



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Advanced Therapy Medicinal Products: how to bring cell-based medicinal products successfully to the market

Workshop Programme

11 September 2014

Maritim Internationales Congress Centrum, Dresden, GERMANY



In collaboration with:



DEUTSCHE GESELLSCHAFT
FÜR TRANSFUSIONSMEDIZIN UND
IMMUNHÄMATOLOGIE E.V.



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Introduction

This workshop aims to strengthen dialogue between CAT and the ATMP developers, to facilitate ATMP development and access to the registration procedure.

This workshop is co-organized by the European Medicines Agency's Committee for Advanced Therapies (CAT) and the German Society for Transfusion Medicines and Immunohematology (DGTI) in collaboration with the German Stem Cell Network (GSCN) with the aims to bringing together industry, academia, hospitals and regulators to discuss how to progress forward the development and authorisation of advanced-therapy medicinal products (ATMPs).

The Workshop will allow for the attendees of the annual conference and for academia and industry involved in the development of ATMPs to:

- Learn about the development and authorisation of cell-based ATMPs in the EU
- Learn about role of the CAT and about the support provided by EMA and the CAT to ATMP developers
- Understand the criteria that CAT applies for the classification of ATMPs
- Hear about CAT's considerations and recent interactions with experts on cell-based therapies for cardiac repair
- Interact directly with the Regulators in an Open Forum discussion.

The workshop features presentations from CAT members, EMA and ATMP developers from industry, hospitals and academia, and includes the lively panel debates and direct interactions with the representatives from CAT and EMA .

The workshop will be of interest to all ATMP developers: industry, including SMEs; academics from gene and cell therapy communities; healthcare professionals in the field; patient associations; regulatory professionals; corporate decision-makers; and regulators.



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Welcome to all participants

On behalf of the Programme Committee, the Committee for Advanced Therapies (CAT), the German Society for Transfusion Medicines and Immunohematology (DGTI) and the German Stem Cell Network (GSCN), we are pleased to welcome you to this workshop on Advanced Therapy Medicinal Products (ATMPs).

Since establishment of the CAT in 2009, the vision of the Committee has been to actively interact with stakeholders in order to support the development of new ATMPs for unmet medical needs. This vision was further developed into a work program that allocates CAT resources annually for such activities. From the beginning, CAT has witnessed the ATMP developers facing specific challenges not foreseen for other medicinal products. Through direct interactions with stakeholders and Interested Parties, specific workshops and training sessions, the CAT has spread information on the regulatory framework of ATMPs, looked for possible solutions for most frequent problems and collected views on possible needs of the field e.g. for additional guidance. The Committee has also worked hard to establish a flexible approach for licensing ATMPs.

This is the third joint meeting of the CAT with learned societies, after ESGCT in 2011 and TRM Leipzig in 2013. We believe that the DGTI meeting of the German, Swiss and Austrian Societies for Transfusion Medicine is a perfect occasion for such an outreach meeting of CAT as it brings together many interested parties and it is well timed, since it will fall together with the ongoing reflections on changes to the ATMP Regulation that would facilitate the market access of these innovative products.

The target of this workshop is to discuss current challenges and latest regulatory developments in the field of ATMPs. Especially the revision of the Reflection Paper on classification of ATMPs will be discussed. You will also hear how CAT and European Medicines Agency (EMA) are able to support ATMP developers and there will be latest news presented from a CAT workshop on cell-based therapies for cardiac repair, held in May 2014.

The agenda is designed to encourage active dialogue between participants. For that, a special Open Forum session is arranged with the possibility for direct interactions with the regulators.

We look forward to meeting you in Dresden in September 2014!

Paula Salmikangas

Torsten Tonn

Programme details

Thursday, 11 September 2014

8.00 **Registration and welcome coffee**

8.30 **Welcome and opening remarks**

Paula Salmikangas

European Medicines Agency, CAT Chair

Torsten Tonn

DGTI, Conference chair

8.35 **Session 1: Development and authorisation of cell-based ATMPs in the EU – session chair: Ilona Reischl**

Challenges during the development of ATMPs

Paula Salmikangas

CAT chair

The Committee for Advanced Therapies: procedures and support to developers

Patrick Celis

CAT Scientific Secretariat

Questions and discussion

9.15 **Session 2: Classification of ATMPs – session chair: Egbert Flory**

CAT's views on classification of ATMPs

Nicolas Ferry

CAT member

Autologous cell therapies manufactured in the hospital: ATMPs or not?

