Results of the Phase III PIVOTAL trial of Nidlegy in melanoma to be presented at ASCO 2024

PIVOTAL (NCT02938299) Phase III trial demonstrated statistically significant and clinically meaningful benefit of neoadjuvant Nidlegy in fully resectable locally advanced melanoma

Primary results to be presented at ASCO on May 31 (today)

Siena, Italy and Mumbai, India, May 31, 2024 - 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 that the primary results of the Nidlegy Phase III PIVOTAL trial (NCT02938299) will be the object of an oral presentation at ASCO by Prof. Dr. Axel Hauschild (Abstract #LBA9501).

PIVOTAL (NCT02938299) is an open label, randomized, multicenter, Phase III trial evaluating Nidlegy as a neoadjuvant intralesional therapy for fully resectable, locally advanced melanoma. The primary endpoint of the study was recurrence-free survival (RFS), assessed by investigators and confirmed by retrospective Blinded Independent Central Review (BICR) of PET/CT scans.

The study was conducted at 22 sites in 4 European countries and enrolled a total of 256 patients randomized 1:1 to the treatment (neoadjuvant Nidlegy followed by surgery) and to the control arm (surgery). More than 90% of the enrolled patients had received previous treatments, including surgery, systemic therapy or radiotherapy.

"We look forward to Axel Hauschild's presentation of the PIVOTAL primary results. These are exciting days for the Company: while PIVOTAL is the most advanced Phase III trial to be completed, we expect the readout of at least six additional ongoing studies with registration potential in the near future," **commented Alfredo Covelli, M.D., Chief Medical Officer, Philogen**.

Hellen De Kloet, Business Head - Western Europe and ANZ, Sun Pharma, said "Sun and Philogen have had a fruitful partnership over the past year, wherein Nidlegy has continued to progress in its journey towards the market. Upon approval, Nidlegy is expected to address a significant unmet clinical need for patients suffering from this life-threatening disease. We are looking forward to the data presentation of the PIVOTAL results."

The primary outcome analysis shows that the RFS HR between the treatment and the control arm is 0.59 [95% CI 0.41-0.86; log-rank p=0.005] as per BICR assessment and 0.61 [0.41-0.92; p=0.018] as per investigator assessment (power = 85%; two-sided $\alpha = 0.05$). Median RFS was 16.7 months in the treatment and 6.9 months in the control arm as per BICR. Moreover, distant metastasis-free survival (DMFS) was significantly improved by the neoadjuvant treatment, with an HR between the two arms of 0.60 [0.37-0.95; p=0.029]. The safety profile of Nidlegy was characterized mostly by low-grade, local adverse events (12.7% grade 3 TEAEs). No Grade 3-4 immune-related Adverse Events and no drug-related death recorded.

Collectively, the analysis of primary (RFS) and secondary (DMFS and safety) endpoints show that neoadjuvant Nidlegy is an effective therapeutic option for this patient population.

Philogen and Sun Pharma entered into a distribution, license and supply agreement in May 2023 for commercializing Nidlegy in Europe, Australia and New Zealand for the treatment of skin cancers. In October 2023, both companies announced that PIVOTAL met the primary endpoint of recurrence-free survival. Nidlegy is the first immunocytokine product for which positive Phase III data have been reported.

Nidlegy data accepted by ASCO include:

Abstract Title	Authors	Abstract Number/Presentation details
Phase 3 study (PIVOTAL) of neoadjuvant intralesional Daromun versus immediate surgery in fully resectable melanoma with regional skin and/or nodal metastases	**Hauschild A.,** Hassel J.C., Ziemer M., Rutkowski P., Meier F., Flatz L., Gaudy-Marqueste C., Santinami M., Russano F., von Wasielewski I., Eigentler T., Maio M., Zalaudek I., Haferkamp S., Quaglino P., Ascierto P.A., Garbe C., Robert C., Schadendorf D., Kähler C.K..	Abstract #LBA9501 Oral presentation: Friday, May 31, 2024, 2:45 – 5:45pm CDT

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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. The trial enrolled 256 patients in Europe across 22 clinical centers in Germany, Italy, France and Poland.

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 leading 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 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 "X" @SunPharma_Live

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Forward-Looking Statements

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