FDA approves Cosmo's submucosal injectable composition SIC 8000

Luxembourg, Luxembourg – September 4, 2015 – Cosmo Pharmaceuticals S.p.A. (SIX: COPN) announced today that the FDA has approved its request for marketing authorization of SIC 8000, its submucosal injectable composition.

The SIC is an injectable liquid composition for use as a submucosal injection agent during endoscopic mucosal resection (EMR), endoscopic mucosal dissection (ESD) and polypectomy procedures in the gastrointestinal tract. The device is intended for use in endoscopic procedures in the upper and lower intestinal tract such as the esophagus, the stomach, the small intestine, the colon, the sigmoid colon and the rectum, as a submucosal injectable agent during the removal of polyps, adenomas, early stage cancers, and other pathological lesions by EMR, ESD or polypectomy. SIC is injected by means of a standard commercially available endoscopic injection needle, which is inserted into the working channel of the endoscope. The agent, when injected, creates a cushion in situ by lifting the gastrointestinal mucosa from the submucosal layer, allowing the endoscopist to perform an easy and safe resection procedure.

Alessandro Della Chà, CEO of Cosmo Pharmaceuticals, commented: "I am very pleased and proud of this approval. It is the first product we entirely developed in house and got approved in a very short time. SIC 8000 will allow endoscopists to do their resection procedures safer and faster than before. Currently there is no other product that is in the market for these applications in the US. We now intend to conduct two marketing trials in order to have the product ready for marketing by the beginning of 2016. In the EU the request for marketing authorization filing was made on July 31st 2015 and we hope to have an approval in early 2016 so that we could start marketing the product in the EU at the same time."

About Cosmo Pharmaceuticals

Cosmo is a specialty pharmaceutical company that aims to become a global leader in the field of optimized therapies for selected Gastrointestinal and topically treated Skin Disorders. The company's proprietary clinical development pipeline specifically addresses innovative treatments for IBD, such as Ulcerative Colitis and Crohn's Disease, and Colon Infections. In addition, the Company is developing a diagnostic for the detection of colon cancer and a medical device for polyp excision as well as a new chemical entities that are being developed by the associate company Cassiopea SpA for the topical treatment of skin diseases. Cosmo's MMX® products that have reached the market are Lialda®/Mezavant®/Mesavancol®, a treatment for IBD that is licensed globally to Giuliani and Shire Limited and Uceris®, the first glucocorticosteroid indicated for the induction of remission in active, mild to moderate ulcerative colitis, licensed in US to Salix and in the Rest of the World except for Japan to Ferring as Cortiment®. 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. The technology is designed to deliver active ingredients in a targeted manner in the colon. For further information on Cosmo, please visit the Company's website: www.cosmopharma.com

Financial agenda

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