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Philogen
innovating targeting

Philogen Provides Corporate Update

- **Nidlegy™ and Fibromun are on track with planned timelines in pivotal clinical trials**
- **Fibromun shows potent activity in last-line glioblastoma in combination with Lomustine**
- **The OncoFAP platform shows promising results beyond radio-conjugates**
- **Cash & cash equivalents of €107.8M**
- **Philogen's management team will hold a Webinar to discuss the news on November 12th, 2021, at 11:00 EST / 16:00 BST / 17:00 CEST (Please find the link to this Webinar here)**

Siena (Italy), 12 November 2021 - Philogen S.p.A., a clinical-stage biotechnology company focused on antibody- and small molecule-based targeted therapeutics provides an update regarding the Company's Third Quarter Results and recent corporate developments.

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

"The past few months have been very important for Philogen, and I am delighted to provide an update on our pipeline and our financial position.

Our late-stage candidates Nidlegy™ and Fibromun are progressing well and patient enrolment for their pivotal clinical trials is on track. We are expecting to complete patient enrollment in the melanoma European Phase III clinical trial of Nidlegy™ in mid-2022. The recruitment of patients in Fibromun's two European clinical studies in newly diagnosed and last-line soft tissue sarcoma is expected to be achieved by the end of 2023.

I am particularly excited about the emerging results in the Phase I/II study of Fibromun as a last-line treatment for glioblastoma, the most common and malignant primary brain tumor. Nine months after the beginning of treatment, the target lesion of the first evaluable patient has disappeared, and we look forward to seeing how long this potent response will last.

I am also pleased to see that we are making progress in the field of small molecule targeted therapeutics beyond OncoFAP-radio conjugates. OncoFAP is a ligand for the delivery of radionuclides and cytotoxic drugs. The excellent targeting performance of OncoFAP in patients with solid tumors was recently validated by PET imaging procedures, and we have now generated new exciting preclinical efficacy data with Small Molecule-Drug Conjugates based on OncoFAP.

Philogen remains committed to developing pharmaceutical products with game changing potential for difficult-to-treat conditions and is well capitalized to pursue this important goal."

MAIN EVENTS 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 to 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 European study in Stage IIIB/C melanoma – the study enrolled 187 patients as of November 12, 2021, with multiple clinical centers opened in Germany, France, Italy, and Poland
- **Fibromun** is a pharmaceutical product, proprietary to Philogen, consisting of the L19 antibody fused to TNF
  - European pivotal studies in soft tissue sarcoma – the studies feature the participation of multiple clinical centers in Germany, Spain, Italy, and Poland
  - Phase I/II study in glioblastoma at first relapse/recurrence – the Phase I part of the study foresees three cohorts (3-6 subjects per cohort), in which patients receive escalating doses of Fibromun and Lomustine. All patients in the first cohort have been enrolled. The historical response rate for recurrent glioblastoma patients treated with Lomustine monotherapy is 4.3%. However, in recurrent glioblastoma patients with unmethylated MGMT promoter status the responses are close to 0% (Wick et al., J Clin Oncol 2010, 28,1168; Weller and Le Rhun et al., Cancer Treat Rev 2020, 87,102029). In the first treated patient (with unmethylated MGMT promoter), the target

glioblastoma lesion has disappeared at nine months after treatment start. Philogen is now planning to further explore different administration schedules in a new clinical trial, which is expected to start in 2022 and which will allow for the collection of more information on the combination treatment.

- **OncoFAP** is a small organic molecule, proprietary to Philogen group, with ultra-high affinity for *Fibroblast Activation Protein* (FAP). The product has the ability to selectively localize in a variety of solid tumors and metastatic lesions.
  - OncoFAP-radio conjugates - excellent targeting properties 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) only one hour after intravenous administration of the drug. Thus, imaging results in cancer patients confirmed the excellent properties of OncoFAP observed in preclinical models, which have been published by the Philogen group in the *Proceedings of the National Academy of Sciences U.S.A.* Clinical investigations of the therapeutic agent (OncoFAP-177Lu) are expected to start in 2022.
  - OncoFAP-drug conjugates – these drugs consist of (i) the OncoFAP ligand, (ii) a cleavable linker and (iii) a cytotoxic payload, which is released selectively at the tumor site. Scientists at Philogen's R&D center have recently discovered the optimal cleavable linker leading to complete tumor eradications in preclinical models of cancer, when administered as single agent. Philogen has discovered yet another potential clinical candidate that will expand the clinical stage pipeline over the next few years.

Partnered products

- **Dekavil** is a pharmaceutical product, licensed to Pfizer, consisting of the F8 antibody specific to the A domain of Fibronectin (EDA) fused to interleukin-10 (IL10). EDA is a protein abundantly expressed at sites of inflammation, but it is virtually undetectable in healthy tissues. IL10 is an inflammatory cytokine suitable for the treatment of chronic inflammatory diseases
  - The product will be investigated in novel clinical studies as a potential treatment in patients with certain chronic inflammatory conditions

FINANCIAL UPDATE

- Philogen ended the third quarter of 2021 with cash and cash equivalents of €107.829M compared to €61.943M on December 31, 2020.
- The net financial position on September 30, 2021, was €90.905M compared to a positive net financial position of €44.238M on December 31, 2020 (an overall increase of over 100%).
- The change in the net financial position compared to December 31, 2020, was mainly due to the proceeds raised during the Initial Public Offering on March 3, 2021, amounting to €65.404M net of commissions paid to the syndicate for the institutional placement and costs related to the issue of new shares of approximately €3.635M.

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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.

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FOR MORE INFORMATION:

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