EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

CDDF
Cancer Drug Development Forum

EMA-CDDF JOINT MEETING

CHALLENGES FOR THE APPROVAL OF ANTI-CANCER IMMUNOTHERAPEUTIC DRUGS

LONDON, UNITED KINGDOM – 4-5 FEBRUARY 2016

PROGRAMME

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Day 1 Thursday 4th February 2016

12:30 **Welcome and Introduction**
Enrica Alteri (European Medicines Agency, UK)
John Smyth (CDDF - University of Edinburgh, UK)

SESSION 1: THE CHALLENGES FOR THE DIFFERENT STAKEHOLDERS

Session chairs: *Bertil Jonsson (Medicinal Products Agency, Sweden)*
John Smyth (University of Edinburgh, UK)

12:40 **Keynote Lecture: status quo and upcoming concepts in immunotherapy of cancer**
Ira Mellman (Genentech, USA)

13:10 **Academic perspective**
Heinz Zwierzina (Innsbruck University, Austria)

13:25 **Industry perspective**
Eric H. Rubin (Merck, USA)

13:40 **Regulatory perspective**
Francesco Pignatti (European Medicines Agency, UK)

SESSION 2: LESSONS LEARNT

Session chairs: *Francesco Pignatti (European Medicines Agency)*
Elena Wolff-Holz (Paul-Ehrlich Institute, Germany)

Melanoma

13:55 **Academic perspective**
Paolo Ascierto (National Tumor Institute, Italy)

14:10 **Industry perspective**
Roger Dansey (MSD, USA)

14:25 **Regulatory perspective**
Paolo Foggi (Italian Medicines Agency - AIFA, Italy)

Non-Small Cell Lung Cancer (NSCLC)

14:40 **Academic perspective**
Enriqueta Felip (Hospital Vall d'Hebron, Spain)

14:55 **Industry perspective**
Catherine Weil (BMS, Belgium)

15:10 **Regulatory perspective**
Jorge Camarero Jiménez (Spanish Agency for Medicines and Medical Devices - AEMPS, Spain)

15:25 **Safety – Immune related Adverse Events (AEs)**
Aaron Hansen (Princess Margaret Cancer Centre, Canada)

15:40 **Panel Discussion**

16:00 Break

SESSION 3: POPULATION SELECTION

***Session chairs**: Maggie Cheang (Institute of Cancer Research,UK)*
Jorge Martinalbo (European Medicines Agency, UK)

Predictive biomarkers

16:30 **Biomarkers for PD-1/L1 inhibitors: regulatory considerations**
Marc Theoret (FDA, USA)

16:45 **Blueprint project PD-L1 coDx comparability**
Rasika Kalamegham (Genentech, USA)

17:00 **Novel biomarkers: pitfalls, limitations, emerging options**
Bernard A. Fox (Providence Portland Medical Center, USA)

17:15 **Panel Discussion**

Panellists : Pamela Bradley (FDA, USA - via TC), Dan Chen (Genentech, USA), Abigail McElhinny (Ventana, USA - via TC), Reena Philip (FDA, USA - via TC), Matthew Robson (BMS, USA), Eric H. Rubin (Merck, USA), Jill Walker (AstraZeneca, UK)

SESSION 4: OTHER STRATEGIES – PEPTIDES, CELL THERAPY

***Session chair**: Marnix Bosch (Northwest Biotherapeutics, USA)*
Martina Schüssler-Lenz (Paul-Ehrlich Institute, Germany)

17:45 **mRNA and peptide-based anticancer immunotherapies**
Michael Platten (German Cancer Research Center, Germany)

18:00 **Chimeric antigen receptor Tcell therapies**
Stanley Frankel (Celgene, USA)

18:15 **Regulatory view**

Thomas Hinz (Paul-Ehrlich Institute, Germany)

18:30 **Panel Discussion**

19:00 End of first day

20:00 CDDF Networking dinner

Day 2 Friday 5th February 2016

SESSION 5: ENDPOINTS, COMBINATIONS AND ANALYSIS

Session chair: *Robert Hawkins (University of Manchester, UK)*
Richard Kaplan (MRC Clinical Trials Unit at UCL, UK)

08:30 **Differences between the use of immunotherapy in the adjuvant as opposed to advanced setting**
Jessica Menis (EORTC, Belgium)

08:45 **Study design and analysis in late-stage cancer immunotherapy trials**
Tai-Tsang Chen (BMS, USA)

09:00 **How do we sequence or combine immunotherapies with targeted therapies: US perspective**
Samir Khleif (GRU Cancer Center, USA)

09:15 **How do we sequence or combine immunotherapies with targeted therapies: EU perspective**
Paolo Ascierto (National Tumor Institute, Italy)

09:30 **Challenges in developing novel-novel immuno-oncology combinations: contribution of components**
Ramy Ibrahim (AstraZeneca, USA)

09:45 **Panel Discussion**

10:15 Break

SESSION 6: HTA ASSESSING RELATIVE EFFICACY

Session chair: *Lothar Bergmann (Frankfurt University Hospital - SAG, Germany)*
Bruno Flamion (University of Namur, Belgium)

10:45 **Challenges in evaluating relative effectiveness**
Mira Pavlovic-Ganascia (MDT Services, France)

11:00 **Capturing added benefit**
Patrick Hopkinson (BMS, UK)

11:15 **Managed entry agreements**
Paolo Foggi (Italian Medicines Agency - AIFA, Italy)

11:30 **Patients' perspectives**
Francesco De Lorenzo (European Cancer Patient Coalition, Belgium)

11:45 **Patient Reported Outcomes: the impact of HRQOL**
David Cella (Northwestern University, USA)

12:00 **Panel Discussion**

SESSION 7: WRAP UP – FUTURE PERSPECTIVES

12:30 **Final panel discussion**

13:00 End of the meeting and lunch

Event Outline

Immunotherapy is becoming a fast growing area of new medicinal products in oncology. These new agents have brought important advances in patient care and have considerably changed the landscape of treatment options in melanoma and lung cancer patients. However, there are still many challenges on how to bring these agents through regulatory approval and into clinical practice. Appropriate patient population selection, new clinical trials designs, rational for the mechanism of action in different tumour types, innovative immunological-based products used in combination and assessing relative efficacy of these novel immunomodulating therapies are some of the key issues that will be addressed in a workshop organised jointly by the European Medicines Agency (EMA) and the Cancer Drug Development Forum (CDDF) together with a multi-stakeholder audience of academics, regulators and industry representatives. The aim is to address these highly relevant issues and their impact on the regulatory environment.

Programme chairs

- Francesco Pignatti (European Medicines Agency, UK)
- Silvy da Rocha Dias (European Medicines Agency, UK)
- Jan Schellens (Netherlands Cancer Institute, Netherlands)
- Martina Schüssler-Lenz (Paul-Ehrlich Institute, Germany)
- John Smyth (CDDF-University of Edinburgh, UK)
- Elena Wolff-Holz (Paul-Ehrlich Institute, Germany)

Meeting Venue

European Medicines Agency
30 Churchill Place
Canary Wharf
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Meeting Secretariat

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