Nidlegy™ Marketing Authorization Application Submitted to EMA

First marketing authorization submission for Nidlegy™ for the treatment of locally advanced, fully resectable melanoma in the neoadjuvant setting

Siena, Italy, and Mumbai, India, 4 June, 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 the submission of a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) for the approval of Nidlegy™, an investigational treatment for neoadjuvant (i.e., prior to surgery) locally advanced fully resectable melanoma. The completed submission was based on clinical data from the Phase 3 PIVOTAL study (PH-L19IL2TNF-02/15), whose primary results were presented at ASCO 2024, and on the Phase 2 trial (PH-L19IL2TNF-02/12). If approved, Nidlegy™ would become the first immunocytokine product to gain marketing authorization.

Nidlegy™ is given intralesionally for 4 weeks and acts by boosting the immune system against neoplastic lesions.

In the PIVOTAL trial, a total of 256 patients were 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. A consistent aliquot of the enrolled subjects presented with in-transit or satellite metastases. These patients, although still resectable and with a locally advanced disease, have a worse prognosis compared to naïve locally advanced patients, who have often been the backbone of patient populations included in registration studies with systemic immune- or targeted therapies in the adjuvant and neoadjuvant settings.

The study allowed for post-surgery adjuvant therapies. 40.5% of patients received post-surgery adjuvants in the control arm, compared to 29.8% in the treatment arm.

In the PIVOTAL trial, Nidlegy™ reduced the risk of relapse or death by 41% compared the control arm [HR 0.59; 95% CI 0.41-0.86; log-rank p=0.005]. Median Recurrence Free Survival was more than doubled. Distant metastasis-free survival (DMFS) was significantly improved, with a HR of 0.60 [0.37-0.95; p=0.029] between

the two arms. 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.

"We are enthusiastic about the possibility to bring an innovative and well-tolerated immunotherapy to patients with locally advanced, fully resectable melanoma in Europe by leveraging Philogen's strong collaboration with Sun Pharma," **commented Dario Neri, chief executive officer and chief scientific officer at Philogen**". This disease is currently managed with surgery, potentially followed by systemic adjuvant therapies that are potentially given for years. Having access to a short, well tolerated, and fast acting therapeutic intervention like Nidlegy™ represents a major advance for patients."

Hellen De Kloet, Business Head - Western Europe and ANZ, Sun Pharma, said "The filing of Nidlegy™ in Europe for its first indication marks an important milestone in our efforts to address a high unmet clinical need to help patients suffering from locally advanced, fully resectable melanoma. Once approved, Nidlegy™'s novel mechanism has the potential to change the treatment paradigm in this life-threatening disease in a neoadjuvant setting. We are excited at the prospect of bringing this important product to the benefit of physicians and patients."

Nidlegy™ is partnered with Sun Pharma for the treatment of Skin Cancers in Europe, New Zealand and Australia. Both companies jointly announced on October 23, 2023, that the Phase 3 PIVOTAL trial met the primary endpoint of recurrence-free survival.

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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. The two ingredients are manufactured independently and 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 a potent 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 the 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 a 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 areas of regional lymph nodes and can appear as micrometastases, satellite/in transit metastases, and/or lymph node metastases. To date, 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 numerous 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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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-

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