Main Office: Loc. Bellaria, 35 - 53018 Sovicille (SI), Italy
e-mail: info@philogen.it – website: www.philogen.com

Philogen
innovating targeting

Philogen announces enrolment of 214 patients in the Nidlegy™ Phase III European clinical trial for the treatment of locally advanced melanoma

- 214 patients recruited in the study, in line with protocol
- Phase III trial to read when 95 events (tumor recurrence or patient death) have occurred

Siena (Italy), 25 June 2022 - Philogen S.p.A., a clinical-stage biotechnology company focused on antibody and small molecule-based targeted therapeutics, is pleased to announce the enrolment of 214 patients, in line with the protocol of its Phase III European trial of Nidlegy™ in locally advanced melanoma.

The patients have been recruited within the expected timelines and the study will read when 95 events have occurred, as per protocol.

The Phase III, international, multi-center, randomized, comparator-controlled, parallel-group study is evaluating the efficacy and safety of intratumoral injections of Nidlegy™ as neoadjuvant (i.e., prior to surgery), 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 metastatic disease, accessible to intralesional injection.

The study is taking place in 21 clinical centers in four different EU countries (France, Germany, Italy, and Poland).

The primary endpoint of the trial is Recurrence-Free Survival. Secondary endpoints include Overall Survival, Local Recurrence-Free Survival and Distant Metastasis-Free Survival, as well as Safety. Two interim analyses have been successfully conducted at 25% (March 2019) and 50% (December 2020) of the expected events

Prof. Dr. Dario Neri, Chief Executive Officer of Philogen commented: "We are pleased to announce the enrolment of 214 patients in our Phase III European clinical trial for Nidlegy™, in line with the study protocol and within the expected timelines.The product is also showing potent therapeutic activity in non-melanoma skin cancer, inducing complete responses in lesions which would have otherwise required disfiguring surgery. Nidlegy™ has the potential to serve a range of dermato-oncology indications, which are not adequately addressed by existing drugs. Besides the Phase III trial of Nidlegy™ in Stage IIIB,C melanoma in Europe, Philogen is currently running six additional clinical studies with pivotal potential with Nidlegy™ and Fibromun, in Europe and in the United States."

* * *

Philogen Group Description

Philogen is an Italian-Swiss company active in the biotechnology sector, specialized in the research and development of pharmaceutical products for the treatment of highly lethal diseases. The Group mainly discovers and develops targeted anticancer drugs, exploiting high-affinity ligands for tumor markers (also called tumor antigens). These ligands - human monoclonal antibodies or small organic molecules - are identified using *Antibody Phage Display Libraries* and *DNA-Encoded Chemical Library* technologies.

The Group's main therapeutic strategy for the treatment of these diseases is represented by the so-called *tumor targeting*. This approach is based on the use of ligands capable of selectively delivering very potent therapeutic active ingredients (such as pro-inflammatory cytokines) to the tumor mass, sparing healthy tissues. Over the years, Philogen has mainly developed monoclonal antibody-based ligands that are specific for antigens expressed in tumor-associated blood vessels, but not expressed in blood vessels associated with healthy tissues. These antigens are usually more abundant and more stable than those expressed directly on the surface of tumor cells. This approach, so called *vascular targeting*, is used for most of the projects pursued by the Group.

The Group's objective is to generate, develop and market innovative products for the treatment of diseases for which medical science has not yet identified satisfactory therapies. This is achieved by exploiting (i) proprietary technologies for the isolation of ligands that react with antigens present in certain diseases, (ii) experience in the development of products targeted at the tissues affected by the disease, (iii) experience in drug manufacturing and development, and (iv) an extensive portfolio of patents and intellectual property rights.

Although the Group's drugs are primarily oncology applications, the *targeting* approach is also potentially applicable to other diseases, such as certain chronic inflammatory diseases.

* * *

FOR MORE INFORMATION:

Philogen - Investor Relations

IR@philogen.com - Emanuele Puca | *Investor Relations*

Consilium Strategic Communications contacts

Mary-Jane Elliott, Davide Salvi

Philogen@consilium-comms.com