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Philogen
innovating targeting

Philogen announces the completion of a second interim analysis of its phase III clinical program with Nidlegy™ for the treatment of melanoma

Nidlegy™ was found to be well-tolerated and 149 out of the anticipated 214 patients have been safely treated

Data Safety Monitoring Board recommends to continue the study as planned

Siena, Italy, January 13th, 2021 - Philogen S.p.A., a clinical-stage biotechnology company focused on antibody-based therapeutics, is pleased to announce that 50% of the expected events for the primary outcome analysis of the PIVOTAL study were reached in December 2020. In this phase III clinical trial, the effect of Nidlegy™ is evaluated in melanoma patients with locally advanced, fully resectable metastatic cancer, and at the time of the second interim analysis, had already recruited 149 out of the anticipated 214 patients (one additional patient was enrolled recently). As a consequence, the second interim data analysis foreseen by the clinical protocol was carried out and submitted to the Data and Safety Monitoring Board of the study for their consideration. On December 22nd, 2020 the DSMB met to review the data and issued to the company a recommendation to continue with the study and patient accrual as detailed by the clinical protocol.

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, followed by standard-of-care treatment (surgery + approved adjuvants), as opposed to standard-of-care treatment alone, in melanoma patients with locally advanced, fully resectable cutaneous, subcutaneous, or nodal metastases, accessible to intratumoral injection. A first interim analysis at 25% of the expected events and 82 enrolled patients had already been carried out in March 2019.

The primary endpoint of the trial comprises the assessment of Recurrence-Free Survival at one year after randomization. Secondary endpoints include Overall Survival, Local Recurrence-Free Survival and Distant Metastasis-Free Survival, as well as Safety.

The study is expected to include 214 patients across more than 20 centers (currently 18 centers) in four different EU countries (France, Germany, Italy, Poland).

Dario Neri, Chief Executive Officer of Philogen commented: "We are extremely pleased to record the PIVOTAL study DSMB's recommendation to carry on with the study as originally planned. This reinforces the confidence in our strategy to bring Nidlegy™ to the market as a new therapeutic opportunity for melanoma patients."

About Philogen

Philogen is a Swiss-Italian clinical-stage company engaged in the discovery and development of novel pharmaceutical and biopharmaceutical products. Philogen's strategy is to deliver bioactive agents, for example cytokines or drugs, to the site of disease using antibodies and other ligands that specifically and efficiently target stromal antigens. This technology has generated a strong proprietary pipeline of clinical-stage products and preclinical compounds in an array of disease indications. Philogen is headquartered in Siena, Italy, and has research activities at its subsidiary company Philochem in Zürich, Switzerland. Philogen is independently owned, and has signed agreements with several major

pharmaceutical companies. For more information please visit www.philogen.com and www.philochem.com.

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