1. New requests – appointment of CAT Co-ordinators

##### 4.1.1. Live attenuated *Listeria monocytogenes* transfected with plasmids encoding HPV-16E7 protein fused to a truncated fragment of the *Lm* protein listeriolysin O

---

Intended for the treatment of cervical cancer

Scope: appointment of CAT Co-ordinator and adoption of timetable

**Action:** for nomination of CAT Coordinator

Document:  
Request received

##### 4.1.2. Heterologous human adult liver-derived progenitor cells (HHALPC)

---

Intended for the treatment of liver diseases

Scope: appointment of CAT Co-ordinator and adoption of timetable

**Action:** for nomination of CAT Coordinator

Document:  
Request received

Note: In May 2011, CAT classified the same product for the indication 'treatment of inborn errors of liver metabolism' as a somatic cell therapy product

#### 4.1.3. Autologous expanded human fibroblasts

---

Intended for the treatment of scar of different aetiology as post- traumatic, post-surgical or outcomes of acne scars

Scope: appointment of CAT Co-ordinator and adoption of timetable

**Action:** for nomination of CAT Coordinator

Document:  
Request received

#### 4.1.4. Autologous concentrated bone marrow

---

Intended for critical limb ischemia without surgical option

Scope: appointment of CAT Co-ordinator and adoption of timetable

**Action:** for nomination of CAT Coordinator

Document:  
Request received

### 4.2. Day 30 Co-ordinators' first reports

#### 4.2.1. Hepatitis B virus DNA vaccine delivered via electroporation

---

Intended for the treatment of chronic hepatitis B virus infection

**Action:** for adoption

Document:  
ATMP classification report

#### 4.2.2. Adeno-associated viral vector containing the ChrimsonR-td tomato gene

---

Intended for the treatment of retinitis pigmentosa

**Action:** for adoption

Document:  
ATMP classification report

#### 4.2.3. Autologous regulatory T lymphocytes CD3<sup>+</sup>CD4<sup>+</sup>CD25<sup>+</sup>CD127<sup>-</sup>FoxP3<sup>+</sup>

---

Intended for the treatment of, and prevention of progression of, recently diagnosed paediatric type I diabetes mellitus

**Action:** for adoption

Document:  
ATMP classification report

#### 4.2.4. Allogeneic Epstein-Barr virus cytotoxic T lymphocytes

---

Intended for the treatment of Epstein-Barr virus-associated post-transplant lymphoproliferative disorder

**Action:** for adoption



Document:  
ATMP classification report

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

#### 4.3.1. Bone marrow derived mesenchymal stem cells

---

Intended for the treatment of children's encephalopathy, children's epilepsy, children's spinal cord injury

**Action:** for adoption

Document:  
Revised ATMP classification report  
Applicant's responses to LoQ

### 4.4. Finalisation of procedures

#### 4.4.1. Allogeneic bone marrow derived mesenchymal cells expanded *ex vivo* in synthetic media

---

Intended for the treatment of acute graft-versus-host disease grades III and IV resistant to first line treatment

**Action:** for adoption

Document:  
Revised ATMP classification report

Comments received from the European Commission

#### 4.4.2. Concentrate of autologous bone marrow-derived mononuclear cells (BM-MNC)

---

Intended for the improvement of heart function (left ventricular ejection fraction) and quality of life in patients with ischaemic post-acute myocardial infarction and in chronic heart disease

**Action:** for adoption

Document:  
Revised ATMP classification report

Comments received from the European Commission

#### 4.4.3. Live-attenuated, double-deleted *Listeria monocytogenes* (*Lm*) expressing human mesothelin

---

Intended for the treatment of non-small cell lung cancer

**Action:** for adoption

Document:  
Revised ATMP classification report

Comments received from the European Commission

#### 4.4.4. Live-attenuated, double-deleted *Listeria monocytogenes* (*Lm*) expressing prostate antigens

---

Intended for the treatment of prostate cancer

**Action:** for adoption

Document:

Revised ATMP classification report

Comments received from the European Commission

#### 4.4.5. Autologous cultured fibroblasts

---

Intended for the indications of:

-Facial skin regeneration;

-Reducing facial wrinkles;

-Treatment of deep lines in the skin;

-Tissue loss and to heal chronic non-closing injuries;

-Treatment of acne scars

**Action:** for adoption

Document:

Revised ATMP classification report

Comments received from the European Commission

#### 4.4.6. Extracellular matrix from adipose tissue

---

Intended for the treatment of non-healing wounds

**Action:** for adoption

Document:

