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Philogen receives authorisation to initiate new study in France to evaluate Nidlegy™ in several nonmelanoma skin cancers

Siena, Italy, February 17, 2022 - Philogen S.p.A. ("Philogen" or "the Company"), a clinical-stage biotechnology company focused on antibody and small molecule-based targeted therapeutics, is pleased to announce that France's National Agency for the Safety of Medicines and Health Products (ANSM) has authorized the Company to run a Phase II study of Nidlegy™ in patients affected by different non-melanoma skin cancer indications. A favourable opinion about the study had already been obtained by one of the country's ethic committees (Comité de Protection des Personnes Sud-Est III) in January 2022.

Patients affected by Basal Cell Carcinoma (BCC), cutaneous Squamous Cell Carcinoma (cSCC), Merkel Cell Carcinoma, Keratoacanthoma, tumoral cutaneous T-Cell Lymphoma, Kaposi's Sarcoma or Adnexal Tumors of the Skin, for whom available alternatives have already been exhausted or who are no candidates to such alternative approaches will be eligible for the clinical study.

Nidlegy™, the combination of the two active principles bifikafusp alfa (L19IL2) and onfekafusp alfa (L19TNF), has already shown promising results in the intralesional treatment of patients with advanced melanoma and in BCC and cSCC in an ongoing Phase II study. The durable responses, excellent safety profile and favourable cosmetic outcome of injected lesions have encouraged the investigation of efficacy and safety of Nidlegy™ in injectable lesions of numerous non-melanoma skin cancer indications, which are underserved by alternatives presently available.

Prof. Dario Neri, co-founder and President of the Scientific Advisory Board of Philogen said: "We are delighted to start this clinical Phase II study in non-melanoma skin cancers in France under the leadership of Prof. Jean-Jacques Grob, a world-class expert in this group of tumors and to explore the potential of Nidlegy™ in patients for whom existing therapeutic alternatives are not or no longer practicable."

About the Philogen group

Philogen is a Swiss-Italian clinical-stage company, listed on the Italian stock exchange, 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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