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Philogen Provides Update on Marketing Authorization Application for Nidlegy™ in the European Union

Siena, Italy 24 June 2025 – Philogen S.p.A (BIT: PHIL) ("Philogen") today announced the decision to voluntarily withdraw the application for marketing authorization to the European Medicines Agency (EMA) for Nidlegy™, a biological investigational medicinal product which is intended to be used for the neoadjuvant treatment of adult patients with locally advanced fully resectable melanoma.

The Marketing Authorization Application (MAA) for Nidlegy™ submitted in June 2024 was supported by data from PIVOTAL (NCT02938299), a randomized Phase 3 study in 256 patients with locally advanced fully resectable melanoma, in which Nidlegy™ reduced the risk of relapse or death by 41% compared to the control arm (Hauschild et al. Journal of Clinical Oncology 2024, 43; Kähler et al Annals of Oncology, 2025, manuscript accepted). The safety profile of Nidlegy™ was characterized mostly by low-grade, local adverse events.

The company's decision to withdraw the MAA was due to the timing of the availability of Chemistry Manufacturing and Controls (CMC) and additional clinical data to better characterize the benefit:risk profile in patients with locally advanced resectable melanoma. Provision of the CMC and clinical data were unlikely to be completed within the current allowed timeframe.

Philogen remains confident in the favorable benefit-risk profile of Nidlegy™, underscored by its clinically meaningful efficacy and tolerable safety profile in both melanoma (Hauschild et al. Journal of Clinical Oncology 2024, 43, Kähler et al. Annals of Oncology, 2025, manuscript accepted) and in non-melanoma skin cancers (Flatz et al. JEADV 2025, 39, e147). Until now, Nidlegy™ has been given to more than 450 patients with different types of skin cancer.

The company continues to closely interact with the EMA and with the medical community, with the goal of making Nidlegy™ available to both melanoma and non-melanoma skin cancer patients as soon as possible.

Prof. Dr. Dario Neri, CEO and CSO of Philogen, commented: "After careful consideration of the feedback and ongoing dialogue with EMA, we have decided to withdraw the MAA for Nidlegy™ and resubmit an updated application, in view of the potential of the product in melanoma and beyond. We are working closely together with EMA to address their requests in preparation of the forthcoming resubmission of the MAA."

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About Nidlegy™ (Daromun)

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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 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.

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