Sun Pharma and Hikma enter into exclusive licensing agreement for ILUMYA™ for Middle East & North Africa regions

Mumbai, India, June 15, 2020: Sun Pharmaceutical Industries Ltd. (Reuters: SUN.BO, Bloomberg: SUNP IN, NSE: SUNPHARMA, BSE: 524715, “Sun Pharma” and includes its subsidiaries and/or associate companies) announced that one of its wholly-owned subsidiaries and Hikma Pharmaceuticals PLC (Hikma) have entered into an exclusive licensing and distribution agreement for ILUMYA™, an innovative biologic product, for the Middle East & North Africa (MENA) region.

ILUMYA™ (tildrakizumab) is an USFDA approved innovative IL-23p19 monoclonal antibody used for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

Under the terms of the licensing agreement, Hikma will be responsible for the registration and commercialization of the product in all MENA markets and Sun Pharma will be responsible for product supply. Sun Pharma is eligible for upfront and milestone payments from Hikma. The term of this agreement is 15 years from first sale, with two years’ automatic renewal periods.

Aalok Shanghvi, Senior Vice President - Emerging Markets, Sun Pharma said, “We are pleased to partner with Hikma to offer ILUMYA™ to patients in the MENA region. Hikma’s strong presence in the MENA region will enable access to a new treatment option for people who are unable to manage their moderate-to-severe plaque psoriasis.”

About ILUMYA™ (tildrakizumab)

ILUMYA™ (tildrakizumab) is a humanized IgG1/k monoclonal antibody designed to selectively bind to the p19 subunit of interleukin-23 (IL-23) and inhibit its interaction with the IL-23 receptor, leading to inhibition of the release of pro-inflammatory cytokines and chemokines. ILUMYA™ is indicated for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

The U.S. Food and Drug Administration (USFDA) approved ILUMYA™ in 2018 based on data from the pivotal Phase-3 reSURFACE clinical development program. The Phase-3 studies (reSURFACE 1 and reSURFACE 2) were randomized, placebo-controlled, multicenter, three-part studies designed to evaluate efficacy and safety of ILUMYA™ 100 mg and 200 mg in moderate-to-severe plaque psoriasis compared to placebo and comparative drug, and to assess safety and tolerability. Researchers evaluated (Psoriasis Area Sensitivity Index or PASI 75) and Physician’s Global Assessment (PGA) response (score of 0 or 1 with ≥2 grade reduction from baseline) and
incidence rates for pre-specified adverse events, including severe infections, cardiovascular events and drug-related hypersensitivities.

Both Phase-3 studies met the primary efficacy endpoints, demonstrating significant clinical improvement with ILUMYA™ 100 mg compared to placebo when measured by at least 75 percent of skin clearance (Psoriasis Area Sensitivity Index or PASI 75) and Physician’s Global Assessment (PGA) score of “clear” or “minimal” at week 12 after two doses. ILUMYA™ was well tolerated with low rates of adverse events.

ILUMYA™ has also been approved in Australia, and in Europe under the brand name ILUMETRI™.

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About Sun Pharmaceutical Industries Ltd. (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 6 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 7% of annual revenues in R&D. For further information, please visit www.sunpharma.com & follow us on Twitter @SunPharma_Live.

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