



CDDF 10TH ALPINE CONFERENCE

Current and Future Challenges of Innovative Oncology Drug Development

Innsbruck, Austria
26 - 28 February 2018



WEDNESDAY MARCH 3

Plenary Session 1

Chairs: Heinz Zwierzina, Harald Enzmann, Anne deBock

15.00 **Welcome and Introduction**
H. Zwierzina

Hurdles in oncology drug development

15.10 **"Partnership – the methodology for drug development in the future"**
J. Smyth

15.35 **Discussion**

15.45 **The future direction of oncology regulation in Europe**
H. Enzmann

16.15 **The future direction of oncology regulation in Japan**
T. Arato

17.15 **COFFEE BREAK**

17.35 **Industry Scenario Setting for discussion**
W. Wein

17.45 **Feedback from BDA- HTA Brussels meeting**
- A pharmaco-economist's view
Christopher McCabe
- A senior clinicians view
Charles Swanton
- Update on EUhtaNET
TBD

18.15 **Panel discussion –**
Moderators Heinz Zwierzina, Christopher McCabe

18.30 **Close of the day**

19.30 – 20.00 **Welcome reception**

20.00 **Dinner**

THURSDAY MARCH 4

Plenary Session 2

Chairs: Max Scheulen, Alexander Moreau, Adrien Tinetti

The Challenges of Combination & Sequential Therapies

8.30 **Introduction and short report from the Brookings Institute September Conference panel for discussion on the development of 2 NMEs**
M. von Euler

8.45 **Novel-novel – Scientific basis for combination treatment**
J. Tabernero

9.00 **Innovative opportunities with new TKI's**
A. Covelli

9.15 **Why develop novel-novel combinations in oncology?**
M. von Euler/representative of Translational research Unit at Roche

9.30 **A perspective on the regulatory issues of 2NME development**
P. Demolis

9.45 **Discussion**

10.00 **Coffee**

BREAKOUT SESSION 1

Chairs: M. von Euler, Alexander Moreau, Leif Hakansson

10.30 **Novel-novel – Combinations in oncology**
M. Von Euler, M. Hope

BREAKOUT SESSION 2

10.30 **Regulators session**
Chairs: John Smyth, Lothar Bergmann, Birge Berns
Comparative scientific advice – Europe and Japan

12.00 **Plenary discussion from breakout sessions 1**

12.45 – 2.00 **Buffet lunch**

THURSDAY MARCH 4

14.00 Paediatrics (Plenary session)

Chairs: Steven Hirschfeld, John Smyth, Birge Berns

14.00 **Will children with cancer benefit from the new European Paediatric Medicines Regulation?**
G. Vassal

14.30 **Industry experience with paediatric legislation to date**
TBD

14.45 **Opportunities and challenges for Paediatric Oncology Development a perspective from the USA**
S. Hirschfeldt

15.00 **Discussion**

15.15 – 15.30 **Coffee**

15.45 BREAKOUT SESSION 3: Paediatrics

Chairs: Steven Hirschfeld, Eva Skovlund, Birge Berns
Follow up from Plenary session

16.00 **BREAKOUT SESSION 4: Impact on the development of oncology drugs of the current trends in PFS**

Chairs: Lothar Bergmann, Bertil Jonsson, Andy Stone

16.45 – 17.45 **Feedback from Breakout sessions and discussion**
Chairs: Louise Gill, Lothar Bergmann

20.00 **Dinner**



10th Alpine meeting

Time to look back for a minute

- **Biomed grant 1994:**
 - "Organization of preclinical and clinical research on anticancer therapy with biological response modifiers" (CT 94-1587)
- **EORTC "Biological Therapeutics Development Group (BTDG)" 1994**
 - Goal was to set up early clinical trials and build translational research programmes around them
- **"Biotherapy Development Association (BDA) 2002**
 - Develop a multistakeholder platform (academia / industry / regulatory authorities)
- **Cancer Drug Development Forum (CDDF) 2014**
 - „Biological“ had become too narrow

Milestones

Alpine Meetings

- Have turned out to become a think tank for CDDF and its partners
- Many Working Group meetings have been organised based on topics that were brought up and agreed among all stakeholders
- Basis for various success stories of CDDF



Milestones

Cancer Drug Development Forum (CDDF)

- **The forum remains a unique platform with interactive discussions among all stakeholders involved**
- **It is continuously growing**
 - **steadily increasing number of partners from industry**
 - **Steadily increasing number of stakeholders**
- **Success stories: ITOC forum and recently the paediatrics forum have become recognized platforms that are (also financially) flying on their own**
- **Opportunity to create new fora (PRO, combination therapy, biomarkers, HTA....) together with our industry partners and the other stakeholders**

Success stories and high points over the years

- **"Gene therapy"**
- **Antibodies (only treatment other than chemotherapy that can cure cancer in the adjuvant setting)**
- **Anti-angiogenesis**
- **Immunotherapy**
 - Only treatment except chemotherapy (!) that has the potential to cure metastatic cancers
- **Individualised molecular targeted therapy**
 - Challenge remains how to apply this technology in clinical trials (except for frequent genetic alterations)
 - In most cases we come back to „good old“ chemotherapy

Ambitions

Biomarkers

- **We must do our best to avoid that potentially active drugs fail in phase III**
 - MMPs, FTIs, vaccines so far, etc.
- **There is an ethical (and financial) need to develop biomarkers that define subgroups of patients who respond / do no respond**
- **Immunotherapy represents the only molecular targeted therapy that has the potential to cure patients**



Cancer Biomarkers in the Era of Personalised Medicines

TUESDAY 5 DECEMBER 2017

15:00 – 17:00

EUROPEAN PARLIAMENT
ROOM A1E-1

The event is hosted by
MEP Marlene Mizzi (S&D, Malta)

