

BDA 5th Alpine Meeting
3rd – 5th March 2010
Innsbruck, Austria

Wednesday March 3rd

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

18.15 Panel discussion –
Moderators Heinz Zwierzina, Christopher McCabe

18.30 Close of the day

Thursday March 4th

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

[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 - S. Dickin

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

Friday march 5th

[Plenary session: 4](#)

8.30 Immunotherapy development – what are the issues

Chair: L. Hakansson, M. Schuessler-Lenz, W. Wein

8.45 The development challenge with anti-cancer vaccines - C. Weil

9.00 Challenges of clinical development in the adjuvant setting in non-metastatic renal tumours - P. Srivastava

9.15 Strategic challenges of an anti-cancer vaccine development in NSCLC - J .P. Marschner

9.30 An academic perspective on anti-cancer immunotherapy approaches - L. Hakansson

9.45 Outline of the methodologies applied by the Committee for Advanced Therapies in evaluation of anti-cancer vaccines - M. Schuessler-Lenz

10.00 Discussion

10.30 Coffee

Chairs: Leif Hakansson, Harish Dave

11.00 Biomarkers – the future generation?

11.00 Report from BDA Proteomics Meeting Berlin - H. Zwierzina

11.40 Report from BDA Biomarker Brussels Meeting - L. Hakansson, A. deBock, B. Jonsson

12.15 Novel biomarkers in drug development: microarrays, circulating tumour cells and beyond - B. Berns

12.30 Discussion

12.30 Summary and close of meeting

H. Zwierzina