Revised ATMP classification report

Comments from the European Commission

#### 4.4.7. Adipose derived MSC

---

Intended for the treatment of non-healing wounds

**Action:** for adoption

Document:

Revised ATMP classification report

Comments from the European Commission

#### 4.4.8. Autologous cultured chondrocytes

---

Intended for the treatment of filling of cartilage loss in knee-joint

**Action:** for adoption

Document:

Revised ATMP classification report

Comments received from the European Commission

#### 4.4.9. Autologous cultured fibroblasts

---

Intended for the treatment of filling of skin connective tissue loss

**Action:** for adoption

Document:

Revised ATMP classification report

Comments received from the European Commission

#### 4.4.10. Autologous cultured keratinocytes

---

Intended for the treatment of non-healing wounds, burns, trophic ulcers

**Action:** for adoption

Document:

Revised ATMP classification report

Comments from the European Commission

#### 4.4.11. Autologous cultured myoblasts

---

Intended for the treatment of faecal and urinary incontinence and of skeletal muscle injury

**Action:** for adoption

Document:

Revised ATMP classification report

Comments received from the European Commission

#### 4.4.12. Autologous cultured melanocytes

---

Intended for the treatment of vitiligo

**Action:** for adoption

Document:

Revised ATMP classification report

Comments received from the European Commission

### 4.5. Follow-ups and guidance

#### 4.5.1. Update to the legal disclaimer for ATMP classification reports

---

**Action:** for information

## 5. Scientific Advice

Disclosure of information related to this section cannot be released at the present time as it is deemed to contain commercially confidential information.

- 5.1. **New requests – appointment of CAT Co-ordinators**
- 5.2. **CAT Rapporteurs' reports**
- 5.3. **Lists of issues**
- 5.4. **Finalisation of Scientific Advice procedures**
- 5.5. **Follow-up of Scientific Advice procedures**

No items

## 6. Pre-Authorisation Activities

Disclosure of information related to this section cannot be released at the present time as it is deemed to contain commercially confidential information.

- 6.1. **Paediatric investigation plans (PIP)**
  - 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**
  - 6.3.2. **Month 1 – Adoption of eligibility**

## 7. Organisational, regulatory and methodological matters

- 7.1. **Mandate and organisation of the CAT**
  - 7.1.1. **Strategic Review & Learning meeting**

CAT-PDCO-CTFG joint Strategic Review & Learning meeting will take place in Utrecht, Netherlands on 1<sup>st</sup>-2<sup>nd</sup> June 2016 under the auspices of the Dutch Presidency of the Council of the European Union

CAT resources: Hans Ovelgönne

Scope: discussion/agreement on topics for the agenda (mainly for the CAT-only session)

**Action:** for discussion

Document:

Final draft of the agenda (CAT only session)

Note: CAT members are asked to send proposals for agenda topics

### 7.1.2. Good manufacturing practice (GMP) requirements for ATMPs

---

CAT drafting group members: Ivana Haunerova, Margarida Menezes-Ferreira, Guido Panté, Ilona Reischl, Paula Salmikangas, Belaid Sekkali, Marcos Timón, Christiane Niederlaender, Jurgen Scherer, M. Hoefnagel

Scope: feedback from the discussions in the drafting groups and next steps

**Action:** for information

## 7.2. Coordination with EMA Scientific Committees

### 7.2.1. Committee for Medicinal Products for Human Use (CHMP)

---

Scope: Summary of Outcomes (SoO) for the April 2016 meeting

**Action:** for information

Documents:

-Summary of Outcomes

## 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

### 7.5.1. International Pharmaceutical Regulators Forum (IPRF) Gene therapy group

---

CAT resource: Paula Salmikangas

Scope: oral feedback from the teleconferences that took place on 7<sup>th</sup> January and 9<sup>th</sup> March 2016

**Action:** for information

Documents:

Agenda

Minutes

## 7.6. CAT Work Plan

### 7.6.1. Guideline on requirements for investigational ATMPs

---

CAT drafting groups: Tiina Palomäki (Rapporteur), Ilona Reischl (Rapp), Metoda Lipnik-Stangelj, Margarida Menezes Ferreira, Maura O'Donovan, Simona Badoi, Tomas Boráň, Christiane Niederlaender

Scope: Feedback from the drafting group meeting of 18<sup>th</sup> May 2016

**Action:** for information

An outline of the structure of the above guideline was provided. CAT will be kept informed of the progress.

#### **7.7. Planning and reporting**

No items

#### **7.8. Others**

No items

### **8. Any other business**

No items

Date of next CAT meeting:  
Wednesday 15<sup>th</sup> to Friday 17<sup>th</sup> June 2016

## 9. Explanatory notes

The Notes give a brief explanation of relevant agenda items and should be read in conjunction with the agenda.

