



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

6 July 2015
EMA/330325/2015
Human Medicines Development and Evaluation

Agenda - First line APL treatment. EU cooperative groups and the pharmaceutical industry

6 July 2015 – Meeting Room 3-F, 14:00 – 17:00

Chairs: Pierre Fenaux/Francesco Lo Coco

Co-Chair: Pierre Demolis (EMA)

Workshop on First line APL treatment. EU cooperative groups and the pharmaceutical industry

6 July 2015, 14:00 – 17:00

Item	Agenda	Name	Time
1.	Introduction (objectives of the meeting)	Pierre Demolis	5' (14:00-14:05)
2.	Historical perspective	Pierre Fenaux	10' (14:05-14:15)
3.	Front-line treatment of APL • APL0406 • AML17	Francesco Lo Coco Alan Burnett	20' (14:15-14:35)
4.	Patient perspective	Jan de Jong	10' (14:35-14:45)
4.	Regulatory perspective – Current ATO license - Paradigms for approval for rare disease: data requirements and incentives	Elias Péan	10' (14:45-14:55)

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5.	Beyond approval, the HTA perspective	Paolo Foggi (AIFA)	10' (14:55-15:05)
6.	Industry perspective	Beatrix Friedeberg Udo Mueller	15' (15:05-15:20)
<i>Coffee-break</i>			30' (15:20-15:50)
7.	Discussion	All	60' (15:50-16:50)
8.	Wrap-up	Lo Coco/Demolis	10' (16:50-17:00)