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

Philogen
innovating targeting

Philogen Provides Corporate Update

- **Nidlegy™ and Fibromun on track with planned timelines in pivotal clinical trials**
- **Use of Nidlegy™ in non-melanoma skin cancer expanded in Phase II clinical trials**
- **Early evidence of potent activity of Fibromun in combination with Standard of Care in last line patients with Glioblastoma and Soft Tissue Sarcoma**
- **Clinical experience with OncoFAP confirms preclinical results, recently published in *Proceedings of the National Academy of Sciences U.S.A*.**
- **Positive net financial position of €96.077M compared to €104.668M at 31 March 2021 (€44.238M at 31 December 2020)**
- **Philogen's management team will hold a Webinar to discuss the news on Wednesday 29th of September 2021 at 12:00 ET / 17:00 BST / 18:00 CEST (Please find the link to this Webinar here)**

Siena (Italy), 29 September 2021 - Philogen S.p.A., a clinical-stage biotechnology company focused on antibody- and small molecule-based targeted therapeutics announces its Interim Results for the six month period ended 30th June 2021 and provides an update regarding recent corporate developments.

Dario Neri, CEO of Philogen, commented on the results for the year and the evolution of the business:

" Following our recent listing, I am delighted to report that Philogen has made significant progress both in our clinical and pre-clinical stage pipeline, showing curative potential in difficult to treat preclinical models of cancer.

Development for pivotal clinical trials is progressing on track. We expect to complete patient enrollment in the European Phase III clinical trial of Nidlegy™ in melanoma by mid-2022. With respect to the two European clinical trials of Fibromun in newly diagnosed and second recurrence sarcoma, completion of recruitment of the respective patients is expected by the end of 2023.

Clinical trials in patients with last line Glioblastoma or with last line Soft Tissue Sarcoma, for which objective responses are very rarely observed using Standard of Care drugs, are showing signs of potent clinical activity when Fibromun is added to the treatment.

I am also pleased to see that we are making progress in the clinical development of small molecules targeted therapeutics. OncoFAP, our proprietary targeting platform directed against Fibroblast Activation Protein, is revealing a significant ability to selectively localize both primary and heavily disseminated tumors in patients. This Nuclear Medicine validation paves the way for the implementation of innovative therapeutic strategies.

Philogen remains committed to the development of pharmaceutical products with game changing potential for difficult to treat conditions and is well capitalized to aggressively perform its industrial plan."

MAIN EVENTS FOR THE FIRST HALF 2021 AND RECENT HIGHLIGHTS

Proprietary products

- **Nidlegy™** is a pharmaceutical product, proprietary to Philogen, consisting of two active ingredients, L19-IL2 and L19-TNF. The L19 antibody is specific for the B domain 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 inflammatory cytokines with anti-tumor activities.
  - Phase III studies in Stage IIIB/C melanoma - New centers opened with the goal of accelerating patient enrollment in both the U.S. and Europe;
  - European Phase III study in Stage III B/C melanoma - enrolled 168 patients as of June 30, 2021. In addition, after the close of the 2021 financial year and up to the present date, additional 13 patients have been recruited after the close of the year, reaching a total number of 181 patients;
  - U.S. Phase III study in Stage III B/C melanoma - signed contract with a *Contract Research Organization* to open up to 38 clinical centers to add to ongoing study;

- US Phase II study in stage IV melanoma - revised clinical protocol submission to US Food and Drug Administration is expected;
- European Phase II study in non-melanoma skin cancers - Promising clinical data at ten months post-treatment on Nidlegy™ in patients with basal cell carcinoma. The clinical trial features the participation of clinical centers in Germany, Switzerland and Poland. Additional countries are planned to be involved in Phase II studies;