Kenneth Kleinhenz

Cytori Therapeutics

Questions and discussion

10.10 **Coffee break**

10.30 **Session 3: Cell-based therapies for cardiac repair – session chair: Marit Hystad**

Introduction: EMA/CAT workshops on cell-based therapies for cardiac repair

Martina Schübler-Lenz

CAT vice-chair

Stem cell therapy for myocardial repair

Birgit Assmus

Cardiology Department, University Hospital Frankfurt

Quality aspects for cell-based therapies for cardiac repair

Paula Salmikangas

CAT chair

Non-clinical aspects for cell-based therapies for cardiac repair

Claire Beuneu

CAT member

Clinical aspects for cell-based therapies for cardiac repair

Pieter Doevendans

CAT member

Questions and discussion

12.00 **Lunch**

12.30 **Session 4: Open Forum discussion with CAT**

Introduction: frequently asked questions to CAT

CAT members / EMA representative

Panel discussion / Questions from the Audience

13.30 **Closing remarks**

Paula Salmikangas and Torsten Tonn

Workshop Co-chairs

List of speakers

Paula Salmikangas	Lääkealan turvallisuus- ja kehittämiskeskus (FIMEA), Finland
Patrick Celis	European Medicines Agency, UK
Nicolas Ferry	Agence nationale de sécurité du médicament et des produits de santé, France
Kenneth Kleinhenz	Cytori Therapeutics, USA
Martina Schübler-Lenz	Paul-Ehrlich-Institut, Germany
Birgit Assmus	Cardiology Department, University Hospital Frankfurt, Germany
Claire Beuneu	Federaal Agentschap voor Geneesmiddelen en Gezondheidsproducten - Agence Fédérale des Médicaments et des Produits de Santé, Belgium
Pieter Doevendans	European Society of Cardiology and University Medical Center Utrecht, The Netherlands.

Workshop Co-chairs

Torsten Tonn	Technische Universität Dresden and DRK-Blutspendedienst Ost, Germany and German Society for Transfusion Medicines and Immunohematology
Paula Salmikangas	Lääkealan turvallisuus- ja kehittämiskeskus (FIMEA), Finland

Session chairs

Ilona Reischl	Bundesamt für Sicherheit im Gesundheitswesen, Austria
Egbert Flory	Paul-Ehrlich-Institut, Germany
Marit Hystad	Statens legemiddelverk Norway

Programme Committee

Torsten Tonn	Congress President and Workshop Co-chair
Paula Salmikangas	CAT chair, Workshop Co-chair
Egbert Flory	CAT member
Ilona Reischl	CAT member
Marit Hystad	CAT member
Romaldas Maciulatis	CAT member, CHMP member
Patrick Celis	EMA, CAT Scientific Secretariat
Hans-Dieter Volk	German Stem Cell Network
Peter Schlenke	German Society for Transfusion Medicines and Immunohematology

Practical information

Venue

International Congress Center Dresden

Registration

For registration to the Workshop, use the online registration on the website of the DGTI Annual meeting: <http://www.dgti-kongress.de/en/registration-abstracts/anmeldung/>

If you are attending the DGTI Annual Meeting, the congress fee includes the participation to the CAT Workshop. For organisational reasons, we ask you to register for the workshop under the Training Programs.

If you plan only to attend the CAT-DGTI workshop, please chose 'CAT workshop' under the Training Programs. The fee of this workshop is 200 EUR. Members from DGTI, GSSN, EMA and members from Competent Authorities will be able to take advantage of the reduced fee (165 EUR).

For travel and accommodation, you can also visit the DGTI annual meeting website: <http://www.dgti-kongress.de/en/>

Other information

The participants are encouraged to provide questions for the Session 4 'Open Forum Discussion with CAT' in advance of the workshop. All registered participants will receive by the end of August 2014 an invitation to submit their questions.

Conference secretariat

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