Press Release - 26 April 2007

EURORDIS welcomes the final adoption by the European Parliament of the proposed Advanced Therapy Medicinal Products Regulation on 25 April 2007

Paris - 26 April 2007 - EURORDIS, the European Organisation for Rare Diseases, welcomes the adoption by the European Parliament, on 25 April 2007, of the Regulation on Advanced Therapy Medicinal Products at first reading. The vote by the plenary recognises the importance of this Regulation for patients and their families who place high hopes on promising advanced therapies for the development of life-saving treatments in the field of rare diseases.

"The vote is great news for European rare diseases patients. The Regulation establishes a robust centralised procedure for assessing the safety, efficacy and quality of advanced therapies. This is of paramount importance to rare disease patients, who most of the time lack any kinds of treatments," says Flaminia Macchia, European Public Affairs Officer at Eurordis.

The purpose of the new Regulation is to facilitate research, development and authorisation of advanced therapy products to improve patient access to them. The key measures in the Regulation are:

- the creation of a central marketing authorisation procedure for advanced therapy products;
- the creation of the Committee for Advanced Therapies (CAT) within the European Medicines Agency (EMEA) to provide advice in the process ; the CAT will be in charge of developing criteria and guidelines for the evaluation of these products;
- the provision of technical and risk management requirements to ensure quality and safety.

Eurordis wishes to express its deep gratitude to all the members of the European Parliament who have listened to the needs of European patients regardless of their political belonging and voted in favour of the compromise package tabled by the PES, ALDE and GUE/NGL.

EURORDIS also wishes to express particular gratefulness to the three MEPs (Dagmar Roth-Behrendt, Frédérique Ries and Adamos Adamou) who demonstrated political courage and restored the outcome of the informal negotiations with the Council and Commission - which had been interrupted by the rapporteur Mikolasik - thereby allowing the adoption of the Regulation at first reading.

Eurordis represents more than 300 rare disease organisations in 33 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.

More information:

Eurordis' past article on advanced therapies:
http://www.eurordis.org/article.php3?id_article=990

European patients' statement (April 2007)
http://www.eurordis.org/IMG/pdf/patients_statement_advanced_therapies_april07.pdf

European patients' call to MEPs to support the compromise package (April 2007)
http://www.eurordis.org/IMG/pdf/advanced-therapies-support_compromise_package-2007.pdf

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Contact person:
Jerome Parisse-Brassens
Communications Officer
Tél : +33 1 56 53 52 61
www.eurordis.org

About EURORDIS

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