



## **LIALDA™ MMX treatment for ulcerative colitis gets FDA approval**

**Lainate, Italy – January 17, 2007** – Cosmo Pharmaceuticals, a specialty pharma company that aims to become a global leader in optimised therapies for certain gastrointestinal diseases, announced today that the U.S. Food and Drug Administration (FDA) has approved LIALDA™ (mesalamine) with MMX™ technology, indicated for the induction of remission in patients with active, mild to moderate ulcerative colitis. LIALDA™ is the first and only FDA-approved once-daily oral formulation of mesalamine. Mesalamines are a part of a drug class called aminosalicylates, which contain 5-aminosalicylic acid (5-ASA), a well-established drug of choice and often a first-line treatment for patients with mild to moderate ulcerative colitis. Shire has announced that it intends to launch LIALDA™ in the U.S. in the first quarter of 2007.

In December 2006, Cosmo announced that the regulatory agencies of 15 European countries agreed to the core labelling information as part of Shire plc's and Giuliani S.p.A's Marketing Authorization Applications for MEZAVANT™ (as LIALDA™ will be named in the EU by Shire) (MMX™ mesalazine), and MESAVANCOL™ (Giuliani).

Cosmo invented the formulation (the active pharmaceutical ingredient mesalazine is off-patent) and licensed it to Giuliani in 2001 who further licensed it to Shire Pharmaceuticals in 2002. Shire has licensed from Giuliani S.p.A. the exclusive rights to develop and commercialize LIALDA in the U.S., Canada, Europe – known as MEZAVANT™ – (excluding Italy) and the Pacific Rim. Giuliani S.p.A retains the development and commercialization rights in Italy and Latin America.

In 2006, the FDA also approved Cosmo's new, highly automated plant built for the production of LIALDA™ for the US market. Cosmo has entered into a manufacturing agreement with Shire plc as well as with Giuliani.

LIALDA™/MEZAVANT™ is the first oral once-daily Mesalamine treatment which will be indicated for the induction of remission in patients with active, mild-to-moderate ulcerative colitis. Randomised, placebo-controlled phase III studies on more than 500 patients with ulcerative colitis, reported by Shire plc, showed that patients receiving the drug achieved remission.

Mauro Ajani, CEO of Cosmo, stated: "The FDA approval is excellent news for Cosmo Pharmaceuticals and our partners Shire and Giuliani. The product is expected to offer ulcerative colitis patients the only known once-daily oral treatment. For us it is also a validation of our MMX technology and gives us confidence about our other interesting MMX products currently in phase II and phase III development."

### **About Ulcerative Colitis**

Ulcerative colitis is a type of inflammatory bowel disease (IBD) that produces inflammation and ulcers along the inside of the large intestine. The inflammation can interfere with the normal function of the colon, often causing cramping, bloating, diarrhoea, bleeding, fatigue, weight loss and frequent bowel movements which strongly affect the quality of life. It is believed that as many as 2.2 million people in Europe have IBD. Ulcerative colitis is a chronic relapsing-remitting illness for which there is no known cure. Patients can manage their symptoms. A known issue that arises with ulcerative colitis patients is medication compliance and excessive pill burden: many currently available ulcerative colitis treatments require multiple pills to be taken several times daily, and often involve inconvenient means of administration.

### **About Cosmo Pharmaceuticals**

Cosmo is a speciality pharma company that aims to become a global leader in optimised therapies for certain gastrointestinal diseases. The company's proprietary clinical development pipeline specifically addresses innovative treatments for IBD, such as ulcerative colitis and Crohn's disease, and colon infections. Cosmo's most advanced development product is LIALDA™ / MEZAVANT™, a treatment for IBD that is licensed globally to Giuliani and Shire Pharmaceuticals. Cosmo's proprietary MMX™ technology is at the core of the company's product pipeline and was developed from its expertise in formulating and manufacturing gastrointestinal drugs for international clients at its GMP (Good Manufacturing Practice) facilities in Lainate, Italy. For further information on Cosmo, please visit the Company's website: [www.cosmopharmaceuticals.com](http://www.cosmopharmaceuticals.com)

### **About Shire plc**

Shire's strategic goal is to become the leading specialty pharmaceutical company that focuses on meeting the needs of the specialist physician. Shire focuses its business on attention deficit and hyperactivity disorder (ADHD), human genetic therapies (HGT), gastrointestinal and renal diseases. The structure is sufficiently flexible to allow Shire to target new therapeutic areas to the extent opportunities arise through acquisitions. Shire believes that a carefully selected portfolio of products with a strategically aligned and relatively small-scale sales force will deliver strong results.

Shire's focused strategy is to develop and market products for specialty physicians. Shire's in-licensing, merger and acquisition efforts are focused on products in niche markets with strong intellectual property protection either in the US or Europe. For further information on Shire, please visit the Company's website: [www.shire.com](http://www.shire.com).

### **About Giuliani S.p.A**

Giuliani S.p.A., founded in 1889, is a privately owned specialty pharmaceutical company strategically focused in gastroenterology and dermatology. It is currently marketing proprietary products for the treatment and management of ulcerative colitis, Crohn's disease, food intolerances and dermatological disorders. Giuliani's R&D pipeline includes new chemical entities and biotechnological products targeted to treat inflammatory and autoimmune diseases.

### **For more information please contact:**

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