



## **Sun Pharma and Philogen enter into a global Exclusive Commercialization, License, and Supply Agreement for Commercializing the specialty product FIBROMUN**

**Mumbai, India and Siena, Italy, 1 October 2024** – 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 S.p.A (BIT: PHIL) (“Philogen”) today announced that they have entered into a global licensing agreement for commercializing Philogen’s specialty product, Fibromun (L19TNF). Fibromun, an innovative anti-cancer immunotherapy, is being investigated in registration trials by Philogen for the treatment of soft tissue sarcoma and glioblastoma.

Under the terms of the agreement, Sun Pharma will have the exclusive worldwide rights to commercialise Fibromun. Philogen will complete the ongoing pivotal clinical trials for the product, pursue Marketing Authorization with 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 45(Philogen):55(Sun Pharma) ratio. Other financial terms were not disclosed.

**Dilip Shanghvi, Chairman and Managing Director of Sun Pharma**, said, “Fibromun’s progress through development has been quite encouraging and it has potential to be an important option for treatment of soft-tissue sarcomas and other cancers with significant unmet medical needs. This partnership expands our clinical pipeline into oncology in alignment with our current portfolio in skin cancers. We keenly look forward to providing this treatment option globally in due course of time.”

**Prof. Dr. Dario Neri, CEO and CSO of Philogen**, commented: “We are pleased to extend our collaboration with Sun Pharma, a leading global pharmaceutical company, from our existing partnership on Nidleg<sup>TM</sup> to Fibromun. This collaboration will focus on the global commercialization of Fibromun, a new immunotherapy that has the potential to serve patients with soft tissue sarcoma and certain malignant forms of brain tumors (e.g., glioblastoma), for which limited therapeutic alternatives exist. Our group has published data reflecting the promising therapeutic activity of Fibromun in glioblastoma, inducing long-lasting anti-tumor responses in a subset of patients. We have also announced that an independent monitoring board has evaluated safety and efficacy data of the pre-planned interim analysis of our Phase III clinical trial in soft tissue sarcoma and recommended continuing the study as planned by the protocol. In view of these promising developments, both companies are committed to the development and commercialization of Fibromun, making it widely available to patients who may benefit from it.”

Previously, the two companies announced that on May 30, 2023, they entered into an Exclusive Distribution, License, and Supply Agreement for commercializing the specialty product Nidleg<sup>TM</sup> in Europe, Australia and New Zealand. The first Marketing Authorization Application for



Nidlegly™ has been submitted to European Medicines Agency (EMA) for the treatment of locally advanced, fully resectable melanoma in the neoadjuvant setting.

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### **About Fibromun (L19TNF, onfekafusp alfa)**

Fibromun is a biopharmaceutical product, proprietary to Philogen, studied for the treatment of advanced soft tissue sarcoma and glioblastoma. It consists of the L19 antibody genetically fused to Tumor Necrosis Factor (TNF). L19 binds selectively to the Extra Domain B of Fibronectin, a protein expressed in tumors (and other diseases) but absent in most healthy adult tissues. TNF is a cytotoxic cytokine with anti-tumor activity that is preferentially localized by the L19 antibody to neoplastic masses. L19TNF is administered via intravenous infusion. Late-stage clinical trials with registration potential are on-going in soft tissue sarcoma and glioblastoma. The product has pan-tumoral potential and could be explored for the therapy of other cancer types (e.g., lung, breast, colon, prostate cancers).

### **About Sun Pharmaceutical Industries Limited (CIN - L24230GJ1993PLC019050)**

Sun Pharma is the world's leading specialty generics company with a presence in Specialty, Generics and Consumer Healthcare products. It is the largest pharmaceutical company in India and is a leading generic company in the US as well as Global Emerging Markets. Sun Pharma's high growth Global Specialty portfolio spans innovative products in dermatology, ophthalmology, and onco-dermatology and accounts for over 18% of company sales. The company's vertically integrated operations deliver high-quality medicines, trusted by physicians and consumers in over 100 countries. Its manufacturing facilities are spread across six continents. Sun Pharma is proud of its multi-cultural workforce drawn from over 50 nations. For further information, please visit [www.sunpharma.com](http://www.sunpharma.com) and follow us on LinkedIn & X (Formerly Twitter).

### **About 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. Philogen's mission is to discover, develop and market innovative pharmaceuticals for the treatment of diseases of high unmet need. 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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