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Philogen
innovating targeting

Philogen Reports Full Year 2021 Results and Provides Corporate Update

- **Patient enrolment in Nidlegy™'s European Phase III trial for the treatment of Stage IIIB/C melanoma is progressing in line with the business plan. 207 out of 214 patients have been recruited. The trial will conclude when 95 events (tumor recurrence or patient death) have occurred, as per protocol.**
- **Fibromun confirms potent activity in recurrent glioblastoma with durable major responses. Pivotal clinical trials in soft-tissue sarcoma and glioma are on track.**
- **Philogen's subsidiary signed a new partnership with Bracco Imaging in the diagnostic imaging field.**
- **^{68}Ga-OncoFAP imaging results have been published, paving the way for pivotal trials.**
- **^{177}Lu-OncoFAP therapy shown to eradicate cancer in pre-clinical studies and is well positioned for clinical development.**
- **OncoFAP also potently active as a small molecule-drug conjugate.**
- **Cash & cash equivalents of €101,6M as of December 31, 2021.**
- **In 2022 Philogen will limit cash burn (or possibly have no cash burn), due to existing and new partnerships, despite increased spending for clinical trials.**
- **Philogen's management team will hold a webinar to discuss the news on April 1, 2022, at 09:00 ET / 14:00 BST / 15:00 CET (Please find the link to this webinar here).**

Siena (Italy), 1 April 2022 - 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 full year 2021 results and recent corporate developments.

"We are excited for the great progress we have made following our listing on the Italian Stock Exchange in March 2021. The IPO proceeds and revenues from industrial collaborations have provided the financial resources to accelerate clinical trials, develop new products and invest in infrastructure. Philogen has a rich pipeline of late-stage clinical assets and continues to innovate by generating new prototypes", **commented Prof. Dr. Dario Neri, Chief Executive Officer of Philogen.**

"The enrolment rate of Nidlegy™ in the Phase III European study for the treatment of Stage IIIB/C *melanoma has advanced according to plan. Shortly after the IPO, we signed a contract with a CRO to speed up recruitment in the Phase III study in the United States with the opening of new centers.*

The Fibromun programs are also making good progress. The trials in soft-tissue sarcoma are ongoing in the U.S., Germany, Poland, Spain, and Italy, with the participation of leading clinical centers. We are also advancing this product for the treatment of glioblastoma, both in first-line and second-line. We are very encouraged by the observation of major objective responses in second-line patients which are normally not seen with standard-of-care drugs. These responses have now been confirmed at long time points (e.g., up to 12 months). We continue to monitor the duration of response and to include more patients in the studies.

I am pleased about the significant advancement we have made with our small molecule platforms. We have partnered with Bracco, a world-leading pharmaceutical company in diagnostic imaging, to develop and commercialize a small molecule for diagnostic imaging applications.

The excellent targeting performance of OncoFAP in patients with solid tumors was reported in a recent study published in the European Journal of Nuclear Medicine and Molecular Imaging, providing the basis for registration activities. Moreover, pre-clinical data for the ^{177}Lu-labeled therapeutic candidate is supporting the initiation of dedicated clinical developments.

Philogen finished 2021 with €101,6M of cash-and-cash equivalents. In 2022, Philogen will limit cash burn (or have no cash burn), due to new and existing partnerships, despite increased spending for clinical trials."

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
    - 207 out of 214 patients have been recruited. The trial will conclude 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
    - 6 clinical sites are currently open. We expect to add up to 20 new sites in 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 pivotal studies in soft-tissue sarcoma
    - The recruitment rate of patients is progressing according to foreseen timelines
  - Phase I/II study in glioblastoma at first relapse/recurrence
    - The Phase I dose escalation part of the study will explore different doses of Fibromun and Lomustine (3-6 subjects per cohort)
    - Cohort 1 has been completed with 6 patients and durable objective responses are being observed
    - Recruitment for cohort 2 is ongoing
    - 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 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)
- **OncoFAP** is a small organic molecule ligand with ultra-high affinity for *Fibroblast Activation Protein* (FAP)
  - OncoFAP-radio conjugates
    - Imaging - excellent targeting properties of OncoFAP-^{68}Ga in patients with various tumor types. Data have been published in the *European Journal of Nuclear Medicine and Molecular Imaging* (Backhaus et al., *Eur J Nucl Med Mol Imaging*, 2021, 10.21203/rs.3.rs-969176/v1)
    - Therapy – BiOncoFAP-^{177}Lu, featuring a bivalent OncoFAP ligand, cures cancer in mice and has been identified as the therapeutic candidate for clinical development
  - 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 and patented an optimal cleavable linker leading to complete tumor eradications in preclinical models of cancer. The new OncoFAP-drug conjugate represents an additional potential clinical candidate with a strong validation and tumor targeting rationale.

Partnered products

- New **partnership** signed **with Bracco Imaging** to develop and commercialize a small molecule for diagnostic imaging applications
- **Dodekin** is a pharmaceutical product consisting of the L19 antibody specific to the B domain of Fibronectin (EDB) fused to interleukin-12 (IL12). EDB is a protein abundantly expressed in different tumors, but it is virtually undetectable in healthy tissues. IL12 is a pro-inflammatory cytokine suitable for the treatment of cancer
  - The product is currently investigated in a Phase I clinical trial
- **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 anti-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 FY 2021 with **cash and cash equivalents of €101,6M** compared to €61,943M on December 31, 2020.
- The net financial position as of December 31, 2021, was €85,184M, compared to a net financial position of €44,238M on December 31, 2020
- 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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