Updated Phase III PIVOTAL Results for Nidlegy™ Published in the Journal of Clinical Oncology

Longer-term analysis confirms the clinical benefit of neoadjuvant Nidlegy™ in locally advanced, fully resectable melanoma

The publication represents an update of the PIVOTAL Phase III results previously published in Annals of Oncology, with longer follow-up and additional event-free survival analyses

Siena, Italy, 17 August 2026 - Philogen S.p.A. (BIT:PHIL) is pleased to announce the publication in the Journal of Clinical Oncology (JCO) of updated efficacy and safety results from the randomized Phase III PIVOTAL study (PH-L19IL2TNF-02/15; NCT02938299), evaluating Nidlegy™ (Daromun; L19IL2/L19TNF) as a neoadjuvant treatment for patients with locally advanced, fully resectable melanoma.

The article, entitled "*Neoadjuvant Intralesional Daromun (L19IL2/L19TNF) in Resectable Locally Advanced Melanoma: An Update on the Efficacy and Safety Results of the PIVOTAL Phase III Trial"*, was published online in the Journal of Clinical Oncology on 11 August 2026 (Vol. 44, Issue 23; doi: 10.1200/JCO-26-00852).

The JCO publication represents an updated analysis of the PIVOTAL Phase III results previously published in Annals of Oncology in 2025 (Kähler et al., Annals of Oncology, 2025, 36, 1166). While the previous publication reported the primary recurrence-free survival analysis at a median follow-up of less than two years, the updated JCO analysis reports efficacy and safety results at a median follow-up of approximately three years from randomization and includes additional post-hoc analyses of event-free survival (EFS).

At the longer follow-up, the updated analysis confirmed a clinically and statistically significant improvement in recurrence-free survival (RFS) for patients receiving neoadjuvant Nidlegy™ followed by surgery compared with patients undergoing upfront surgery. The hazard ratio for recurrence or death was 0.55 (95% CI, 0.38-0.78; P<0.001), corresponding to a 45% reduction in the hazard of recurrence or death. Median RFS was 23.8 months in the Nidlegy™ plus surgery arm compared with 6.5 months in the surgery-only arm. The 3-year RFS rates were 35.7% and 16.6%, respectively.

The updated analysis also confirmed a significant benefit in distant metastasis-free survival (DMFS), with a hazard ratio of 0.53 (95% CI, 0.33-0.83; P=0.005). Median DMFS was 38.7 months in the Nidlegy™ plus

surgery arm compared with 14.0 months in the surgery-only arm, while the 3-year DMFS rates were 51.2% and 28.7%, respectively.

In addition, a post-hoc EFS analysis in the overall study population was consistent with the primary RFS results, with a hazard ratio of 0.71 (95% CI, 0.51-0.98; P=0.034). The publication also reports analyses in patients with recurrent melanoma, who represented 87% of the study population, showing a consistent clinical benefit from neoadjuvant Nidlegy™, including in patients who had previously received systemic therapies.

The updated safety profile of Nidlegy™ remained manageable, with no new safety signals of concern. No treatment-related adverse events above Grade 3 and no treatment-related deaths were reported.

Prof. Dr. Dario Neri, Chief Executive Officer and Chief Scientific Officer of Philogen, commented: "The publication of these updated PIVOTAL results in the Journal of Clinical Oncology provides important longer-term confirmation of the clinical benefit initially reported in Annals of Oncology. With median follow-up now of approximately three years, Nidlegy™ continues to demonstrate meaningful improvements in recurrence-free and distant metastasis-free survival compared with upfront surgery, with a manageable safety profile and no new safety signals. We are particularly encouraged by the consistency of the results in patients with recurrent melanoma, including patients previously treated with systemic therapies. These findings further support the potential role of Nidlegy™ as a neoadjuvant treatment for patients with locally advanced, fully resectable melanoma."

Nidlegy™ is partnered with Sun Pharma for the treatment of Skin Cancers in Europe, New Zealand and Australia.

* * *

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.

* * *

FOR MORE INFORMATION:

Philogen - Investor Relations

- Emanuele Puca | *Investor Relator*

* * *

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.