Paediatric Oncology Workshop - Enhancing the Efficacy of Cancer Drugs - the need for a paradigm shift

5th-6th December 2011
London, United Kingdom

BDA WORKSHOP IN COLLABORATION WITH ITCC, ENCCA AND EMA

New Oncology Drug Development for Children and Adolescents in Europe: Current Status and where to go?

There is a major need for new oncology drugs for children and adolescents with cancer to increase cure rate and quality of cure.

In January 2007, the European Union Paediatric Regulation was introduced with the objective to improve the health of children in Europe by:

- Facilitating the development and availability of medicines for children aged 0 to 17 years;
- Ensuring that medicines for use in children are of high quality, ethically researched and authorised appropriately;
- Improving the availability of information on the use of medicines for children.

In 2011, ENCCA, an EU-funded Network of Excellence, was launched to structure clinical and translation research in paediatric and adolescent oncology in Europe.

The Workshop will:

- share recent advances in the field of paediatric oncology,
- evaluate the impact of the EU and US regulations on paediatric oncology,
- propose solutions to identified bottlenecks and hurdles.

All stakeholders will participate: Academia, Parents and Patients, Pharma Industry, European Medicine Agency, EMA Paediatric Committee, Government bodies, Members of the Parliament
The goal of the meeting is to provide an action plan in order to increase the likelihood that children and adolescents with cancer will benefit from new, safe, efficacious and age-appropriate medicines and from EU funded structuring activities along the lines of the EU Paediatric Medicine Regulation.

The meeting will be published in European Journal of Cancer.

Monday, 05 December 2011

09.30am – 09.40am
Welcome and Introduction of the meeting:
Heinz Zwierzina (BDA), Gilles Vassal (ITCC-ENCCA)

I. Session 09.40am – 10.40am
Chair: Pierre Demolis, CHMP
Setting up the landscape
09:40 The needs for innovative therapies for children and adolescents with cancer. Andy Pearson, Royal Marsden, ITCC

10.00 Developing oncology drugs in adults in the era of personalised medicine. Raphael Rousseau, Roche
10:20 Approving oncology drugs in the era of personalised medicine. Ralf Herold, EMA

II . Session 10.40am – 12.00am
Chair: Kathy Pritchard Jones, UCL, ENCCA
New oncology drugs for children and adolescents: Where are we? What are the issues?
10:40 Impact of the EU and US regulatory initiatives: point of view from each stakeholder
EMA – Ralf Herold
EU Cooperative groups – Bruce Morland, Birmingham, ITCC
FDA – Greg Reaman
COG – Peter Adamson, Chair of COG (USA)
Industry 1 – Max Wegner, Bayer
Industry 2 – Angela Howes, Janssen R&D

Coffee Break

Round table discussion 12.15pm – 01.45pm
Chair: Gilles Vassal, ITCC
Patricia Blanc – Imagine for Margo
Daniel Brasseur – PDCO
Ruth Ladenstein – CCRI, Vienna, ENCCA
Agnès Saint Raymond – EMA
Stefan Schwoch – Lilly

Lunch Break

Parallel breakout sessions 02.30pm – 04.15pm

Breakout session 1
Chairs: Andy Pearson, ITCC; Katrin Rupalla, Celgene; Lynley Marshall, EMA
How to improve early access to innovative drugs and meeting the needs of children and adolescents in Europe?

Breakout session 2
Chairs: André Baruchel, ITCC; Henk van den Berg, PDCO; Stephan Schwoch, Lilly
How to prioritise oncology compounds for development in children and adolescents with cancer?

Coffee Break

Wrap up 04.30pm – 06.30pm
Chair: Lothar Bergmann, BDA
Early access to innovative drugs for children and adolescents in Europe
04:30 The Strategy for New Drug development by disease Gilles Vassal, ITCC-ENCCA
04:45 Integrating paediatric oncology drug development in the strategy of Pharmaceutical companies Raphael Rousseau, Roche
05:00 Summary and proposal by the Breakout session group 1 – chairs

Prioritisation oncology drugs
05:30 The PPTP and TARGET NCI initiatives Malcolm Smith, Bethesda
05:45 The KidsCancerKinome project Huib Caron, Amsterdam
06.00 Summary and proposal by the Breakout Session group 2 - chairs

Reception

Tuesday, 06 December 2011

How safe is the drug 08.30am – 09.15am

Chair: Malcolm Smith, Bethesda
08:30 Handling early non-clinical and clinical Safety signals Jacqueline Carleer, PDCO
08:50 Paediatric safety: a sponsor perspective Jeffrey Skolnik, Astra-Zeneca

Parallel breakout sessions 9.15am – 10.45am

Breakout session 3

Chairs: Angela Howes, Janssen R&D; Koen Norga, PDCO; Lars Hjorth, Pancare
How to set up long term follow up of children and adolescents exposed to new drugs and make it available for all stakeholders?

Breakout session 4

Chairs: Bruce Morland, ITCC; Stephanie Mondabon, Bayer; Ralf Herold, EMA
How to facilitate cooperation and collaboration between all stakeholders?

Coffee Break

Wrap up 11.00am – 12.00pm

Chair: Heinz Zwierzina, BDA
Long term follow-up
11:00 Summary and proposal by the Breakout session group 3 - chairs
Cooperation between all stakeholders
11:30 Summary and proposal by the Breakout session group 4 - chairs
Conclusion and action plan 12.00am – 12.30pm
12:00 Conclusion and action plan Gilles Vassal, Ralf Herold, Lothar Bergmann

Lunch Break