



Cosmo's CB-03-01 phase II pilot study in acne demonstrates superiority over Retin A[®]

Lainate, Italy – 11 December 2009 – Cosmo Pharmaceuticals S.p.A. (“Cosmo”) (SIX: COPN) announced today positive results in a phase II pilot study of its novel topical anti-androgen 1% cream, CB-03-01. The preliminary data of the trial showed that CB-03-01 met all clinical end points and was clinically superior to placebo and to Retin-A[®] in the treatment of facial acne vulgaris after 8 weeks of drug application. The detailed clinical report will be available in a few weeks.

CB-03-01 is a new steroid proprietary to Cosmo with anti-androgenic and anti-inflammatory properties; the compound is intended to be indicated for the topical treatment of skin disorders influenced by androgens including acne and potentially, hirsutism or androgenetic alopecia.

This phase II pilot study was designed as a three arm, randomized, double-blind, parallel-groups, controlled study versus placebo and versus Retin-A[®] 0.05% cream, in facial acne vulgaris.

- Treatment: single daily topical application.
- Treatment duration: 8 weeks + 2 weeks of follow up.
- N° of patients randomized: 77 males, 18-45 years of age.
- N° of patients evaluated: 72 (ITT population); 67 (PP population)
- Evaluation parameters: Total Lesion Count (TLC), Inflammatory Lesion Count (ILC), Acne Severity Index (ASI), Investigator's Global Assessment (IGA) as efficacy variables; all these parameters were assessed at baseline and after 2, 4, 6 and 8 weeks of treatment. Local Irritancy Score (IS) was evaluated at weeks 2, 4, 6 and 8.

CB-03-01's mechanism of action is based on the competitive activity between testosterone and DHT for androgen-receptors in the skin. CB-03-01 is devoid of systemic anti-androgenic activity, in as far as it does not inhibit gonadotropins hypersecretion, and has a moderate anti-inflammatory effect. In preclinical studies, CB-03-01 was shown to be rapidly metabolized by the skin to the parent compound cortexolone, which is a physiological steroid lacking anti-androgen activity and is completely safe. CB-03-01 has also been shown to have good penetration through the skin, making it the first anti-androgen suitable for topical application.

Commenting on the results, Mauro Ajani, CEO of Cosmo, said: “This is a further breakthrough for Cosmo. Skin diseases have been long neglected by major pharmaceutical companies and the drugs available for the treatment of acne are either not very effective or have substantial negative side effects. With CB-03-01 we have the opportunity of creating a new first line treatment that is both effective and safe. We will now proceed with completing the requirements to file an IND and then

seek a partner to fulfil the clinical evaluation process. At the same time we will initiate a proof of concept study in alopecia.”

About acne, alopecia and hirsutism

Acne is a persistent dermatological disorder that is characterised by the formation of lesions such as comedones, papules, pustules, and cysts mainly located on the face, and less commonly on the back and chest. Acne is caused by the obstruction of the pilosebaceous follicles due to excessive sebum production and abnormal skin cells desquamation. The obstructed hair follicle and the annexed sebaceous gland may then be infected by bacteria that inhabit the surface of the skin. The enzymes possessed by bacteria metabolize the sebum, generating by-products that may irritate the wall of the follicle causing further inflammation. Acne can be triggered by a number of factors including genetics, stress, physical aggravation, exposure to medicines and cosmetics, external stimuli such as heat, humidity and pollution, and changes in hormonal levels in the suffers.

There are four commonly used classes of therapeutics used to treat acne, with each featuring a differentiated mechanism of action:

- Topical antibiotics and antiseptics: these act to reduce the bacteria which are involved in acne. Such treatments include topical and systemic antibiotics such minocycline, doxycycline, erythromycin and clindamycin as well as antiseptics such benzoyl peroxide, which features prominently as a first line treatment for acne
- Treatments that interfere with the pattern of keratinisation: the most significant treatments are tretinoin, tazoratene, and isotretinoin
- Anti-inflammatories: drugs like topical corticosteroids help to reduce the level of inflammation and represent useful additions to treatment regimens due to their antiirritant properties. Antiandrogens and estro-progestins, administered by oral route, are also used to treat the severe forms of acne.

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.

Alopecia (androgen-induced hair loss in males) affects approximately 12% of all men over 20 years of age.

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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