

## EXTRAORDINARY INFORMATION

### **Egis is first to launch biosimilar monoclonal antibody within the European Union**

Egis Pharmaceuticals PLC announces that, the European Commission has approved the marketing authorization of Remsima™ containing the active ingredient infliximab for the indications of its reference originator product, Remicade® such as rheumatoid arthritis, pediatric and adolescent Crohn disease, pediatric and adolescent colitis ulcerosa, spondylitis ankylopoetica, arthritis psoriatica, psoriasis.

This is a milestone for European healthcare, as Remsima™ is the first biosimilar monoclonal antibody (mAb) to receive approval from the European Commission based on the European Medicines Agency's opinion. With its launch, Egis pioneers the biosimilar mAb therapies, providing patients wider access to advanced, affordable and more cost-effective treatment of autoimmune diseases in Central Eastern Europe.

Monoclonal antibodies have brought breakthrough advances in the treatment of cancer and autoimmune disorders providing new chance for survival or better quality of life for hundreds of thousands of patients around the world. However, it is becoming increasingly difficult for governments to provide access for all eligible patients to these highly effective, yet costly therapies. Patients in lower income European countries have significantly less access to biological treatment, primarily due to reasons of unaffordability.

Biosimilar mAb medicinal products provide less costly treatment without compromising the quality of care, thus offer the potential to improve patient access to biological medicines and to contribute to the financial sustainability of EU healthcare systems.

As communicated earlier Egis and the Korean biopharmaceutical company, Celltrion Group signed a collaboration agreement in 2010 for the distribution of 8 biosimilar products. Remsima™/Flammegis® (infliximab) is the first product among those specified in the cooperation agreement. Egis gained exclusive rights for the distribution of these mAbs in 5 CIS countries including Russia, and semi-exclusive rights in further 12 countries including the CEE region.

Based on the European Commission's marketing authorization and on the agreement with Celltrion Egis will launch Remsima™ in Central and Eastern European countries, namely in Bulgaria, Czech Republic, Hungary, Latvia, Lithuania, Poland, Romania and Slovakia.

In the past months Flammegis® (infliximab) has been granted marketing authorization in Azerbaijan, Belorussia, Georgia, Kazakhstan and Moldova. Flammegis® is the trademark of Egis for biosimilar infliximab in the CIS countries.

In order to deliver the therapeutic value of Remsima™/Flammegis® to patients and healthcare systems Egis is committed to work together with payers, policy makers and prescribers in establishing sustainable market access for this new class of medicines.

### **About Celltrion**

Celltrion Group is a leading biopharmaceutical group of companies in Korea specializing in monoclonal antibody capabilities to develop, manufacture and distribute biologics that contribute to human life. Based on its world-class technology in monoclonal antibody manufacturing, Celltrion achieves strategic collaboration with a number of global pharmaceutical companies. In addition, Celltrion is in preparation to be an initiative on newly emerging world mAb biosimilar market with its advanced development technology and state-of-the-art facility. Now Celltrion develops large portfolio of biosimilar products of blockbuster biologics.

### **About Egis**

Egis Pharmaceuticals Public Limited Company, headquartered in Budapest, Hungary, is one of the leading pharmaceutical companies operating principally in Central Europe. The company focuses on research, development and commercialization of pharmaceuticals and active pharmaceutical ingredients for the treatment of cardiovascular, central nervous system, respiratory and digestive system disorders. The company sells its products in many countries across the world through business partners and strong subsidiary companies network.

Remsima™ is the trademark Celltrion Group

Flammegis® is the trademark of Egis Pharmaceuticals PLC

Remicade® is the trademark of Centocor Ortho Biotech Inc./Janssen Biotech, Inc.

Budapest, September 13, 2013

Egis Pharmaceuticals PLC

