



Press Release – July 9, 2009

Two EURORDIS patient representatives appointed to the Committee for Orphan Medicinal Products of the European Medicines Agency

EURORDIS welcomes the appointment of two of its members as patient representatives at the Committee for Orphan Medicinal Products (COMP) of the European Medicines Agency (EMA). Ms Lesley Greene has been elected as member of the Committee for the first time and Ms Birthe Byskov Holm has been elected for the third consecutive time. They are both two long-standing and active members of the rare disease community and bring over 20 years experience working with rare disease patients and orphan drugs.

Birthe Holm has been involved in rare diseases since her son Michael was diagnosed with Osteogenesis Imperfecta (OI) in 1983. After having been actively involved in the Danish OI Association, she founded the Danish national alliance for rare diseases, of which she is currently Vice President. She is also the Chair of the Board of the Danish Centre for Rare Diseases and Handicaps, and is an active member of the European OI Federation.

Birthe was first nominated based on her extensive experience working for patient groups in collaboration with health regulators and professionals. After six years serving at the COMP, she has a deep understanding of regulatory affairs, clinical development and research stimulation, as well as widespread contacts with patients from a broad range of rare diseases. She also brings to the position a degree in law, and a professional background in public service. She is fluent in English and has been promoting the Orphan Drug Regulation at conferences and workshops all over Europe.

Lesley Greene has been appointed as a new member of the COMP. As the mother of a patient affected by the rare metabolic disease cystinosis, she contributes her personal experience with clinical trials and a solid knowledge of the drug development process.

As a result of her interest in orphan drugs and active exchanges with US based patient groups, Lesley was instrumental in starting discussions about orphan drug legislation in Europe. She strongly advocated for the adoption of the Orphan Drug Regulation in Europe in 1999, and subsequently served as President of EURORDIS from 2001 to 2003. She is also the founder of the UK charity CLIMB (Children living with Metabolic Inherited Diseases), which she created to improve the lives of those affected by metabolic diseases and to raise awareness of their impact.

The COMP was the first scientific committee at the EMA where patients were represented. Since the appointment of Yann Le Cam, CEO of EURORDIS, in 2000, patient representatives have been actively involved in the decisions of the Committee and have traditionally occupied the Vice Chairmanship. Mr Le Cam stepped down from his position as Vice Chair and patient representative in April 2009. He leaves a

legacy of fruitful collaboration, which will be taken on with the same degree of enthusiasm and commitment by the three patient representatives currently sitting at the Committee.

Patient representatives at the COMP have opened the way for increased patient representation at the EMEA. EURORDIS patient representatives are also present in other EMEA Committees and Working Parties: Patients' and Consumers' Working Party (PCWP), since 2005; the Paediatric Committee (PDCO), since 2008 and, most recently, the Committee for Advanced Therapies (CAT).

"With these six recent appointments in the relevant EMEA Scientific Committees and Working Parties, EURORDIS is in a unique position to best represent and serve patients living with rare diseases in the EU Drug Regulatory Agency EMEA as well as in the international drug development and clinical trials pathways," says Yann Le Cam, CEO of EURORDIS and former Vice Chair of the COMP.

Contact person:

Paloma Tejada
Communications Manager
EURORDIS
Tel. 33 (1) 56.53.52.61
e-mail: paloma.tejada@eurordis.org

About the COMP

The Committee for Orphan Medicinal Products (COMP) is responsible for reviewing applications from persons or companies seeking 'orphan medicinal product designation' for products they intend to develop for the diagnosis, prevention or treatment of life-threatening or very serious conditions that affect not more than 5 in 10,000 persons in the European Union.

The COMP is also responsible for advising the European Commission on the establishment and development of a policy on orphan medicinal products in the EU, and assists the Commission in drawing up detailed guidelines and liaising internationally on matters relating to orphan medicinal products. For more information visit the EMEA website at : www.emea.europa.eu

About EURORDIS

The European Organisation for Rare Diseases (EURORDIS) represents more than 350 rare disease organisations in 39 different countries, covering more than 1,000 rare diseases. It is therefore the voice of the 30 million patients affected by rare diseases throughout Europe.

EURORDIS is a non-governmental patient-driven alliance of patient organisations and individuals active in the field of rare diseases, dedicated to improving the quality of life of all people living with rare diseases in Europe. It is supported by its members and by the French Muscular Dystrophy Association (AFM), the European Commission, and corporate foundations and the health industry. EURORDIS was founded in 1997. Further details concerning EURORDIS and rare diseases are available at: <http://www.eurordis.org>