CDDF
Cancer Drug Development Forum

CDDF 8TH ALPINE CONFERENCE

CURRENT AND FUTURE CHALLENGES OF INNOVATIVE ONCOLOGY DRUG DEVELOPMENT

INNSBRUCK, AUSTRIA 2-4 MARCH 2015

PROGRAMME

Workshop objectives

The goal of the CDDF 8th Alpine conference is to discuss the current and future challenges of innovative oncology drug development together with experts from academia, regulatory authorities and the pharmaceutical industry. Some topics discussed during the conference will then lead to further working groups during the year.

Conference chairs

- Renzo Canetta (USA)
- Markus Kosch (Germany)
- Heinz Zwierzina (Austria)

Who should attend ?

- Academics
- Policymakers
- Regulators from European and International bodies
- Representatives from the pharmaceutical industry

Conference venue

Interalpen-Hotel Tyrol
Dr.-Hans-Liebherr-Alpenstrasse 1
6410 Telfs-Buchen/Seefeld, Austria
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Conference secretariat

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Registrations at www.cddf.org

DAY 1 MONDAY 2 MARCH 2015

MEETING ROOM: INNSBRUCK

15:00 WELCOME AND INTRODUCTION

KEYNOTE LECTURE: HOW IMPROVED PROGNOSIS AND SURVIVORSHIP HAVE EVOLVED OVER THE LAST FEW YEARS

15:15 Keynote lecture: How improved prognosis and survivorship have evolved over the last few years
Martin Gore (The Royal Marsden Hospital / EMA Scientific Advisory Group on Oncology, UK)

PLENARY SESSION 1 : CHOICE OF ENDPOINTS

Chairs:
Markus Kosch (Pfizer, Germany)
Tatiana Prowell (Office of Hematology & Oncology Products, FDA - Johns Hopkins Kimmel Cancer Center, USA)
Heinz Zwierzina (Innsbruck University, Austria)

15:45 The need for "surrogate" endpoints
Lothar Bergmann (J.W. Goethe University / EMA Scientific Advisory Group on Oncology, Germany)

16:05 PFS as a surrogate endpoint and the impact of post-progression treatments
Robert Clay (Kinapse, UK & Highbury Regulatory Science, UK)

16:25 Use of pCR after neoadjuvant / preoperative therapy as an endpoint
Gunter von Minckwitz (German Breast Group, Germany)

16:45 Long term effects of therapy of advanced disease : novel approaches to their evaluation
Renzo Canetta (BMS, USA)

17:05 "Surrogate" endpoints in oncology - The regulatory point of view
Pierre Demolis (EMA Committee for Medicinal Products for Human Use, France)

17:25 Discussion

18:00 BREAK

REPORT FROM THE LAST CDDF WORKING GROUPS

18:30 CDDF- ITCC - ENCCA - SIOPE pediatric oncology platform
Gilles Vassal (Institut Gustave Roussy, France)

18:40 Companion Diagnostic workshops (Brussels, December 2013 and 2014)
Silvia Marsoni (Cancer Institute of Candiolo - FPO-IRCCS, Italy)

18:50 Access to innovative oncology medicines in Europe (Bonn, January 2014)
Lothar Bergmann (J.W. Goethe University / EMA Scientific Advisory Group on Oncology, Germany)

19:00 Minimal residual disease and pathological complete response : endpoints in clinical trials (London, May 2014)
John Smyth (University of Edinburgh, UK)

19:10 END OF DAY 1

19:15 CDDF and Industry Panel Meeting (per invitation only)

20:00 WELCOME RECEPTION AND DINNER (@ hotel Restaurant)

DAY 2 TUESDAY 3 MARCH 2015

MEETING ROOM: INNSBRUCK

PLENARY SESSION 2 : FDA BREAKTHROUGH DESIGNATION : WHAT IS THERE FOR THE PATIENTS? CAN WE 'IMPORT' IT IN THE EU?

Chairs :
Pierre Demolis (EMA Committee for Medicinal Products for Human Use, France)
Katrin Rupalla (BMS, France)
Jan Schellens (The Netherlands Cancer Institute / EMA Scientific Advisory Group on Oncology, The Netherlands)

08:30 What can we learn from FDA's experience with breakthrough therapy designation?
Tatiana Prowell (Office of Hematology & Oncology Products, FDA - Johns Hopkins Kimmel Cancer Center, USA)

08:50 Advantages of EMA conditional approval? Is there a future for adaptative licencing?
Stiina Aarum (European Medicines Agency, UK)

09:10 What risks is the patient ready to take?
Francesco De Lorenzo (European Cancer Patient Coalition / former member of the italian parliament and former minister of health, Italy)

09:30 Discussion

10:00 BREAK

PLENARY SESSION 3 : THE EXPANDING ROLE OF MOLECULAR TARGETED THERAPIES

Chairs :
Rosa Giuliani (S. Camillo-Forlanini Hospital, National Health System / EMA SAG-O, Italy)
Martin Gore (The Royal Marsden Hospital / EMA Scientific Advisory Group on Oncology, UK)
Kinga Komar-Malinowska (Bayer, Germany)

10:30 Targeted therapies
Jan Schellens (The Netherlands Cancer Institute / EMA Scientific Advisory Group on Oncology,The Netherlands)

