



PRESS RELEASE

CDDF facilitates dialogue between academia, industry and regulators.

Brussels 23 September 2014: The Biotherapy Development Association (BDA) has announced a change of name to the Cancer Drug Development Forum (CDDF).

“While our focus was initially around immunotherapy, in recent years we have embraced all forms of cancer drug development and therefore wanted a name that better reflects our breadth of interests,” said CDDF chairman Professor Heinz Zwierzina.

The CDDF, founded in 2001 as the BDA, aims to facilitate interactions between academia (both preclinical and clinical scientists), industry, regulatory authorities, patient advocacy groups and health technology assessors. Each year, the not-for-profit organization hosts four to five workshop meetings in locations across Europe and every 18 months the longer Alpine meeting. “Our aim is to facilitate frank discussions and find ways to expedite effective drug development and delivery,” explained Zwierzina, from Innsbruck Medical University, Austria.

Recent workshops have featured biomarker based drug development, oncology drug development for children, bench to bedside in breast cancer management, access to innovative oncology medicines in Europe, and accelerating patient access to innovative drugs. Additionally a three day Alpine meeting, held every 18 months in Innsbruck, Austria, allows for more in depth explorations of current and future challenges in oncology drug development.

Meetings are overseen by the board of eight clinical scientists and statisticians and funded by registration fees and unrestrictive educational grants from multiple pharmaceutical companies. “A unique aspect of our workshops is that they operate Chatham house rules,” said CDDF board member Professor John Smyth. This, he explained, is where attendees are free to use the information from discussions but not to reveal who made the comments.

The “Minimal Residual Disease and Pathological Complete Response: Endpoints in Clinical Trials” workshop, held in London this May, broke new ground when European Medicines Agency (EMA) representatives were present to listen to a debate on the EMA’s draft concept paper on minimal residual disease in chronic lymphocytic leukaemia (CLL) that was out for consultation. “This allowed the EMA to get a real feel for the strength of feeling and agreement and disagreement,” said Smyth, from University of Edinburgh, UK.

In addition to wanting to hold more future events around EMA consultations, the CDDF hope to encourage representatives from health technology assessments organizations to attend meetings. “This would allow us to involve all the players in drug development and really take issues around cost effectiveness into consideration,” said Smyth.

The new paradigm of precision [also known as personalized medicine] while enormously exciting throws up a myriad of complex issues that the CDDF plan to consider. “Where once we thought that cancers such as breast, colon, lung, and melanoma could be subdivided by pathologists into a small number of subsets we now appreciate an ever increasing diversity within these pathological groups,” said Smyth.



The evolving landscape, he added, will need a careful rethink of clinical trials, since in future smaller numbers of patients will be eligible for individual trials which may take longer to recruit. There will also be a need for robust genetic and proteomic profiling to assign more precise medicines. Identifying such needs the CDDF is holding a Workshop on Companion Diagnostics in Brussels, 11 to 12 December 2014 which will explore issues such as the importance of quality assurance.

Furthermore, the CDDF's new Biomarker Initiative, which will be led by Leif Hakansson, the Vice chair of the CDDF, will be launched during the Immunotherapy of Cancer Conference (ITOC-2) next March. "The project recognises that immune therapy is evolving at a rapid pace, that treatments will be expensive and that all the stakeholders need to be involved in developing biomarkers to select the most appropriate patients," explained Hakansson, from the University of Lund, Sweden.

Cancer biomarkers are present in tumor tissues or serum and encompass a wide variety of molecules, including DNA, mRNA, transcription factors, cell surface receptors, and secreted proteins. They have a variety of uses including helping doctors decide which patients are likely to respond to given drugs. "First we plan to brainstorm to list all the biomarkers that have been identified and then facilitate use of biomarkers in clinical trials," said Zwierzina.

Upcoming CDDF meetings include:

- CDDF Society Session at ESMO Congress at 14.15 on 27 September 2014 at the IFEMA-Feria de Madrid. The session, which is open to all ESMO delegates, will look at how to improve equal access to innovative oncology drugs across Europe.
- Workshop on Companion Diagnostics, held in Brussels, Belgium, 11-12 December, 2014.
- Prioritization in Paediatric Oncology Drug Development, Vienna, Austria, 5-6 February, 2015.
- 8th Alpine Meeting: Current and Future Challenges of Innovative Oncology Drug Development, Innsbruck, Austria 2-4 March 2015.
- 2nd Immunotherapy of Cancer Conference (ITOC-2) held in Munich, Germany, 25 to 27 March 2015.

Interviews

At the ESMO meeting in Madrid, Professor Heinz Zwierzina and Professor John Smyth will be available for one to one briefings about the work of the CDDF. To arrange interviews please visit the CDDF booth (S35 at ESMO) or email: marjorie.recorbet@ecco-org.eu

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