

## **Market Patient Access to New Oncology Products in Europe**

Brussels, 29th November 2007

09.30 Coffee and welcome

Chairs: Lothar Bergmann, Bengt Jönsson, Mikael von Euler

10.00 Conference opening address - Heinz Zwierzina

### Session 1

#### Regulatory Endpoints for new oncology studies

10.10 - 10.30 A review of the current global challenges -Nils Wilking

10.30 - 10.40 Discussion

10.40 - 11.00 An industry perspective on the importance of agreed endpoints for pivotal studies - Mikael von Euler

11.00 - 11.10 Discussion

11.10 - 11.30 The limited evidence base with new biologics in cancer is there room to consider paradigm changes? - Karl-Josef Kallen

11.30 - 11.40 Discussion

11.40 - 12.00 The challenge faced by the regulatory authorities - Harald Enzmann

12.00 - 12.30 Panel discussion

12.30 - 13.30 Buffet lunch

### Session 2

#### New access and pricing strategies for oncology products - What can be done?

Chairs: Nick Bosanquet, Nils Wilking and Chris Teale

13.30 - 13.50 Conditional coverage, reimbursement and risk share scenarios - Paul Trueman

13.50 - 14.00 Discussion

14.00 - 14.20 Biologics production - a more flexible scenario required - Christopher McCabe

14.20 - 14.30 Discussion

14.30 - 14.50 The dilemma of balancing clinical outcomes and cost effectiveness for new oncology products - how can it be resolved? - Britta Paschen

14.50 - 15.00 Strategies for reform in cancer care provision - Nick Bosanquet

15.00 - 15.30 Panel discussion

15.30 - 16.00 Coffee break

### Session 3

Moving forward - What needs to happen for new oncology products in Europe?

Chairs: Paul Trueman, Harald Enzmann and Don Newling

16.00 - 16.10 The perspective of the Regulatory Authorities - Bertil Jönsson

16.10 - 16.20 The perspective of Industry- Raf De Wilde

16.20 - 16.30 The perspective of the payers - Mark Harries

16.30 - 16.40 The perspective of the postregulatory agencies - Carole Longson

16.40 - 17.30 Open Forum Discussion

17.30 - 17.40 Meeting summary and close - Heinz Zwierzina