### Abbreviations / Acronyms

AR: Assessment Report

ATMP: Advanced Therapy Medicinal Product

BWP: Biologics Working Party

CAT: Committee for Advanced Therapies

CHMP: Committee for Medicinal Product for Human Use

COMP: Committee for Orphan Medicinal Products

DG: Drafting Group

EC: European Commission

FDA: Food and Drug Administration

FL: Final Letter

GCP: Good Clinical Practice

GLP: Good Laboratory Practice

GMO: Environmental Risk Assessment

GMP: Good Manufacturing Practice

HTA: Health Technology Assessment Bodies

HSPC: Hematopoietic Stem and Progenitor Cells

ITF: Innovative Task Force

JR: Joint Report

LoOI: List of outstanding issues

LoQ: List of questions

MA: Marketing Authorisation

MAA: Marketing Authorisation Applicant

MAH: Marketing Authorisation Holder

MSC: Mesenchymal stem cells

PDCO: Paediatric Committee

PMDA: Pharmaceuticals and Medical Devices Agency (Japan)

PIP: Paediatric Investigation Plan

PL: Package leaflet

PRAC: Pharmacovigilance and Risk Assessment Committee #

PRIME: Priority Medicines

RMP: Risk Management Plan

RP: Reflection paper

RSI: Request for supplementary information

SA: Scientific Advice  
SAG-O: Scientific Advisory Group Oncology  
SAWP: Scientific Advice Working Party  
SR: Summary Report  
SWP: Scientific Working Party  
SME: Small and medium size enterprises  
SmPC: Summary of Products Characteristics  
TT: Timetable

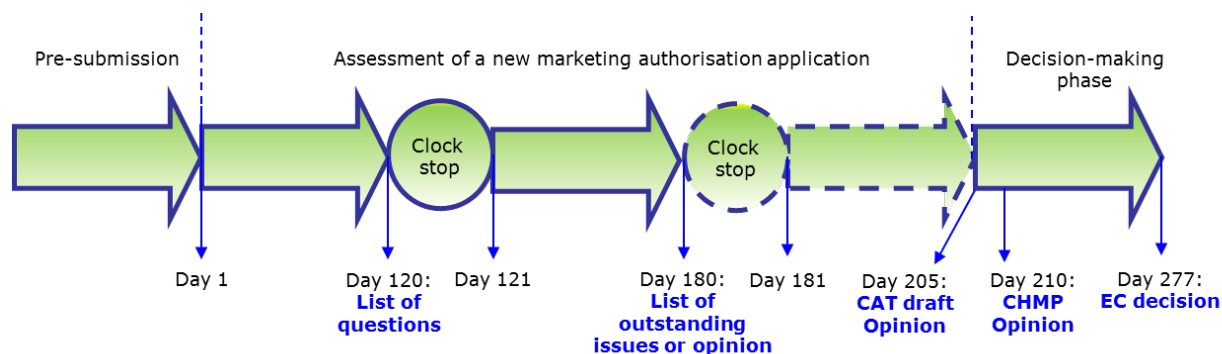
## Evaluation of ATMPs (section 2)

This section lists applications for marketing authorisations of new Advanced Therapy Medicinal Products (ATMPs) that are to be discussed by the Committee. It also lists any ATMP related inspection requests (*section 2.9*) and Post-authorisation activities (*section 2.10*).

### *New applications (sections 2.1. to 2.12.)*

Section 2.1 is for ATMPs nearing the end of the evaluation and for which the CAT is expected to adopt a draft **opinion** at this meeting on whether marketing authorisation should be granted. Once adopted, the CAT opinion is transmitted to the CHMP for final adoption. The CHMP opinion will be forwarded to the European Commission for a final legally binding decision valid throughout the EU. More information on the evaluation of ATMPs can be found [here](#).

The other items in the section are listed depending on the stage of the evaluation, which is shown graphically below:



The assessment of an application for a new medicine takes up to 210 'active' days. This active evaluation time is interrupted by at least one 'clock-stop' during which time the applicant prepares the answers to questions from the CAT. The clock stop happens after day 120 and may also happen after day 180, when the CAT has adopted respectively a **Day 120 list of questions** (*section 2.3*) or a List of outstanding issues to be addressed by the company, which is listed in the agenda under sections 2.7 (**Ongoing evaluation procedures**). Section 2.7 also includes the CAT discussions at any other timepoint of the evaluation procedure of new applications.

