DIA

1st Joint DIA-EUCOPE Workshop on ATMPs, Innovative Gene and Cell Therapies in the EU

29-30 October 2019 | Basel, Switzerland

PROGRAMME COMMITTEE

Maren von Fritschen
DIA Regional Advisory Council Chair,
EUCOPE, Belgium

Alexander Natz
Secretary General,
EUCOPE, Belgium

Thomas Bols
SVP and Managing Director
DIA EMEA, Switzerland

Inka Heikkinen
Associate Director, Scientific Programmes
DIA EMEA, Switzerland

Overview

This workshop on cell and gene therapies aims to meet the needs of the developers of advanced therapies to discuss a range of topics that will help them make more informed decisions on regulatory strategies and evidence packages - as well as market access challenges - which are key topics for cell and gene therapy developers.

It will feature speakers from regulators, payers, patients, industry and academic organisations. Participants will benefit from the direct interaction with these stakeholders as a part of the main programme and during the networking events.

Key Topics

- Development challenges and solutions for cell and gene therapies
- Regulatory tools and pathways, including early interaction with decisions
- Emerging gene editing technologies and the ethical challenges
- Hospital exemption issues
- Post-licensing evidence with examples from country-level initiatives
- HTA and value assessment for curative therapies with high upfront fee
- Case study for a launch in Europe

Who Should Attend

- Research and Development, regulatory and access professionals from organisations developing cell and gene therapies
- Regulators, payers and patients who are impacted by or participating the decisions or policies related to cell and gene

Conference Venue

Hotel Bildungszentrum 21
Missionstrasse 21
CH-4055 Basel
Switzerland

Phone: +41 61 260 2121
info@bildungszentrum-21.ch

DAY ONE | TUESDAY, 29 OCTOBER 2019

DAY 1

REGULATORY REQUIREMENTS AND PRECONDITIONS FOR DEVELOPING GENE AND CELL THERAPIES IN THE EU

Conference Chair:
MAREN VON FRITSCHEN, DIA Regional Advisory Council Chair, EUCOPE, Belgium

08:30 REGISTRATION

09:15 SESSION 1

DEVELOPMENT OF ADVANCED THERAPY MEDICINAL PRODUCTS (ATMPS) – CHALLENGES AND OPPORTUNITIES FROM INDUSTRY AND AUTHORITY PERSPECTIVE

Global Development Program: Reality or Illusion?
ANNE DUPRAZ, Chief Regulatory Officer, Orchad Therapeutics, UK

Regulatory framework in the EU – Learnings from the Regulator's perspective
ANA HIDALGO-SIMON, Head of Specialised Scientific Disciplines Department, European Medicines Agency

Regulatory early access tools for cell and gene therapies in the EU
Speaker Invited

Panel discussion

10:45 REFRESHMENT BREAK

11:15 SESSION 2

EMERGING TECHNIQUES ON GENE EDITING (CRISPR, ZINC SCISSORS AND OTHERS)

Editing the Human Genome: Science Revolution - State of Play and What's next?
SINAN KILIC, Researcher, University of Zurich, Switzerland

Challenges of CRISPR and other Gene Editing Technologies - Legal and Ethical Perspectives
ZINA CHATZIDIMITRIADOU, Associate, Sidley Austin LLP, UK

Discussion with the audience

13:00 LUNCH

14:00 SESSION 3

HOSPITAL EXEMPTION AND IMPLICATIONS FOR DRUG DEVELOPMENT

Hospital Exemption for ATMPs from the Regulator's Perspective
JÜRGEN SCHERER, Head of Section, Advanced Therapy Medicinal Products, Tissue Preparations, PEI, Germany

Learnings from the Hospital Exemption in Different National EU Member States from a Manufacturer's Perspective Plus Future Challenges
PIETRO STERNINI, Head of Market Access Europe, Atara Bio, Switzerland

Discussion with the audience

15:00 SESSION 4

REGISTRIES

WHO Approach of a Global Registry of Clinical Studies Editing the Human Genome
ZINA CHATZIDIMITRIADOU, Associate, Sidley Austin LLP, UK

EMA Approach on Post-licensing Evidence Collection and Registries
ANA HIDALGO-SIMON, Head of Specialised Scientific Disciplines Department, European Medicines Agency

German GSAV Proposal for Mandatory OMP & CMA Registries
ALEXANDER NATZ, Secretary General, EUCOPE, Belgium

16:15 WRAP UP OF DAY 1

16:30 END OF DAY ONE

DAY TWO | WEDNESDAY, 30 OCTOBER 2019

DAY 2

MARKET ACCESS AND PRICING & REIMBURSEMENT OF ATMPS IN THE EU – CHALLENGES AND POLITICAL IMPLICATIONS

Conference Chair:
ALEXANDER NATZ, Secretary General, EUCOPE, Belgium

09:00 SESSION 5

THE PRICING AND REIMBURSEMENT PERSPECTIVE

Status quo of ATMP Launches in Europe
ALEXANDER NATZ, Secretary General, EUCOPE, Belgium

ATMPs from the HTA Viewpoint – Learnings until now
HELEN KNIGHT, Programme Director, National Institute for Health & Care Excellence (NICE), UK

Payer Considerations
MICHELA GABALDO, Head of Alliance Management and Regulatory Affairs, Fondazioni Telethon, Italy

Panel discussion

10:45 REFRESHMENT BREAK

11:15 SESSION 6

PRICING & HTA CHALLENGES FOR CELL AND GENE THERAPIES

Learnings from Launching Kymriah
ETIENNE JOUSSEAUME, Head Market Access Cell & Gene Europe, Novartis, Switzerland

Learnings from Launching Yescarta
KONSTANTINOS LYKOPOULOS, Senior Director Market Access & Reimbursement, Kite Pharma, UK

RWE4Access: Payer Initiave for Post-Licensing Evidence for Cell and Gene Therapies
KAREN FACEY, Evidence Based Health Policy Consultant, UK

Discussion with the audience

13:00 LUNCH

13:45 SESSION 7

CASE STUDY OF AN ATMP LAUNCH IN EUROPE

Case Study from Bluebird Bio
LEO STRICAN, Head of Access Value & Evidence Strategy, Europe, Bluebird Bio, Switzerland

Discussion with the audience

14:45 CLOSING REMARKS

THOMAS BOLS, SVP and Managing Director, DIA EMEA, Switzerland

15:00 END OF WORKSHOP

| Continuing Education

DIA meetings and training courses are approved by the SwAPP (Swiss Association of Pharmaceutical Professionals) Commission for Professional Development (CPD) and SGPM (Swiss Society of Pharmaceutical Medicine) and are honoured with credits for pharmaceutical medicine. All meeting and training course participants are eligible for applicable credits.

The CMC workshop has been accredited with 13,5 credits. The CMC Short Course has been accredited with 10 credits.

SwAPP | Swiss Association of Pharmaceutical Professionals