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National Stock Exchange of India Limited
Scrip Symbol: SUNPHARMA

BSE Limited
Scrip Code: 524715

Subject: Press Release - Results of the Phase III PIVOTAL trial of Nidlegy

Enclosed herewith is a copy of the Press Release relating to results of the Phase III PIVOTAL trial of Nidlegy in melanoma to be presented at ASCO 2024, which shall be released after this intimation.

For **Sun Pharmaceutical Industries Limited**

(Anoop Deshpande)
Company Secretary and Compliance Officer
ICSI Membership No.: A23983

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

PIVOTAL (NCT02938299) Phase III trial demonstrated statistically significant and clinically meaningful benefit of neoadjuvant Nidlegly 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 Nidlegly 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 Nidlegly 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 Nidlegly 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 Nidlegly has continued to progress in its journey towards the market. Upon approval, Nidlegly 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 Nidlegly 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 Nidlegly 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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FOR MORE INFORMATION:

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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 all forward-looking statements contain these words. Forward-looking statements in this press release include, but are not limited to, statements regarding anticipated advancement of preclinical development efforts and initiation and progression of clinical trials; anticipated enrollment in and progression of Philogen’s clinical trials; the availability of data from clinical trials and preclinical studies; anticipated regulatory filings; the therapeutic potential of Philogen’s product candidates; Philogen’s ability to achieve planned milestones. Philogen may not actually achieve the plans, intentions or expectations disclosed in these forward-looking statements, and you should not place undue reliance on these forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in these forward-looking statements as a result of various factors, including: risks to site initiation, clinical trial commencement, patient enrollment and follow-up, as well as to Philogen’s and its partners’ abilities to meet other anticipated deadlines and milestones; uncertainties inherent in the initiation and completion of preclinical studies and clinical trials and clinical development of Philogen’s product candidates by Philogen or its partners; the risk that Philogen may not realize the intended benefits of its technology; availability and timing of results from preclinical studies and clinical trials; whether the outcomes of preclinical studies will be predictive of clinical trial results; whether initial or interim results from a clinical trial will be predictive of the final results of the trial or the results of future trials; the risk that trials and studies may be delayed and may not have satisfactory outcomes; potential adverse effects arising from the testing or use of Philogen’s product candidates; risks related to Philogen’s ability to maintain existing collaborations and realize the benefits thereof; expectations for regulatory approvals to conduct trials or to market products; other factors which could cause our actual result to differ from those contained in the forward-looking statements, as also described in greater detail in the Risk Factors section in the prospectus drafted by Philogen and approved by Consob on February 17, 2021. Any forward-looking statements contained in this press release speak only as of the date hereof, and Philogen expressly disclaims any obligation to update any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise, except as otherwise required by law. The information and contents of this press release do not: (i) constitute an order or an offer to purchase or to sell financial products or financial services; (ii) relate to special investment goals or to the financial situation or particular requirements of specific users. All information presented, reports published, and opinions expressed are intended purely for information purposes, and do not constitute an offer for the conclusion of a contract or other legal transaction. In particular,

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