



MEZAVANT™ MMX treatment for ulcerative colitis gets label agreement for Europe

Lainate, Italy – December 19, 2006 – Cosmo Pharmaceuticals, a specialty pharma company that aims to become a global leader in optimised therapies for certain gastro intestinal (GI) diseases, announced today that the regulatory agencies of 15 European countries (including Germany, UK, France and Spain) participating in the decentralized procedure agreed to the core labelling information as part of Shire plc's and Giuliani S.p.A's Marketing Authorization Applications for MEZAVANT™ (Shire) (MMX™ mesalazine), and MESAVANCOL™ (Giuliani). The product will be indicated for induction of endoscopic and clinical remission and maintenance of remission of active, mild-to-moderate ulcerative colitis (UC).

Cosmo invented the formulation (the active pharmaceutical ingredient mesalazine is off-patent) and licensed it to Giuliani in 2001 who licensed it further on to Shire in 2002. In 2002 Cosmo entered into an agreement to manufacture the product for Shire. In 2006 the FDA approved Cosmo's new, highly automated plant built for this purpose for the production of MEZAVANT™ for the US-market. Cosmo will manufacture MEZAVANT™ for Shire plc for the North American as well as European markets.

As far as known, MEZAVANT™ is the only once-daily oral treatment which will be indicated in inducing endoscopic and clinical remission of mild-to-moderate UC. Randomised, placebo-controlled phase III studies on more than 500 patients with UC, reported by Shire plc, showed that patients receiving MEZAVANT™ with MMX™ technology achieved remission.

Mauro Ajani, CEO of Cosmo, said, "We are delighted to be starting the production of MEZAVANT™ on behalf of Shire plc for the European market. This demonstrates strong commitment from both parties to move expeditiously towards bringing MEZAVANT™ to market."

The Company's proprietary and innovative MMX™ technology was developed from the Company's expertise in formulating and manufacturing GI drugs for international clients at the GMP facilities (Good Manufacturing Practice) in Lainate, Italy. This technology allows the delivery of active pharmaceutical ingredients into the lumen of the colon in a delayed and controlled extent with the effect that the active drug can be applied to the full length of the colon. A pH-sensitive acrylic copolymer delays the release until the tablet reaches the indicated intestinal location where the dissolution of the drug begins.

Through its innovative MMX™ technology Cosmo addresses a range of inflammatory bowel diseases (IBD), a group of chronic, progressive, recurring and debilitating disorders leading to the damage of the gastro-intestinal tract. It is believed that inflammatory bowel diseases currently affect 0.5% of the Western world's population.

About Ulcerative Colitis

Ulcerative colitis (UC) 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. UC is a chronic relapsing-remitting illness for which there is no known cure. Patients can manage their symptoms. One issue that arises with UC patients is medication compliance and pill burden: many current available UC treatments require multiple pills to be taken several times daily.

About Cosmo Pharmaceuticals

Cosmo is a speciality pharma company that aims to become a global leader in optimised therapies for certain gastro intestinal (GI) diseases. The company's proprietary clinical development pipeline specifically addresses innovative treatments for inflammatory bowel diseases (IBD), such as ulcerative colitis and Crohn's disease, and colon infections. Cosmo's most advanced development product is 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 GI drugs for international clients at its GMP (Good Manufacturing Practice) facilities in Lainate, Italy. More on 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), gastro intestinal (GI) 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.

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.

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