



CDDF 10TH ALPINE CONFERENCE

Current and Future Challenges of Innovative Oncology Drug Development

Innsbruck, Austria
26 - 28 February 2018

PROGRAMME



PROGRAMME

Day 1 Monday 26th February 2018

Lecture hall: Innsbruck 1+2

- 15:00 **Introduction**
Heinz Zwierzina (CDDF Managing Director, AT)
- 15:05 **Keynote Lecture: Clinical Trial Design in 2050; or: The Disappearance of Clinical Trials?**
Jaap Verweij (Erasmus MC, NL)

PLENARY SESSION 1: CLINICAL TRIAL DESIGN IN AN ERA OF HORIZONTAL DRUG DEVELOPMENT

Co-chairs: Stefan Schwach (Lilly, DE) & Jaap Verweij (Erasmus MC, NL)

- 15:30 **The Clinical Development on Larotrectinib (LOXO-101)**
Theodore Laetsch (UT Southwestern Medical Centre, USA)
- 15:50 **Case Story**
To be announced
- 16:10 **Statistician's Perspective**
Lindsay Renfro (Mayo Clinic, USA)
- 16:30 **Current Statistical Considerations and Regulatory Perspectives on the Planning of Confirmatory Basket, Umbrella and Platform Trials**
Olivier Collignon (Luxembourg Institute of Health/EMA, UK) - *via video conference*
- 16:50 **Industry Perspective**
Davy Chiodin (Acerta/AstraZeneca Group, USA)
- 17:10  **Roundtable discussion**
All presenters & Rosa Giuliani (S. Camillo-Forlanini Hospital, National Health System/EMA SAG-O, IT)
- 17:40  Coffee break

PLENARY SESSION 2 (PART 1): RARE CANCERS

Co-chairs: Lothar Bergmann (Frankfurt University Hospital, DE) & Francesco De Lorenzo (ECPC, IT)



- 18:10 **The Joint Action on Rare Cancers (JARC): European initiatives**
Paolo Casali (Fondazione IRCCS Istituto Nazionale Tumori/University of Milan, IT)
- 18:40 **EU Reference Networks**
Jean-Yves Blay (Léon Bérard Centre, FR) - *via video conference*
- 19:10 End of day 1
- 19:45  Welcome Reception @ Salon Bellevue
Networking Dinner @ Interpalen Hotel Restaurant

Day 2 Tuesday 27th February 2018

Lecture hall: Innsbruck 1+2

PLENARY SESSION 2 (PART II) : RARE CANCERS

Co-chairs: *Lothar Bergmann (Frankfurt University Hospital, DE) & Francesco De Lorenzo (ECPC, IT)*

- 08:30 **General Introduction on Rare Cancers**
Francesco De Lorenzo (ECPC, IT)
- 08:40 **Development of Osimertinib for EGFR mutated NSCLC**
Mohamed Raza Dewji (AstraZeneca, UK)
- 09:00 **Statistician's Perspective**
Lucinda Billingham (University of Birmingham, UK)
- 09:20 **US Regulatory Perspective**
Amy Barone (FDA, USA)
- 09:40 **Industry Perspective**
Hubert Caron (Roche, USA)
- 10:00  **Roundtable discussion**
All presenters & Annie Pannelay (UK)
- 10:30  Coffee break

PLENARY SESSION 3: DEVELOPMENT AND APPROVAL PATHWAY FOR CHANGES IN DOSING REGIMES

Co-chairs: *Stefan Schwach (Lilly, DE) & Jaap Verweij (Erasmus MC, NL)*

- 10:50 **Finding the Right Dose and Schedule of New Drugs - Clinical Considerations**
Axel Hanauske (academic consultant, DE)
- 11:10 **Clinical and Statistical Challenges of Bridging Approaches to Alternative Dosing Regimen or Formulations**
Dominik Heinzmann (Roche, CH)
- 11:30 **Regulatory Considerations of Bridging Approaches to Alternative Dose Schedule or Formulation**
Essam Kerwash (MHRA, UK)
- 11:50 **Report on the CDDF workshop on Innovation in Oncology Clinical Trial Design**
Jaap Verweij (Erasmus MC, NL)
- 12:00  **Roundtable discussion**
- 12:15-13:15  Lunch @ Interpalen Hotel Restaurant

PLENARY SESSION 4: PATIENTS' REPORTED OUTCOMES IN ONCOLOGY PATIENT-CENTERED DRUG DEVELOPMENT: OPPORTUNITIES & CHALLENGES

Co-chairs: Sarah Bobiak (EMD Serono/Merk KGaA, USA) & Eva Skovlund (Norwegian University of Science and Technology, NO)

