



Cosmo successfully completes the first phase I clinical trial of its anti-androgen, CB-03-01, for the treatment of skin disorders

Lainate, Italy – September 2, 2008 – Cosmo Pharmaceuticals SpA (“Cosmo”) (SWX: COPN) announced today positive results from the first phase I clinical trial of its novel anti-androgen 1% cream, CB-03-01. The trial results showed that the drug was well tolerated both locally and systemically and devoid of measurable side effects for all the doses tested.

CB-03-01 is a new chemical entity, belonging to the family of cortexolone derivatives, patented by Cosmo as an anti-androgenic drug; the compound is indicated for the topical treatment of androgen-dependent skin disorders including Acne, Hirsutism or Androgenetic Alopecia.

The trial was designed as a randomized, double-blind, placebo-controlled, single ascending doses trial to assess drug safety, tolerability and pharmacokinetics following single dose administration. The trial was carried out at the Department of Clinical Pharmacology of the Medical University Hospital of Vienna, under the supervision of the main investigator Prof. Markus Muller. In the study, 3 doses of cortexolone 17 α -proprionate (“CB-01-03”) were administered to 24 healthy male volunteers divided in to three cohorts. Each cohort included 2 subjects receiving only placebo cream on both forearms and 6 subjects receiving CB-03-01 1% cream on one forearm and placebo cream on the other forearm. Safety and tolerability assessments, as well as PK evaluations, were performed up to 36 hours following drug application.

CB-03-01 was shown to permeate the skin and to be quantifiable in the plasma of approximately 40% of the treated subjects: the maximum recorded concentration of the unchanged compound in plasma was below 10 ng/ml. In all subjects, CB-03-01 was undetectable 24-36 hours after dosing.

CB-03-01’s mechanism of action is the competition with Testosterone and DHT at the human androgen-receptor level. CB-03-01 is devoid of systemic anti-androgenic activity, as far as it does not inhibit gonadotropins hypersecretion, and it possesses a moderate anti-inflammatory activity. In preclinical studies, CB-03-01 was shown to be not mutagenic and rapidly metabolized to the parent cortexolone, a physiological substance lacking anti-androgen activity, by human plasma and skin. CB-03-01 has also been shown to be well tolerated and devoid of toxicity when applied repeatedly.

Commenting on today’s announcement, Mauro Ajani, CEO of Cosmo, said: “CB-03-01 is the first new chemical entity that Cosmo is developing and the first product that is not based on our innovative MMX™ technology. CB-03-01 has the potential to be the first topically effective anti-androgen treatment on the market and we look forward to initiating a phase II proof-of-concept trial later in the year

About acne, alopecia and hirsutism

Acne affects almost 45 million people in the USA i.e. around 16% of the population. The worldwide market for Acne is valued at over US\$2.8 billion. Roaccutane™ of Roche had sales exceeding US\$253 million in 2004 but these decreased following FDA warning for side effects.

Alopecia (androgen-induced hair loss in males) affects approximately 12% of all men over 20 years of age. Propecia™ (Merck), a systemically applied drug, had sales of US\$405 million in 2007.

Hirsutism (androgen-induced growth of facial and/or body hair in women) affects about 10% of the female population. The world wide market remains largely undeveloped.

About Cosmo Pharmaceuticals

Cosmo is a specialty 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 product is LIALDA™ / MEZAVANT™ 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

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