



Cosmo announces the beginning of the phase III trials in males for the treatment of androgenetic alopecia

Dublin, Ireland – June 29, 2023: Cosmo Pharmaceuticals N.V. (SIX: COPN, XETRA: C43) (“Cosmo”) today announced the beginning of the phase III trials of clascoterone solution in males for the treatment of androgenetic alopecia (AGA).

- The phase III trials will evaluate and assess the use of clascoterone topical solution in males
- AGA is the most common form of hair loss and a substantial market with high unmet needs. It is an extremely common disorder that affects roughly 50% of men
- Clascoterone topical solution is a potential first new mechanism of action in AGA in nearly three decades

About the phase III trials and study design

The program consists of two identical 6-month phase III, multicenter, prospective, randomized, double-blind, vehicle-controlled studies, to evaluate the efficacy and safety of topically applied Clascoterone (Cortexolone 17 α -Propionate) Solution for the treatment of androgenetic alopecia in males, each followed by a 6-month, single-blind treatment with Clascoterone solution 75mg BID¹ or vehicle BID solution (SCALP 1 and SCALP 2 studies).

The two trials will be conducted in about 60 centers and a total of 1,500 male subjects aged over 18. SCALP 1 with approx. 750 male subjects will be performed in the US and Georgia and SCALP 2 with approx. 750 male subjects will be performed in the US, Germany and Poland.

Co-primary endpoints for both studies are Target Area Hair Count (TAHC) and Patient Reported Outcome (PRO).

Substantial AGA market with high unmet needs

Androgenetic Alopecia (AGA), also known as male pattern baldness or female pattern baldness, is a chronic, progressive condition and the most prevalent form of hair loss in both men and women, affecting an estimated 50% of males over 40 years and up to 75% of females over 65 years. Characterized by a defined hair loss pattern in both sexes, genetics plays a strong role in its etiology. Genetic variations in the human androgen receptor (AR) gene may trigger early-onset AGA and the extent to which these receptors respond to dihydrotestosterone (DHT) is also genetically influenced. However, early treatment targeting DHT’s interaction with AR may reverse or temper the effects of DHT on hair loss.

In AGA, high local DHT concentrations bind to the androgen receptors within the scalp hair follicles, resulting in shortening of the hair cycle and gradual miniaturization of the scalp follicles. Over time, these progressively smaller, thinner hair follicles are unable to produce new hair, thus resulting in AGA’s characteristic patterned baldness. DHT dependent effects are considered, in most cases, reversible, and may be responsive to medical treatment with androgen receptor inhibitor drugs such as clascoterone.

It is estimated that 194 million² patients in seven major markets (US, France, Germany, Italy, Spain, UK, and Japan) are affected by AGA, of which over 80 million in the US alone. Hair loss is often a cause of great concern to affected subjects for cosmetic and psychological reasons. Most AGA sufferers may not seek treatment likely due to limitations of current treatments and lack of

¹ BID = bis in die / twice a day

² DelveInsight’s “Androgenetic Alopecia – Epidemiology Forecast – 2032”, <https://www.delveinsight.com/report-store/androgenetic-alopecia-epidemiology-forecast>



available options. A new therapeutic drug option indicated for AGA has not been introduced for nearly 30 years.

Diana Harbort, President of Cosmo's Dermatology Division, said: *"We are pleased to finally have the first patient recruited in this key phase III program. The global hair loss market is very large and very underserved with only OTC products and generic therapies available. Therefore, our product, if approved, could serve a substantial global audience and improve the life of many people suffering from hair loss."*

About Clascoterone solution

Clascoterone solution is a novel androgen receptor inhibitor that targets androgen receptors in the scalp and is currently being studied for the treatment of androgenetic alopecia (AGA).

Clascoterone, a new chemical entity, is a topically applied anti-androgen first approved by FDA in August 2020 for the treatment of acne (in a 1% cream) and is now being studied for AGA in a different formulation (solution) and in a higher strength. Clascoterone is believed to address AGA by directly inhibiting testosterone and dihydrotestosterone binding to local hair follicle androgen receptors. If approved by the FDA, clascoterone solution has the potential to be the only topical androgen receptor inhibitor for AGA and the first drug with a new mechanism of action for the treatment of AGA in nearly three decades.

Clascoterone is quickly metabolised to cortexolone, a metabolite with a known safety profile. Due to its rapid metabolism and local activity, there appears to be limited systemic exposure to clascoterone and therefore potential systemic side effects are likely minimised.

Following a successful phase IIa proof of concept trial, a phase II dose-ranging study was conducted in males and results were announced in 2019. The results showed statistically significant improvement versus vehicle (placebo) for Target Area Hair Count (TAHC) for every dose tested along with directional improvement for Hair Growth Assessment (HGA). The results indicate that clascoterone stops the loss of hair, promotes the growth of new hair, and has a safety profile similar to the vehicle for both adverse events and local skin reactions, even after 12 months treatment.

About Cosmo

Cosmo is a pharmaceutical company focused on developing and commercializing products to treat selected gastrointestinal disorders, to improve endoscopy quality measures through aiding the detection of colonic lesions and to treat selected dermatological conditions. Cosmo develops and manufactures products which are distributed globally by selected partners including Lialda®/Mezavant®/Mesavanco®, Uceris®/Cortiment®, Aemcolo®/ Relafalk® and Winlevi®. Cosmo has also developed medical devices for endoscopy and has a partnership with Medtronic for the global distribution of GI Genius™ which uses artificial intelligence to help detect potential signs of colon cancer. The company also has a rich development pipeline. For additional information on Cosmo and its products, please visit www.cosmopharma.com.

Upcoming Calendar of Events

Half Year Results 2023	July 26, 2023
Investor Access, Paris	October 9-10, 2023
Jefferies London Healthcare Conference 2023	November 14-16, 2023
CF&B Communication European Midcap Event, Geneva	December 1-2, 2023

Disclaimer

Some of the statements in this press release may be forward-looking statements or statements of future expectations based on currently available information. Such statements are naturally subject to risks and uncertainties. Factors such as the development of general economic conditions, future market conditions, unusual catastrophic loss events, changes in the capital markets and other circumstances may cause the actual events or results to be materially different from those anticipated by such statements. Cosmo does not make any representation or warranty, express or implied, as to the accuracy, completeness or updated status of such statements. Therefore, in no case whatsoever will Cosmo and its affiliate companies be liable to anyone for any decision made or action taken in conjunction with the information and/or statements in this press release or for any related damages.



Contact:

Hazel Winchester

Head of Investor Relations

Cosmo Pharmaceuticals N.V.

Tel: +353 1 817 03 70

hwinchester@cosmopharma.com