EURORDIS
ROUND TABLE OF COMPANIES

20th Workshop

EURORDIS Round Table of Companies (ERTC)

A 10 Year Anniversary Workshop!

Unlocking Europe's Potential in Rare Disease Therapies

Wednesday 26 February, 2014 (9:30 to 16:00)
Le Plaza Brussels, Belgium

AGENDA

Morning session chaired by: • **Dr. Sabine Jülicher** (Head of Unit Medicinal Products- authorisations, EMA. DG SANCO D5, EC) • **Dr. Richard Bergström** (Director General of EFPIA)	
9:30 – 9:50	**Welcome address**: **Mr. Yann Le Cam** (Chief Executive Officer, EURORDIS)
9:50 – 11:20	*A Multi-Stakeholder Common Vision for Success by 2020*
9:50 -10:20	Presentation by representatives of the EBE-Europabio Task Force on Rare Diseases and Orphan Medicines: • **Ms. Wills Hughes-Wilson** (VP External Affairs, SOBI; Chairperson of the EBE-OMP Task Force) • **Dr. Kevin Loth** (Executive Director, Corporate Affairs & Policy EMEA, Celgene; Vice-Chair of the EBE-OMP Task Force)
10:20 -10:50 (or 11:00)	**Panel discussion** involving leaders of OMP companies: Shire: **Kim Stratton** (Head International Commercial); SOBI: **Dr. Geoffrey McDonough** (President & CEO); Pfizer: **Dr. Adam Heathfield** (Senior Director, Worldwide Policy); BioMarin: **Mr. James Lennertz** (VP General Manager EUMEA); Sigma-Tau Rare Diseases: **Dr. Marco Brughera** (Global Head, Business Unit)
10:50 – 11:20	Coffee break
11:20 - 11:35	**How Can Regulation Stimulate Therapeutic Innovation?** 15' **Dr. Fernand Sauer** (Honorary Director General, European Commission/ Former EMA Executive Director; Member of the French National Council for Public Health)
11:35 – 11:50	**How Can EMA Support Therapeutic Innovation across its Activities?** 15' **Dr. Jordi Llinares Garcia** (Head of Product Development Scientific Support, EMA)
11:50 – 12:20	**How Can Patients Contribute to Therapeutic Innovation?** 15' **Ms. Flaminia Macchia** (Director for European Public Affairs, EURORDIS)
12:20 – 12:50	Panel discussion with leaders of OMP Companies
13:00 – 14:30	LUNCH

Afternoon session chaired by: • **Dr. Marlene Haffner** (Former Director of the Office of Orphan Products Development (OOPD), FDA) • **Prof. Bruno Sepodes** (Chairperson of the Committee for Orphan Medicinal Products (COMP), EMA and Univ. Lisbon)	
14:30 – 16:00	*Opportunities for Orphan Medicinal Products in the Research Agenda 2014-2020*
14:30 – 14:45	**State of play at 150th COMP Meeting and 1200 Orphan Drug Designations** – 15' **Prof. Bruno Sepodes** (COMP, EMA)
14:45 – 15:00	**Success Factors for Research into Orphan Drug Development** – 15' **Dr. Ségolène Aymé** (International Affairs Director, Orphanet, and IRDiRC Scientific Secretariat) – Presented by **Virginie Hivert** (Pharmaceutical Affairs and Expert Resources Team Manager, Orphanet - Inserm, France)
15:00 – 15:15	**Horizon 2020 and Rare Disease Therapies** – 15' **Dr. Irene Norstedt** (Head of Unit: Innovative and Personalised Medicine, DG Research, European Commission)
15:15 – 15:30	**Innovative Medicines Initiative (IMI) 2 and Rare Disease Therapies** – 15' **Prof. Michel Goldman** (Executive Director, Innovative Medicines Initiative - IMI)
15:30 – 16:00	**Panel discussion** with leaders of OMP companies Shire: **Kim Stratton** (Head International Commercial); SOBI: **Dr. Geoffrey McDonough** (President & CEO); Pfizer: **Dr. Adam Heathfield** (Senior Director, Worldwide Policy); BioMarin: **Mr. James Lennertz** (VP General Manager EUMEA); Sigma-Tau Rare Diseases: **Dr. Marco Brughera** (Global Head, Business Unit)
16:00	Meeting ends