Philogen
innovating targeting

Courtesy English Translation

Nidlegy™ Marketing Authorization Application Resubmitted to EMA

Updated application for Nidlegy™ for the neoadjuvant treatment of locally advanced, fully resectable melanoma submitted to the European Medicines Agency

The submission follows Philogen's previously communicated timelines

Siena, Italy, 27 July 2026 - Philogen S.p.A. (BIT:PHIL) is pleased to announce the submission of an updated Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) for the approval of Nidlegy™, an investigational product for the neoadjuvant treatment of adult patients with locally advanced, fully resectable melanoma.

The updated submission is based on clinical data from the randomized Phase III PIVOTAL study (PH-L19IL2TNF-02/15; NCT02938299). Compared with the MAA submitted in June 2024, the updated dossier is based on a longer median patient follow-up (33 months as opposed to 21 months) and includes additional post-hoc analyses focused on event-free survival. Clinical data supporting the 2024 submission were published in Annals of Oncology (Kähler et al., Annals of Oncology, 2025, 36, 1166). The updated data forming the basis of this resubmission have been accepted for publication in the Journal of Clinical Oncology (doi 10.1200/JCO-26-00852) and are expected to be published online in the coming weeks.

In the PIVOTAL study, Nidlegy™ reduced the risk of relapse or death compared with the control arm, and its safety profile was characterized mostly by low-grade, local adverse events. The updated application also includes additional Chemistry, Manufacturing and Controls (CMC) information intended to address the outstanding questions raised during the previous procedure.

Additional supporting data included in the dossier comprise efficacy and safety data from the Phase II study PH-L19IL2TNF-02/12 (NCT02076633), safety data from the ongoing Phase III NeoDREAM study PH-L19IL2TNF-01/18 (NCT03567889), and safety data from the Phase II study PH-L19IL2TNFNMSC-04/19 (NCT04362722) in non-melanoma skin cancer.

Prof. Dr. Dario Neri, Chief Executive Officer and Chief Scientific Officer of Philogen, commented: "Philogen remains fully committed to advancing Nidlegy™ in melanoma and non-melanoma skin cancers. Since the previous MAA procedure, our team has worked intensively to address the clinical and CMC questions raised during the review. In parallel, we have continued to expand the global Phase III NeoDREAM

melanoma study and have launched additional registrational studies in non-melanoma skin cancers. We are encouraged by the data generated to date and will continue working with our partners and regulators with the aim of bringing this innovative treatment to patients in need."

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.