



## **Cosmo Pharmaceuticals reports completion of enrolment in Phase III EU study of Budesonide MMX® for Ulcerative Colitis**

**Lainate, Italy – December 3, 2009** – Cosmo Pharmaceuticals SpA (SIX:COPN) announced today that it had completed enrolment of its Phase III Budesonide MMX® clinical trials in Europe. Data is expected to be available in H1 2010.

Cosmo Technologies Ltd., a subsidiary of Cosmo Pharmaceuticals SpA (SIX: COPN), has completed enrolment of 514 patients in the European Phase III clinical trial to evaluate Budesonide MMX® administered over 8 weeks for the induction of remission of mild or moderate active ulcerative colitis. This is the first of two induction phase clinical trials being conducted as part of the Budesonide MMX® Phase III clinical program. Cosmo and its US cooperation partner Santarus expect to report preliminary top line results from the European Phase III clinical trial in the first half of 2010. The U.S. Phase III Budesonide MMX® clinical trial is approximately 60% enrolled.

“We are pleased to reach this significant milestone in the Budesonide MMX® Phase III clinical program,” said Mauro Ajani, chief executive officer of Cosmo. “We look forward to announcing the results of this trial and completing the induction phase of the U.S. Budesonide MMX® Phase III trial during the first half of 2010.”

### **Budesonide MMX® Phase III Clinical Program**

Budesonide MMX® is being evaluated for the treatment of ulcerative colitis in two Phase III clinical trials, both of which are intended to support EU and U.S. regulatory submission. The primary end point is superiority versus placebo in the number of patients achieving remission (“UCDAI” <1) after 8 weeks treatment. UCDAI is composed of four elements: stool frequency score, rectal bleeding score, mucosal appearance score and physician rating score of disease activity. Patients in remission must score 0 in stool frequency, bleeding and mucosal appearance. The Phase III clinical program is expected to enrol approximately 1,000 patients in the two studies.

Each clinical trial is a double-blind, placebo-controlled, four-armed trial.

The European Phase III clinical trial is comparing a single tablet of Budesonide MMX® 6 mg or Budesonide MMX® 9 mg dosed once daily to placebo and there is a reference arm using three Entocort EC® (budesonide) capsules 3 mg dosed once daily (9 mg).

The U.S Phase III clinical trial is comparing a single tablet of Budesonide MMX® 6 mg or Budesonide MMX® 9 mg dosed once daily to placebo and in the reference

arm two Asacol® (mesalamine) delayed-release tablets 400 mg dosed three times daily (2.4 grams) were used.

The European and U.S. clinical trials are powered to show a statistical difference between Budesonide MMX® and placebo. The reference arms using Entocort EC in the European trial and Asacol in the U.S. trial are not powered to show statistical differences versus Budesonide MMX®.

Additionally, up to approximately 150 patients are expected to continue in a 12-month double-blind extended use trial to evaluate the long term safety and tolerability of Budesonide MMX® 6 mg and to collect data on the efficacy of Budesonide MMX® 6 mg in the maintenance of remission of ulcerative colitis compared to placebo. The U.S. Food and Drug Administration (FDA) requested that the results of the 12-month extended use trial be included in the Phase III clinical program to support a U.S. regulatory submission.

The protocols for the Budesonide MMX® Phase III clinical program were reviewed and approved by EMEA and the FDA under Special Protocol Assessments.

### **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 first MMX® product that has reached the market 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)

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