Philogen Completes Patient Enrollment of the Phase III FIBROSARC Trial in Soft Tissue Sarcoma

Siena (Italy) & Mumbai (India), February 4, 2025 - 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. ("**Philogen"**) are pleased to announce the successful completion of patient enrollment in the Phase III FIBROSARC trial for Soft Tissue Sarcoma (STS). All ongoing Fibromun trials remain on track with their expected timelines.

Dario Neri, CEO of Philogen, commented: *"We are highly encouraged by the progress of Fibromun's pivotal trials in both Soft Tissue Sarcoma and Glioblastoma. In October 2024, the program entered a strategic commercial partnership with Sun Pharma, a leading multinational pharmaceutical company.*

The Soft Tissue Sarcoma trials are proceeding as planned across Europe and the United States. Key readouts from our most advanced studies—Phase III FIBROSARC and Phase II FLASH—are anticipated between March and June 2025. These results represent critical milestones for Philogen, as Fibromun has the potential to become our second product to successfully complete multinational clinical trials with registration potential.

We are also seeing faster-than-expected patient enrollment in the Glioblastoma trials. The Phase II GLIOSTAR trial, originally projected to complete enrollment by December 2025, is now expected to conclude recruitment in Q2 2025.

Philogen remains committed to advancing innovative therapies and delivering meaningful outcomes for patients worldwide."

Dilip Shanghvi, Chairman and Managing Director of Sun Pharma, said: "*We look forward to the Fibromun readouts over the next few months. Fibromun has the potential as a valuable treatment option for soft-tissue sarcomas and other cancers with high unmet medical needs. The candidate aligns well with our current portfolio in skin cancers.*"

Fibromun is a biopharmaceutical product, consisting of the L19 antibody fused to tumor necrosis factor (i.e., L19TNF). The status of the ongoing pivotal studies is provided below.

- European Phase III study STS (FIBROSARC study)
  - Patient population: first line locally advanced or metastatic STS
  - Combination partner: Doxorubicin

- Geography: Germany, France, Italy, Spain, Poland
  - Enrolment Status: 129 out of 118 patients
  - Study read-out expected between March and June 2025, based on the occurrence of the events
  - If the trial reads-out positively, Philogen plans to request a pre-BLA meeting with FDA to discuss opportunities for accelerated approval procedures in the US
- European Phase II study STS (FLASH study)
  - Patient population: last line locally advanced or metastatic STS
  - Combination partner: Dacarbazine
  - Geography: Germany, France, Italy, Spain, Poland
  - Enrolment Status: 94 out of 86 patients
  - Study read-out expected between April and July 2025, based on the occurrence of the events
  - If the trial reads-out positively, Philogen plans to request a pre-BLA meeting with FDA to discuss opportunities for accelerated approval procedures in the US
- US Phase IIb study STS (FIBROSARC US study)
  - Patient population: first line metastatic Leiomyosarcoma
  - Combination partner: Doxorubicin
  - Geography: US
  - Enrolment Status: 74 out of 158 patients
- EU Phase I/II study GBM (GLIOSTAR study)
  - Patient population: GBM at first progression
  - Combination partner: Lomustine
  - Geography: Italy, Switzerland, Germany, France
  - Enrolment Status Phase 1: complete
  - Enrolment Status Phase 2: 139 out of 158 patients
  - Expected completion of enrolment between April and June 2025
- US Phase I/II study GBM (GLIOSTELLA study)
  - Patient population: GBM at first or later progression
  - Combination partner: Lomustine
  - Geography: US
  - Enrolment Status: 36 out of up to 90 patients
  - Expected completion of enrolment Q4 2025 – Q1 2026
- EU Phase I/II/IIb study GBM (GLIOSUN study)
  - Patient population: newly diagnosed GBM
  - Combination partner: Radiotherapy and Temozolomide
  - Geography: Switzerland. Expansion to European countries ongoing
  - Enrolment Status Phase 1: complete
  - Enrolment Status Phase 2: in preparation
  - Data on the Phase 1 part of the study will be presented in 2025

Philogen has entered an Exclusive Distribution, License, and Supply Agreement with Sun Pharma for commercializing Fibromun globally, which strengthens their ongoing collaboration on Nidlegy™ in Europe, Australia and New Zealand.

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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 and follow us on LinkedIn & X (Formerly Twitter).

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. 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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