Panelists

- Andrew Bottomley (EORTC, BE)
 - Daniel O'Connor (MHRA, UK)
 - Amylou Dueck (Mayo Clinic, USA)
 - Dan Danielson (Premera, USA)
 - Paul Kluetz (FDA, USA) - *via teleconference*
- 13:15 **Introduction of Panelists and Topics**
Sarah Bobiak (EMD Serono/Merck KGaA, USA)
- 13:35 **Study Design**
Daniel O'Connor (MHRA, UK)
- 14:15 **Endpoints**
Amylou Dueck (Mayo Clinic, USA)
- 14:55 **Instruments, Measure Validity**
Andrew Bottomley (EORTC, BE)
- 15:35 **Closing remarks**
Eva Skovlund (NTNU, NO)


PLENARY SESSION 5: TRANSLATION OF CANCER BIOMARKERS INTO CLINICAL PRACTICE

Co-chairs: Tatiana Prowell (Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins, USA) & Heinz Zwierzina (CDDF/University of Innsbruck, AT)

- 16:10 **Critical Current Assessment on Companion Diagnostics**
Tatiana Prowell (Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins, USA)
- 16:30 **Regulatory Perspective**
Markus Paulmichl (EMA, UK)
- 16:50 **Patient Representatives' Perspective**
Francesco De Lorenzo (ECPC, IT)
- 17:10 **Challenges of Biomarker Development in Europe: an Industry Perspective**
David Brunel (Biosesix, USA)
- 17:30 **Challenges of Getting an NGS Assay to the EU Market**
Thomas Holtschke (Foundation Medicine, USA)
- 17:50 **Perspectives from the Healthcare Ecosystem**
Annie Pannelay (UK)
- 18:00  **Roundtable discussion: How to Improve Acces of Biomarkers to the EU Market**
- 18:30  Coffee break

PLENARY SESSION 6: REPORT FROM CDDF MULTI-STAKEHOLDER WORKSHOPS

Co-chair: John Smyth (CDDF/University of Edinburgh, UK)

- 18:45 **Minimal Residual Disease (October 2017, London, UK)**
John Smyth (CDDF/University of Edinburgh, UK)
- 18:55 **Access to Innovative Oncology Drugs in Europe (September 2017, Madrid, Spain)**
Sonia Garcia Perez (AEMPS, Spain)
- 19:05 **ACCELERATE Platform**
Heinz Zwierzina (CDDF/University of Innsbruck, AT)
- 19:15 End of Day 2
- 19:45  Networking Dinner @ InterAlpen-Mountain Hut

Day 3 Wednesday 28th February 2018

Lecture hall: Leutasch

PLENARY SESSION 7: CELL THERAPY

Co-chairs: Marnix Bosch (Northwest Biotherapeutics, USA) & Jolanda De Vries (Radboud Institute for Molecular Life Sciences, NL)

- 09:00 **Clinical-case Examples**
Christoph Scheid (University Clinic of Cologne, DE)
- 09:20 **Early CAR-T Development Experience from an Academic Perspective**
Jakub Svoboda (University of Pennsylvania, USA)
- 09:40 **Dendritic Cells**
Jolanda De Vries (Radboud Institute for Molecular Life Sciences, NL)
- 10:00 **Technical Development**
Mark Lowdell (Centre for Cell, Gene & Tissue Therapeutics, UK)
- 10:20 **Data from Lymphoma Pivotal Study and pALL study**
Oezlem Anak (Novartis, CH)
- 10:40  Coffee break
- 11:10 **Challenges with CAR T Cells: a European Regulatory Perspective**
Martina Schussler-Lenz (Paul-Ehrlich-Institut, DE)
- 11:30 **Clinical Considerations for Cancer Cell Therapy: US FDA Perspective**
Ke Liu (FDA, USA)
- 11:50  Roundtable discussion
- 12:20 **Concluding remarks**
Heinz Zwierzina (CDDF/University of Innsbruck, AT)
- 12:30 End of the meeting & lunch

Event Outline

The Alpine conference is a unique forum organised by the Cancer Drug Development Forum that convenes every 18 months and gathers the leaders in the world of innovative cancer therapy development.

The 10th edition takes place from 26 to 28 February 2018, in Innsbruck, Austria. This multi-stakeholder, interactive meeting offers small group lectures with moderated discussions, plenary lectures including case studies and networking opportunities.

The programme focuses on the latest and future challenges with a special emphasis on biomarkers, cell therapy, rare cancers, patients' reported outcomes, clinical trial design and horizontal drug development.

Programme Committee

- Marnix Bosch (Northwest Biotherapeutics, USA)
- Davy Chiodin (Acerta/AstraZeneca Group, USA)
- Sonia Garcia Perez (AEMPS, ES)
- Jaap Verweij (Erasmus MC, NL)
- Heinz Zwierzina (CDDF/University of Innsbruck, AT)

Conference Venue

Interalpen Hotel Tyrol
Doktor-Hans-Liebherr-Alpenstraße 1
6410 Telfs-Buchen/Seefeld
Austria

Conference Secretariat

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