### *Oral explanation (section 2.2.)*

Prior to adoption of the CAT opinion, marketing authorisation applicants are normally invited to the CAT plenary meeting to address questions raised by the Committee.



Oral explanations normally relate to ongoing applications, but they can also relate to any other issue for which the CAT would like to discuss with company representatives in person.

### *Re-examination procedures (new applications) under article 9(2) of regulation no 726/2004 (section 2.6.)*

This section lists applications for new marketing authorisation for ATMPs for which the applicant has requested a re-examination of the opinion previously issued by the CHMP. Similar to the initial evaluation of a marketing authorisation of an ATMP, CAT will adopt a draft re-examination opinion, which is transmitted to the CHMP for final adoption.

### *Withdrawal of applications (section 2.7.)*

This section includes information on marketing authorisation applications that are withdrawn by the applicant. Applicants may decide to withdraw applications at any stage during the assessment and a CAT opinion will therefore not be issued. Withdrawals are included in the agenda for information or discussion, as necessary.

### *New applications (section 2.9.)*

In this section, information is included on upcoming marketing authorisation applications for ATMPs, as well as information on appointment of Rapporteurs for new ATMP applications.

### *GMP and GCP Inspections Issues (section 2.10.)*

This section lists inspections that are undertaken for ATMPs. Inspections are carried out by regulatory agencies to ensure that marketing authorisation holders comply with their obligations. Inspection can relate to good manufacturing practice (GMP), good clinical practice (GCP), good laboratory practice (GLP) or good pharmacovigilance practice (GVP).

### *Post-authorisation activities (section 2.12.)*

This section lists type II variations, extension application according to Annex I of Reg. 1234/2008, re-examination procedures for type II variations (including extension of indication applications) for which the applicant has requested re-examination of the opinion previously issued by the CHMP and other issues concerning authorised medicines that are not covered elsewhere in the agenda such as annual reassessments, 5-year renewals, supply shortages, qualify defects. Issues that have been discussed at the previous meeting of the PRAC, the EMA's committee responsible for evaluating and monitoring safety issues for medicines, will also be included here.

## **Certification of ATMPs (section 3)**

This section includes the scientific evaluation by the CAT of quality and non-clinical data that small and medium-sized enterprises have generated at any stage of the ATMP development process. More information on the ATMP certification procedure can be found [here](#).

## **Scientific Recommendation on Classification of ATMPs (Section 4)**

This section includes the scientific recommendation by the CAT on whether medicines based on genes, cells or tissues meet the scientific criteria that define ATMPs. More information on the ATMP classification procedure, including the outcomes of finalised classifications, can be found [here](#).

## **Scientific Advice (section 5)**

This section includes all scientific advice given to companies during the development of an ATMP. Information related to the number of ATMP related scientific advices discussed by CAT can be found in the CAT Monthly reports. Further information on SAWP can be found [here](#).

## **Pre-Authorisation (section 6)**

### *Paediatric Investigation Plan (PIP)*

This section includes the discussion of an ATMP before a formal application for marketing authorisation is submitted. These cases refer for example to requests for an accelerated assessment for medicines that are of major interest for public health or can be considered a therapeutic innovation: in case of an accelerated assessment the assessment timetable is reduced from 210 to 150 days.

CAT contributes to the evaluation of a Paediatric Investigation Plan (PIPs) for ATMPs by the Paediatric Committee. These PIPs are included in this section of the Agenda.

### *ITF Briefing meeting in the field of ATMPs*

This section refers to briefing meetings of the Innovation Task Force and International co-operations activities of the CAT

The Innovation Task Force (ITF) is a body set up to encourage early dialogue with applicants developing innovative medicines. Minutes of meetings with applicants developing ATMPs and of other ITF meetings of interest to the CAT are included in this section of the agenda. Further information on the ITF can be found [here](#).

## **Organisational, regulatory and methodological matters (section 7)**

This section includes topics related to regulatory and procedural guidance, CAT workplan, CAT meeting organisation (including CAT membership), planning and reporting, co-ordination with other committees, working parties and scientific advisory groups.

Furthermore, this section refers to the activities of the CAT drafting groups developing scientific guidelines for gene therapy medicinal products and for cell-based medicinal products, cooperation within the EU regulatory network and international regulators as well as direct interaction with interested parties. It also includes topics of scientific interest for the Committee that are not directly related to the work of the CAT drafting groups or CAT associated working parties.

## **Any other business (section 8)**

This section is populated with miscellaneous topics not suitable under the previous headings.

More detailed information on the above terms can be found on the EMA website: [www.ema.europa.eu/](http://www.ema.europa.eu/)