10:50 Industry point of view
Barry Childs (Bayer, USA)

11:10 Clinical trial design driven by genomics
Wolfgang Wick (Universitätsklinik Heidelberg, Germany)

11:30 Genomic driven trials : are there grounds for new type of indications ?
Jonas Bergh (Karolinska Institute / EMA Inter-Committee Scientific Advisory Group on Oncology, Sweden)

11:50 Discussion

12:30 LUNCH (@ hotel Restaurant)

PLENARY SESSION 4 : THE EMERGING ROLE OF IMMUNOTHERAPY OF CANCER

Chairs:
Renzo Canetta (BMS,USA)
Harald Enzmann (BfArM / EMA Committee for Medicinal Products for Human Use, Germany)
Leif Hakansson (University of Lund, Sweden)

13:30 Key note lecture : immunotherapy of cancer , a new mainstay in cancer treatment
Samir Khleif (Georgia Cancer Center, USA)

13:50 Unique aspects of immunotherapy of cancer agents
Steinar Aamdal (Oslo University Hospital /EMA Inter-Committee Scientific Advisory Group on Oncology, Norway)

14:10 Combination of immunotherapies in a development portfolio
Jose Saro (F. Hoffmann-La Roche , Switzerland)

14:30 Regulatory dilemmas in immunotherapy of cancer
Rosa Giuliani (S. Camillo-Forlanini Hospital. National Health System / EMA Scientific Advisory Group on Oncology, Italy)

14:50 Discussion

15:30 BREAK

PLENARY SESSION 5 : CHALLENGES IN COMBINING INNOVATIVE THERAPY

Chairs:
Steinar Aamdal (Oslo University Hospital / EMA Scientific Advisory Group on Oncology, Norway)
Alexandre Moreau (EMA Committee for Medicinal Products for Human Use, France)
Irmela Radtke (F. Hoffmann-La Roche, Switzerland)

16:00 Challenges in combining innovative therapy with standards of care
Heinz Zwierzina (Innsbruck University, Austria)

16:20 Identifying and developing best combinations in hematology/oncology
Michael Wenger (Genentech, USA)

16:40 Regulatory perspective
Ulrike Hermes (BfArM, Germany)

17:00 Discussion

PLENARY SESSION 6: CHOICE OF COMPARATORS

Chairs:
Lothar Bergmann (J.W. Goethe University/ EMA Scientific Advisory Group on Oncology, Germany)
Arlette Duvelleroy (Sanofi, France)
Silvia Marsoni (Cancer Institute of Candiolo - FPO-IRCCS, Italy)

17:30 Choice of comparator: labeled vs medical practice
Marina Garassino (Istituto Nazionale dei Tumori, Italy)

17:50 Industry point of view
Markus Kosch (Pfizer, Germany)

18:10 Regulatory perspective
Concha Prieto Yerro (Agencia Española de Medicamentos y Productos Sanitarios / EMA Committee for Medicinal Products for Human Use, Spain)

18:30 Discussion

19:00 END OF DAY 2

19:30 DINNER (@ hotel Restaurant)

DAY 3 WEDNESDAY 4 MARCH 2015

MEETING ROOM: INNSBRUCK

PLENARY SESSION 7 : THE CHALLENGE OF CLINICAL BENEFIT ASSESSMENT IN THE EVOLVING LANDSCAPE OF NOVEL CANCER THERAPIES

Chairs :
Ulrike Hermes (BfArM, Germany)
Markus Kosch (Pfizer, Germany)
John Smyth (The University of Edinburgh, UK)

09:00	Treatment Switching in Clinical Trials *Bernhard Wörmann (Deutsche Gesellschaft für Hämatologie und Medizinische Onkologie , Germany)*
09:20	PFS and PFS2 from a regulatory perspective: *Ulrike Hermes (BfArM, Germany)*
09:40	PFS vs. OS: How industry navigates through the endpoints *Stefan Schwoch (Eli Lilly, UK) & Markus Kosch (Pfizer, Germany)*
10:00	Discussion
10:15	BREAK
10:30	HTA / Payer assessment on clinical benefits in Europe: present and future *Bruno Flamion (University of Namur / Past Chair of the Scientific Advice Working Party EMA* *Past Chair of the Committee for Reimbursement of Medicines, Belgium)*
10:50	FDA assessment of clinical benefit *Tatiana Prowell (Office of Hematology & Oncology Products, FDA - Johns Hopkins Kimmel Cancer Center, USA)*
11:10	Regulatory point of view on clinical benefit assessment *Stiina Aarum (European Medicines Agency, UK)*
11:30	Discussion: Can we define common grounds?
12:30	CLOSURE OF THE MEETING
12:45	LUNCH (@ Business Center)

The Cancer Drug Development Forum (CDDF)

The Cancer Drug Development Forum (CDDF), previously known as the Biotherapy Development Association (BDA), is a not-for-profit association whose mission is to provide a unique platform to facilitate interactions between all stakeholders (academia, regulatory authorities, policymakers, the pharmaceutical industry and patient advocates) to improve the efficiency of cancer drug development.

For the past 14 years, CDDF has strived to leverage the discussion on the most promising advances in oncology drug development, uniting experts from academia, the pharmaceutical industry and regulatory authorities in the quest of overcoming the main challenges in cancer treatment.

For more information please visit:

www.cddf.org