CDDF
Cancer Drug Development Forum

CDDF MULTI - STAKEHOLDER WORKSHOP

MINIMAL RESIDUAL DISEASE (AML - CLL)

London, United-Kingdom
8 - 9 November 2018

PROGRAMME

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DAY 1: Thursday 8th November 2018

INTRODUCTORY SESSION

Co-chairs: Ralf Herold (EMA, UK) & John Smyth (CDDF/University of Edinburgh, UK)

12:30 **Welcome and Introduction into the Topic**
Axel Glasmacher (CDDF, DE)

13:00 **Regulatory Aspects – AML & CLL**
Beatriz Flores (EMA/MHRA, UK)

WORKSHOP ON MRD IN AML

Co-chais: Konstanze Döhner (University Hospital of Ulm, DE) & Nicole Gormley (FDA, USA)

13:30 **New Developments in AML**
Gerhard Ehninger (Technishe Universität Dresden, DE)

14:00 **Clinical Overview MRD in AML**
Konstanze Döhner (University Hospital of Ulm, DE)

14:45 **European LeukemiaNet Guidelines**
Arjan Van De Loodsdrecht (VU University Medical Center, NL)

15:30 Coffee break

16:00 **Methodological Overview MRD in AML**
Chris Hourigan (National Institutes of Health, USA)

16:45 **Standardization of MRD Measurement**
Christian Thiede (Technische Universität Dresden, DE)

17:30 **Consortium on MRD in AML and Industry Perspective**
Sharon McBain (Johnson & Johnson, USA)

18:15 **Roundtable discussion**

18:45 End of Day 1

19:30 Networking event

DAY 2: Friday 9th November 2018

08:00 **Regulatory Aspects AML & CLL**
Nicole Gormley (FDA, USA)

WORKSHOP PROGRESS ON MRD IN CLL

Co-chairs : Robert Gale (Celgene, USA) & Andy Rawstron (Leeds Teaching Hospitals NHS Trust, UK)

08:30 **Clinical Overview: MRD in CLL**
Mathias Ritgen (University Medical Center Schleswig-Holstein, DE)

09:15 **Methodological Overview: MRD in CLL**
Andy Rawstron (Leeds Teaching Hospitals NHS Trust, UK)

10:00 **Industry Perspective**
Davy Chiodin (Acerta/AstraZeneca, USA)

10:30 Coffee break

ROUNDTABLE: LESSONS LEARNED AND OPEN QUESTIONS FOR AML & CLL, NEXT STEPS

Moderator: John Smyth (CDDF/University of Edinburgh, UK)

11:00 **Regulators** (B. Flores, N. Gormley), **Academia** (K. Döhner, A. Rawstron), **Industry** (D. Chiodin, C. Pallaud, I. Radtke)

12:30 End of workshop

Event Outline

- The success of new treatment options has transformed the prognosis of many patients with haematological malignancies. Now, median progression-free survival is over five years for many entities and populations.
- To ensure a timely and cost-effective assessment of new therapeutic options, there is need for alternative response evaluation methods that allow regulatory assessment of investigational compounds in an earlier time-frame than the traditional endpoints of progression-free survival and overall survival.
- Minimal (or rather measurable) residual disease (MRD) has come to the forefront of these efforts as novel therapies achieve high rates of complete remissions by conventional criteria and more sensitive measures are needed to predict long-term outcomes.
- The use of MRD in hematologic malignancy trials is rising among other clinical endpoints. In a recent analysis (Gormley N et al., JCO 2017; 35: 2541) nearly 40% of applications submitted to the FDA Division of Hematology Products between 2014 and 2016 included MRD data. While the data submitted was deemed adequate for inclusion in the PI in 46% of cases, 31% of applications contained MRD data that the Agency deemed un-interpretable.
- Regulatory agencies have released guidelines that acknowledge the need for alternative endpoints and describe the use of MRD endpoints and what is needed to move further.
- CDDF multi-stakeholder workshop on MRD have been held in 2014 (breast cancer and haemotological malignancies) and in 2017 (Multiple Myeloma) and have generated useful discussions and reports for the further development of the field (www.cddf.org).
- In Acute Myeloid Leukemia (AML) and in Chronic Lymphatic Leukemia (CLL) new data and scientific guidelines have moved the field forward and warrant an updated discussion.
- This workshop will focus on current status and next steps for the use MRD in AML and CLL clinical trials as well as on open exchange, learning and collaborative search for agreements from regulatory, academic and industry perspectives.

Programme committee

- CDDF Board: Axel Glasmacher, John Smyth
- Industry: Davy Chiodin (Acerta/AstraZeneca), Celine Pallaud (Novartis), Irmela Radtke (Roche)
- Regulatory Agencies: To be announced

Target Audience

The target is a multidisciplinary audience of hematologists-oncologists, research scientists, government officials (EMA, FDA, HTA representatives), pharmaceutical industry, assay developers, patient representatives and policymakers

Workshop venue

Radisson Blu Edwardian New Providence Wharf Hotel
5 Fairmont Avenue
London E14 9JB