- **Fibromun** is a pharmaceutical product, proprietary to Philogen, consisting of the L19 antibody fused to TNF.
  - Soft tissue sarcoma - Opening of new clinical centres in Germany, Spain, Italy, Poland and the United States, with the aim of accelerating enrolment in the three ongoing clinical trials (two European and one American);
  - European Phase II study in soft tissue sarcoma with at least two recurrences (i.e., ≥ third line of treatment) - Completed patient enrollment in the Run-in portion of the study. The objective of this phase is to confirm drug tolerability and to monitor early signs of efficacy in a limited number of patients. In this setting, Fibromun is administered in combination with Dacarbazine. An objective response has been observed. The historical objective response rate for this population is 4.3% (Garcia-del-Muro et al., J Clin Oncol 2011, 29,2528). The randomized phase is planned to begin, subject to approval by the Data and Safety Monitoring Board;
  - Glioblastoma (i.e., grade IV glioma) - Completed a *Parallel Scientific Advice* (PSA) with the *European Medicines Agency* and the *U.S. Food and Drug Administration* in June 2021. The development plan for the treatment of glioblastoma and the proposed strategy for marketing authorisation have been discussed and agreed with the relevant authorities. Philogen will follow the recommendations that were provided during the PSA;
  - Phase II study in Grade III-IV wildtype IDH glioma at first relapse/recurrence - Promising interim survival benefits observed in the European Phase I/II study, in which Fibromun is being studied as monotherapy. Data on *Progression Free Survival* at six months from the start of treatment are being completed, while data on *Overall Survival* will be consolidated by the end of 2021;
  - Phase I/II study in glioblastoma at first relapse/recurrence - monitoring of Safety, presence of Objective Responses and *Progression Free Survival* in patients treated during the dose *escalation* portion (i.e., Phase I of the study). The first patient in the trial, treated with Fibromun plus Lomustine, exhibited a tumor shrinkage of 74% at 18 weeks and of 92% at 24 weeks. The patient (and the ones who have been treated after him, for whom follow-up time is still insufficient) will continue to be monitored at regular intervals. The historical objective response rate for this patient population upon Lomustine treatment is 4.3% and responses of this magnitude and duration are virtually never observed (Wick et al., J Clin Oncol 2010, 28,1168).
- **OncoFAP** is a small organic molecule, proprietary to Philogen group, with affinity for *Fibroblast Activation Protein* (FAP). The product has the ability to selectively localize in a variety of metastatic solid tumors.
  - Excellent *targeting* capabilities of OncoFAP in patients with various tumor types. Clinicians at the Department of Nuclear Medicine of the University Hospital Münster have used OncoFAP radiolabeled with gallium-68 (OncoFAP-68Ga) to detect neoplastic lesions of both primary and metastatic origin. Of note is the intense uptake in the tumor and the low absorption in healthy organs (including kidneys) after only 1h after intravenous administration of the drug. Thus, imaging results in cancer patients confirmed the excellent properties of OncoFAP observed in preclinical models, which have recently been published by the Philogen group in the *Proceedings of the National Academy of Sciences U.S.A.*;
  - Several international Phase I/II clinical trials are currently being designed, with the aim of studying OncoFAP-68Ga (diagnostic agent) and OncoFAP-177Lu (diagnostic and therapeutic agent) in a larger number of patients with different types of cancer. These studies will provide an indication of which tumor(s) will be the focus of clinical trials. These studies are expected to begin in 2022.

Licensed products

- Continue partnerships on Dodekin (Confidential Partner) and Dekavil (Pfizer);
- **ABBV-022** is a product generated and out-licensed by Philogen. The drug consists of the cytokine interleukin 22 fused to a monoclonal antibody;
  - Start of a phase I clinical trial for the treatment of ulcerative colitis

GMP

- The structural work on the second GMP production plant, located at the Philogen site in Rosia (Siena), was completed on schedule in line with the business plan. The new plant has been designed to meet the highest regulatory standards for the production of therapeutic protein-based drugs and will be used for the production of commercial pharmaceuticals and clinical trial drug products. The installation and validation of the process machines at the new GMP site is expected to be completed in the first quarter of 2022, following which authorization from the Italian

competent authority (AIFA) will be sought for the production and marketing of the drugs. It should be noted that the Company already has a production site in Montarioso that is authorized by AIFA solely for the production of experimental drugs for clinical trials;

Financial Highlights

- **Revenues from contracts with customers amounting to €1.548M** (€2.308M at 30 June 2020)
- **EBITDA of negative €8.107M** (negative €5.646M at 30 June 2020)
- **EBIT of negative €8.860M** (negative €6.352M at 30 June 2020)
- **Net loss of €8.653M** (net loss of €8.424M at 30 June 2020)
- **Positive net financial position of €96.077M compared to** €104.668M at 31 March 2021 (€44.238M at 31 December 2020)

* * *

Philogen Group Description

Philogen is an Italian-Swiss company active in the biotechnology sector, specialised 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 tumour markers (also called tumour antigens). These ligands - human monoclonal antibodies or small organic molecules - are identified using *Antibody Phage Display Libraries* and DNA-Encoded *Chemical Libraries* 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