Combination New Molecular Entities in Oncology – Opportunities and Challenges

7th December 2010

The Crowne Plaza Hotel, Brussels Airport

Session 1: Why the need for the combination of New Molecular Entities (NME'S)
Chairs: Leif Hakansson, Bertil Jonsson, Mark Hope

8.30 Welcome and Introduction - Heinz Zwierzina

8.45 An NCI Perspective on Combination Studies with NME's in oncology - Percy Ivy

9.15 How are the current unmet clinical needs being met - what are the deficiencies and how can combination new molecular entities (NME's) help? - Mike von Euler

9.45 Issues and challenges in the evaluation of combination new molecular entities - Alan Barge

10.15 A European Regulatory Perspective on combination new molecular entities - Bertil Jonsson

10.45 Update on discussions in the USA - Brookings Institute overview and next steps - Adam Clark

11.15 Coffee and refreshments

Session 2: The preclinical and early clinical studies
Chairs: Max Scheulen, Harald Enzmann, Chris Schoenlein

11.30 The scientific basis for combination of new molecular entities in oncology - Yoseph Yarden

12.00 Identification and validation of biomarkers in combination studies with new molecular entities - Ian Ellis

12.30 The challenges of designing and setting up combination Phase 1 trials with novel molecular compounds - Bruno Osterwalder

13.00 Regulatory thoughts on the challenges of product approvals with combination new molecular entities - Harald Enzmann

13.30 Buffet Lunch

Session 3: Clinical Phase II-III studies
Chairs: Lothar Bergmann, Pierre Demolis, Stefan Schwoch

14.30 Establishing the relative effect - Phase II vs Phase III approaches - Max E. Scheulen

15.00 Trial designs to establish the active contribution of each new molecular entity - Andy Stone

15.30 Coffee and refreshments

Session 4: Wrapping it all up and next steps
Chairs: John Smyth, Eva Skovlund, Mark Hope

15.45 Open forum discussion, key messages and next steps

17.00 Conclusions and close the meeting - John Smyth