



Sun Pharma and Philogen enter into an Exclusive Distribution, License, and Supply Agreement for Commercializing specialty product, NIDLEGY™ in Europe, Australia and New Zealand

Mumbai, India and Siena, Italy, 30th May 2023 – Sun Pharmaceutical Industries Limited (Reuters: SUN.BO, Bloomberg: SUNP IN, NSE: SUNPHARMA, BSE: 524715 (together with its subsidiaries and/or associated companies, “Sun Pharma”)) and Philogen S.p.A (BIT: PHIL) today announced that they have entered into a licensing agreement for commercializing Philogen’s specialty product, Nidlegly™ (Daromun) in the territories of Europe, Australia and New Zealand. Nidlegly™, currently in Phase III clinical trials, is a new anti-cancer biopharmaceutical which is being developed by Philogen for the treatment of melanoma and non-melanoma skin cancers.

Under the terms of the agreement, Sun Pharma will have exclusive rights to commercialise Nidlegly™ for indications of skin cancers in the territories of Europe, Australia and New Zealand. Philogen will complete pivotal clinical trials for the product in Europe, pursue Marketing Authorization with the regulatory authorities and manufacture commercial supplies. Sun Pharma will be responsible for commercialization activities. The two partner companies will share post-commercialization economics in about 50:50 ratio. Other financial terms were not disclosed. Philogen will retain the IP rights for Nidlegly™ for other territories and indications other than skin cancers.

Hellen De Kloet, Business Head - Western Europe and ANZ, Sun Pharma, said “We are delighted to partner with Philogen for Nidlegly™, a close to market, new immunotherapy treatment in skin cancers. This collaboration is in line with our goal to bring innovative products to patients. With the expected addition of Nidlegly™ to our existing Odomzo™ franchise, we will be well-positioned to provide patient solutions across a broad spectrum of skin cancers in various disease stages.”

Prof. Dr. Dario Neri, CEO and CSO of Philogen, commented: “We are pleased to establish a collaboration with Sun Pharma, a leading global pharmaceutical company, in the onco-dermatology space. This collaboration will focus on the commercialization of Nidlegly™, a new immunotherapy that brings promise to improve the therapeutic options for patients suffering from melanoma and non-melanoma skin cancers, high-risk conditions with unmet medical need. Both companies are committed to the development and commercialization of Nidlegly™ making it widely available to patients who may benefit from it.”

About Nidlegly™ (Daromun)



Nidlegly™ is a biopharmaceutical product, proprietary to Philogen, designed for the treatment of skin cancer. It consists of two active ingredients, L19IL2 and L19TNF which are manufactured independently, and which are mixed prior to intralesional administration. The L19 antibody is specific to the Extra Domain B of Fibronectin, a protein expressed in tumors (and other diseases) but absent in most healthy tissues. Interleukin 2 (IL2) and Tumor Necrosis Factor (TNF) are pro-inflammatory cytokines with anti-tumor activity. Nidlegly™ is currently being investigated in two Phase III clinical trials for the treatment of locally advanced melanoma, and in Phase II clinical trials for the treatment of High-Risk Basal Cell Carcinoma and other non-melanoma skin cancers.

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

About Philogen group

Philogen is an Italian-Swiss company active in the biotechnology sector, specialized in the research and development of pharmaceutical products for the treatment of highly lethal diseases. The Group mainly discovers and develops targeted anticancer drugs, exploiting high-affinity ligands for tumor markers (also called tumor antigens). These ligands - human monoclonal antibodies or small organic molecules - are identified using *Antibody Phage Display Libraries* and *DNA-Encoded Chemical Library* technologies.

The Group's main therapeutic strategy for the treatment of these diseases is represented by the so-called *tumor targeting*. This approach is based on the use of ligands capable of selectively delivering very potent therapeutic active ingredients (such as pro-inflammatory cytokines) to the tumor mass, sparing healthy tissues. Over the years, Philogen has mainly developed monoclonal antibody-based ligands that are specific for antigens expressed in tumor-associated blood vessels, but not expressed in blood vessels associated with healthy tissues. These antigens are usually more abundant and more stable than those expressed directly on the surface of tumor cells. This approach, so called *vascular targeting*, is used for most of the projects pursued by the Group.

The Group's objective is to generate, develop and market innovative products for the treatment of diseases for which medical science has not yet identified satisfactory therapies. This is achieved by exploiting (i) proprietary technologies for the isolation of ligands that react with antigens present in certain diseases, (ii) experience in the development of products targeted at the tissues affected by the disease, (iii) experience in drug manufacturing and development, and (iv) an extensive portfolio of patents and intellectual property rights.

Although the Group's drugs are primarily oncology applications, the *targeting* approach is also potentially applicable to other diseases, such as certain chronic inflammatory diseases.

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