FOR IMMEDIATE RELEASE

Sun Pharma and Cosmo Announce Territory Expansion of License and Supply Agreements for WINLEVI® to include Japan, Australia, New Zealand, Brazil, Mexico and Russia

Mumbai, India and Dublin, Ireland, July 26, 2022: Sun Pharmaceutical Industries Limited (Reuters: SUN.BO, Bloomberg: SUNP IN, NSE: SUNPHARMA, BSE: 524715, "Sun Pharma" and includes its subsidiaries and/or associate companies) and Cassiopea, a subsidiary of Cosmo Pharmaceuticals N.V. (SIX: COPN, XETRA: C43) ("Cosmo") today announced the signing of addendums to the License and Supply Agreements for WINLEVI (clascoterone) cream 1% expanding the territory to include Japan, Australia, New Zealand, Brazil, Mexico and Russia. In 2021, Sun Pharma and Cassiopea had signed License and Supply Agreements for the United States and Canada markets. Sun Pharma launched WINLEVI in the US market in November 2021.

Under the terms of the above referred agreements, Sun Pharma will receive from Cassiopea the exclusive right to develop and commercialize WINLEVI in Japan, Australia, New Zealand, Brazil, Mexico and Russia. Cosmo will be the exclusive supplier of the product. Cassiopea will receive an upfront payment of US$ 7 million, potential regulatory and sales milestones and customary double-digit royalties on net sales.

Aalok Shanghvi, EVP & Head - Generic R&D, Generic Global BD and Emerging Markets, Sun Pharma said, "WINLEVI is a new class of topical medication and it continues to generate significant interest amongst dermatologists in the US. The expansion of our agreement with Cosmo will enable us to make this new acne treatment available to patients in many more countries and is in line with our strategy to build a global portfolio of specialty products."

Diana Harbort, President of Cosmo Dermatology Division, said: "We are very pleased to expand our agreement with Sun Pharma making WINLEVI available to more patients around the world. Sun Pharma's early success with WINLEVI in the US makes us highly confident of their ability to maximize the opportunity in the expanded territory."

A first-in-class topical androgen receptor inhibitor, WINLEVI was approved by the U.S. Food and Drug Administration (FDA) in August 2020 for the topical treatment of acne vulgaris in patients 12 years of age and older. Although its exact mechanism of action is unknown, laboratory studies suggest that WINLEVI works by inhibiting the effects of androgen receptors in cells of the sebaceous glands (oil-producing glands in the skin) to help reduce sebum (oil) production and inflammation.[3] It is suitable for use in both males and females.[1] WINLEVI is the first FDA-approved acne drug with a first-in-class mechanism of action in nearly 40 years.[1,2]

About Cosmo
Cosmo is a pharmaceutical company focused on developing and commercialising 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® (mesalamine) delayed release tablets, Uceris®/Cortiment® (budesonide) extended release tablets 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. Cosmo has licensed Aemcolo® (rifamycin) delayed-release tablets to Red Hill Biopharma Ltd. for the US and has licensed Relafalk® (rifamycin) to Dr. Falk Gmbh for the EU and other countries. The company also has a rich development pipeline. For additional information on Cosmo and its products please visit the Company's website: www.cosmopharma.com

About Sun Pharmaceutical Industries Limited (CIN - L24230GJ1993PLC019050):

Sun Pharma is the world's fourth largest specialty generic pharmaceutical company and India's top pharmaceutical company. A vertically integrated business and a skilled team enables it to deliver high-quality products, trusted by customers and patients in over 100 countries across the world, at affordable prices. Its global presence is supported by manufacturing facilities spread across six continents and approved by multiple regulatory agencies, coupled with a multi-cultural workforce comprising over 50 nationalities. Sun Pharma fosters excellence through innovation supported by strong R&D capabilities across multiple R&D centers, with investments of approximately 6% of annual revenues in R&D. For further information, please visit www.sunpharma.com and follow us on Twitter @SunPharma_Live.

About WINLEVI® (clascoterone) cream 1%

WINLEVI is approved in the U.S. for the topical treatment of acne vulgaris in people aged 12 and older. Although the exact mechanism of action for WINLEVI is unknown, laboratory studies suggest the active ingredient, clascoterone, competes with androgens, specifically dihydrotestosterone (DHT), for binding to the androgen receptors within the sebaceous gland and hair follicles.[2] WINLEVI is rapidly metabolized in the skin, limiting systemic absorption. Most common adverse reactions include erythema/reddening, pruritus, and scaling/dryness.

Androgens are widely recognized as the most important of all hormones in terms of regulating sebum production.[7] Within the skin, androgens bind to androgen receptors, causing increased sebum production and inflammation.[3] In particular, the skin of patients with acne vulgaris produces higher levels of the androgens testosterone and DHT than the skin of healthy individuals.[8] Current oral hormonal therapies have been shown to be effective in treating acne regardless of whether androgen levels are elevated.[7] However, whereas certain oral hormonal therapies are recommended for use in some female patients with acne, their use in males has been limited due to the potential risk of systemic side effects such as gynecomastia (overdevelopment or enlargement of breast tissue) and the inability to grow a beard.[1,7]

WINLEVI is supplied in an epoxy-lined aluminum tube. Each gram of WINLEVI contains 10 mg of clascoterone in a white to almost white cream. Patients are instructed to cleanse the affected area gently, and after the skin is dry, to apply a uniform layer of WINLEVI twice per day, in the morning and the evening.[9]

For complete prescribing information please click here.

U.S. INDICATION

WINLEVI (clascoterone) cream 1% is an androgen receptor inhibitor indicated for the topical treatment of acne vulgaris in patients 12 years of age and older.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS:

None.

WARNINGS AND PRECAUTIONS

Local Irritation: Pruritus, burning, skin redness or peeling may be experienced with WINLEVI cream. If these effects occur, discontinue or reduce the frequency of application of WINLEVI cream.

Hypothalamic-pituitary-adrenal (HPA) axis suppression may occur during or after treatment with WILEVI In the PK trial, HPA axis suppression was observed in 1/20 (5%) of adult subjects and 2/22 (9%) of adolescent subjects at Day 14. All subjects returned to normal HPA axis function at follow-up 4 weeks after stopping treatment. Conditions which augment systemic absorption include use over large surface areas, prolonged use, and the use of occlusive dressings. Attempt to withdraw use if HPA axis suppression develops.

Pediatric patients may be more susceptible to systemic toxicity.

Hyperkalemia: Elevated potassium levels were observed in some subjects during the clinical trials. Shifts from normal to elevated potassium levels were observed in 5% of WINLEVI-treated subjects and 4% of vehicle-treated subjects.

ADVERSE REACTIONS

Most common adverse reactions occurring in 7 to 12% of patients are erythema/reddening, pruritus and scaling/dryness. Additionally, edema, stinging, and burning occurred in >3% of patients and were reported in a similar percentage of subjects treated with vehicle.

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