Nidlegy™ Phase III PIVOTAL trial meets the study's primary objective demonstrating statistically significant and clinically meaningful improvement in Recurrence-Free Survival for patients with locally advanced fully resectable melanoma

Intratumoral Nidlegy™ followed by surgery significantly improved the Recurrence-Free Survival compared to surgery alone

PIVOTAL (NCT02938299) is the first and so far only Phase III trial demonstrating statistically significant and clinically meaningful benefit of a neoadjuvant therapy in fully resectable locally advanced melanoma patients

Nidlegy™ is the first immunocytokine product to show positive data in a Phase III randomized clinical trial

The results will be presented at an upcoming international medical meeting and submitted to peer-reviewed journal, as well as to regulatory authorities

Nidlegy™ is also currently developed for the treatment of high-risk locally advanced basal cell carcinoma and other types of non-melanoma skin cancers

Siena, Italy, and Mumbai, India, 16 October, 2023 - Philogen S.p.A. (BIT:PHIL) and Sun Pharmaceutical Industries Limited (Reuters: SUN.BO, Bloomberg: SUNP IN, NSE: SUNPHARMA, BSE: 524715 (together with its subsidiaries and/or associated companies, "Sun Pharma")) are pleased to announce positive results from the Phase III PIVOTAL trial in patients with locally advanced fully resectable melanoma (NCT02938299). The study compared neoadjuvant intratumoral Nidlegy™ (Daromun) followed by surgery (treatment arm) vs. surgery alone (control arm). Patients were allowed to receive approved adjuvant systemic therapies after surgery in both arms.

According to the protocol, the primary endpoint of the study was the Recurrence-Free Survival (RFS) assessed per Blinded Independent Central Review (BICR) for patients treated with Nidlegy™, compared to the control arm. At median follow-up of 27.6 months in both groups, the study met its primary endpoint with a statistically significant and clinically meaningful improvement in RFS of the treatment arm compared to the control arm. This positive outcome was consistently in line with the Investigators' Assessment: a significant reduction of the hazard risk ratio of 33% (HR = 0.67) and 37% (HR = 0.63), respectively, favoring the treatment arm, was observed both in the BICR and in the Investigators' Assessment analysis.

Treatment-related adverse events observed with Nidlegy™ were benign and manageable, consistent with the proposed mechanism of action and with the favorable safety profile previously reported in the Phase II study [Danielli et al. (2015) Cancer Immunol. Immunother., 64, 999]. Grade 3 adverse events occurred in 24.8% of the treated patients.

Neither grade 4 toxicity nor treatment-related deaths were observed in the study. Nidlegy™ treatment was not associated with the induction of autoimmune conditions.

PIVOTAL enrolled 257 patients in Europe across 22 clinical centers in Germany, Italy, France and Poland. The results, including sub-group analyses, will be presented at a forthcoming medical meeting.

Nidlegy™ is also being developed in dedicated Phase II clinical trials for the treatment of aggressive forms of non-melanoma skin cancer, including high-risk locally advanced basal cell carcinoma and cutaneous squamous cell carcinoma.

Prof. Dario Neri, **co-founder, CEO and CSO of Philogen, commented:** *"We are extremely pleased to announce positive topline data emerging from our PIVOTAL program in locally advanced resectable melanoma. The clinical data in melanoma and high-risk non melanoma skin cancers bode well for the possible adoption of intralesional Nidlegy™ in a series of Dermato-Oncology indications. Philogen is currently executing six additional advanced clinical trials with registration potential featuring either Nidlegy™ or Fibromun, the company's most advanced product candidates, as active ingredients."*

Alfredo Covelli, MD, **Chief Medical Officer of Philogen, commented:** *"Neoadjuvant cytokine therapy for the treatment of locally advanced skin cancers enables a robust expansion of tumor-infiltrating lymphocytes. By anchoring interleukin-2 and tumor necrosis factor within the tumor mass through the L19 antibody moiety, we minimize systemic side effects while mounting a systemic robust anti-cancer immune response. This Phase 3 study merged the intralesional approach with IL2, pioneered by Prof. Claus Garbe more than 20 years ago, with the concepts of antibody-based tumor targeting, and with neoadjuvant therapy in locally advanced melanoma. The approach may find a broad applicability in different types of cancer."*

Hellen De Kloet, Business Head - Western Europe and ANZ, Sun Pharma, said: *"We are looking forward to commercializing Nidlegy™ in Europe, Australia and New Zealand as the first neoadjuvant immunotherapy for patients with resectable advanced melanoma. Nidlegy™, as an intralesional therapeutic option, addresses the existing significant unmet need for effective and well-tolerated treatments in patients, before undergoing surgery".*

Philogen and Sun Pharma announced on May 30th, 2023, to have entered into distribution, license and supply agreement for commercializing Nidlegy™ in Europe, Australia and New Zealand for the treatment of skin cancers.

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About Nidlegy™ (Daromun)

Nidlegy™ 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. Nidlegy™ 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 PIVOTAL Phase III study

PIVOTAL is a phase III, international, multi-center, randomized, comparator-controlled, parallel-group study evaluating the efficacy and safety of intratumoral injections of Nidlegy™ as a neoadjuvant treatment, followed by standard-of-care treatment (surgery), as opposed to standard-of-care treatment (i.e., surgery alone), in melanoma patients with locally advanced, fully resectable cutaneous, sub-cutaneous (including satellite/in transit metastases), or nodal metastases. accessible to intratumoral injection. For both arms, adjuvant treatment with approved drugs was allowed. Nidlegy™ was injected intralesionally up to four times, once a week before surgery.

About locally advanced fully resectable melanoma

Melanoma is skin tumor which begins when melanocytes start growing without control. Melanocytes are found in the basal layer of the epidermis at the boundary with the next layer (the dermis). Locally advanced melanoma is a metastatic cancer in which neoplastic lesions have spread to drainage area of regional lymph nodes and can appear as micrometastases, satellite/in transit metastases, and/or lymph node metastases. To date, these patients with resectable disease receive surgery, possibly followed by approved adjuvant systemic therapies. There is no approved drug for the treatment of locally advanced fully resectable melanoma in the neoadjuvant setting.

About Philogen

Philogen (https://www.philogen.com) is an Italian-Swiss biotechnology company specialized in the research and development of innovative pharmaceuticals for the treatment of cancer. The Group's main therapeutic strategy is based on the use of ligands capable to selectively deliver potent payloads (such as pro-inflammatory cytokines, drugs or radionuclides) to the tumor mass, sparing healthy tissues. Over the years, Philogen has discovered and developed monoclonal antibody- and small molecule-based ligands with high affinity to tumor-associated antigens. The Group is headquartered in Siena, Italy, with a subsidiary and research center in Zurich, Switzerland. In addition to its main oncology focus, Philogen is also active in the development of novel pharmaceuticals for the treatment of chronic and debilitating conditions.

About Sun Pharmaceutical Industries Ltd. (CIN - L24230GJ1993PLC019050):

Sun Pharma is the world's fourth largest specialty generics company with 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's high growth Global Specialty portfolio spans innovative products in dermatology, ophthalmology, and onco-dermatology and accounts for over 16% 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 "X" @SunPharma_Live

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Forward-Looking Statements

The forward-looking statements contained in this press release may be identified by words such as "aims," "anticipates," "believes," "could," "estimates," "expects," "forecasts," "goal," "intends," "may," "plans," "possible," "potential," "seeks," "will" and variations of these words or similar expressions that are intended to identify forward-looking statements, although not

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