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Philogen
innovating targeting

Philogen Provides Corporate Update

- **211 out of 214 patients recruited in European Phase III trial investigating the neoadjuvant Nidlegy™ treatment of Stage IIIB/C melanoma, in line with expectations.**
- **Fibromun further demonstrates potent activity in recurrent glioblastoma with durable major responses. Pivotal clinical trials in soft-tissue sarcoma and glioblastoma are on track.**
- **OncoFAP shows potent activity as a small molecule-drug conjugate.**
- **^{177}Lu-BiOncoFAP therapy shown to eradicate cancer in pre-clinical studies. Signed contract with Senn Chemicals for the GMP manufacturing of the product. Clinical trials expected to start in 2H 2023.**
- **Limited or no cash burn expected in 2022 due to existing and new partnerships, despite increased spending for clinical trials.**
- **Philogen's management team will hold a webinar to discuss these updates on June 23, 2022, at 10:00 ET / 15:00 BST / 16:00 CEST (Please find the link to this webinar here).**

Siena (Italy), 23 June 2022 - Philogen S.p.A., a clinical-stage biotechnology company focused on antibody- and small molecule-based targeted therapeutics, provides an update regarding recent corporate developments.

Prof. Dr. Dario Neri, Chief Executive Officer of Philogen commented: *"Philogen has made significant progress over the past few months as we continue investing our IPO proceeds to strengthen our GMP manufacturing capacity and speed up patient enrolment in clinical trials. We are particularly pleased with the progress of our Phase III European study investigating Nidlegy™ treatment of Stage IIIB/C melanoma, of which we have nearly completed patient recruitment.*

Fibromun's trials in soft-tissue sarcoma are also ongoing in the U.S., Germany, Poland, Spain, and Italy (France planned), with the participation of leading clinical centers. We expect to have more than 30 active clinical centers by the end of this year for the European and US pivotal studies.

My thanks go to our investors and to everyone at Philogen for their hard work and unwavering support."

MAIN EVENTS AND RECENT HIGHLIGHTS

Proprietary products

- **Nidlegy™** is a pharmaceutical product, proprietary to Philogen, consisting of two active ingredients, L19IL2 and L19TNF. 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
    - 211 out of 214 patients have been recruited. The trial will read when 95 events (tumor recurrence or patient death) have occurred, as per protocol
    - 21 clinical centers opened in Germany, France, Italy, and Poland
  - Phase III U.S. study in Stage IIIB/C melanoma
    - 13 clinical sites are currently open. We expect to have more than 25 centers active by the end of 2022 to speed up recruitment
  - Non-melanoma skin cancer
    - Progress in Phase II studies ongoing in France, Germany, Poland, and soon in Italy
- **Fibromun** (L19TNF) is a pharmaceutical product, proprietary to Philogen, consisting of the L19 antibody fused to TNF
  - European Phase III study in metastatic/advanced soft-tissue sarcoma
    - 32 patients have been recruited. The recruitment rate of patients is progressing according to planned timelines
    - 10 clinical centers opened in Germany, Spain, Italy, and Poland. We expect to have more than 20 centers active by the end of 2022
  - Phase I/II study in glioblastoma at first progression

- The Phase I dose escalation part of the study is exploring different doses of Fibromun and Lomustine (3-6 subjects per cohort)
- Cohort 1 has been completed with 6 patients.
- Recruitment for cohort 2 is ongoing, with 4 out of 6 patients recruited.
- The historical objective response rate (ORR) for recurrent glioblastoma treated with Lomustine is 4.3-13.9%. The median progression free survival of these patients with lomustine monotherapy is 6 weeks. In unmethylated MGMT tumors, objective responses are virtually never observed (0% ORR) (Wick et al., J Clin Oncol 2010, 28,1168; Weller and Le Rhun et al., Cancer Treat Rev 2020, 87,102029). In cohort 1, we observed durable major responses in 2 out of 6 patients which are ongoing for more than 12 months. In addition, 3 patients had disease stabilization for over 4.5 months (follow up ongoing), while one patient had Covid-19 and had to exit the study without receiving the combination treatment.

- **OncoFAP** is a small organic molecule ligand with ultra-high affinity for *Fibroblast Activation Protein* (FAP)
  - OncoFAP-radio conjugates
    - Imaging - excellent targeting properties of ^{68}Ga-DOTAGA-OncoFAP confirmed in more than 50 patients with various types of malignancies.
    - Therapy – ^{177}Lu-DOTAGA-BiOncoFAP, featuring a bivalent OncoFAP ligand, cures cancer in murine models and has been identified as the therapeutic candidate for clinical development.
    - Signed a contract with Senn Chemicals to manufacture DOTAGA-BiOncoFAP
  - 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. A novel OncoFAP-drug conjugate, featuring an optimized cleavable linker, is being studied in animal models of cancer and may represent a novel potential clinical candidate.
- The R&D center in Zürich has recently generated promising novel prototypes, including a highly active **small molecule drug conjugate targeting PSMA.** The company is well poised for the definition of the clinical candidates to be moved into the clinic in 2023.

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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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