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 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, the content of the press release is not to be understood as an invitation or recommendation to buy or sell securities of Philogen, or as an advertisement for securities of Philogen. Neither does it constitute an offer to participate in any other transaction, including (but not restricted to) trading in derivatives. The mere use of the website does not give rise to any contractual relationship of any kind between the user and Philogen. Philogen expressly draws your attention to the fact that its share price is subject to fluctuation, and that the future development of the share price cannot be derived either from the previous price history or from the information and content shown on this website. Results achieved in the past provide no guarantee in regard to the future development of the share price. Philogen provides no guarantee of any kind that the capital invested will increase in value or maintain its value. In light of these given risks, we strongly advise you to seek professional advice before making any investment decision. The material contained on the website does not relieve the user from having to make his own decisions. This press release may contain links to external websites of third parties (external links) the content of which is outside the sphere of influence of Philogen. Visiting and using such websites that are accessible via such links are subject to the conditions of the data protection policy of these websites and the liability of the respective operators. Philogen accepts no responsibility and offers no guarantee of any kind for the content or websites of third parties and gives no assurances of any kind in this regard. Philogen accepts no responsibility for the data protection policy and customer information of websites of third parties and shall not be liable for the content or web pages of third parties which are linked to the Philogen website, or which display the Philogen website in frames.