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Philogen Announces First Quarter 2021 Results and Provides Update on Pipeline Progress

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- *Nidlegy™ on track for Phase III European trial in stage IIIB/C melanoma. Opening of additional clinical centers to boost recruitment rate is ongoing. Emerging promising data in non-melanoma skin cancers*
- *Fibromun on track for the six ongoing trials in Soft Tissue Sarcoma and High-Grade Glioma*
- *Philogen is well capitalized, with cash & cash equivalents of about € 120 million*
- *Philogen's management team will hold a webinar to discuss the news on Thursday, 13th May at 10:00am EST / 14:00pm BST / 15:00pm CEST– please find the link to this webinar here*

Siena (Italy), 12 May 2021 – (Globe Newswire) – Philogen S.p.A. (BIT:PHIL) - a listed clinical-stage biotechnology company focused on the development of innovative medicines based on tumor targeting antibodies and small molecule ligands, is pleased to announce progress updates for its fully-owned immunocytokine and small molecule programs.

"*We are excited to report for the first time, after our successful Initial Public Offering in March 2021, the progress of our late- and early-stage product candidates,*" **commented Prof. Dr. Dario Neri, Co-Founder, Chief Executive Officer and Chief Scientific Officer of Philogen S.p.A**. *"Our most advanced programs are running on track. With the proceeds of the IPO, Philogen intends to bring Nidlegy™ and Fibromun to registration and start direct marketing in certain territories as envisaged in our Business Plan. We are also completing the construction of a second GMP facility in Rosia (Siena), which will further boost our in-house manufacturing capabilities, in anticipation of our expected marketing activities.*"

Nidlegy™

- **European Phase III trial for the neo-adjuvant treatment of locally advanced Stage IIIB/C melanoma**
  - The study has so far recruited 164 out of 214 patients planned for the study
  - Two interim analyses, foreseen by the study protocol, have been successfully passed. The independent Data Safety Monitoring Board has recommended in both occasions a continuation of the trial, without change to the statistical assumptions.
  - Focus on pre-treated patients with locally advanced disease who now receive Nidlegy™ in neo-adjuvant setting prior to surgery
  - Harmonized primary endpoint (Recurrence-Free Survival) in both European and American Phase III clinical trials
  - Expansion of clinical centers (currently 18 centers in Germany, Italy, Poland and France)

- **US Phase III trial for the treatment of locally advanced Stage IIIB/C melanoma**
  - Opening of additional clinical centers in the United States
  - Initial activities for the potential expansion of the clinical trial in additional countries, including Australia

- **European Phase II trial for the treatment of non-melanoma skin cancers**
  - Encouraging results from a Phase II trial in Europe in patients with non-melanoma skin cancer
  - Current focus on basal cell carcinoma and squamous cell carcinoma of the skin, but potential for additional non-melanoma skin cancers
  - Expansion of the trial to include Poland and Germany, in addition to Switzerland
  - Addition of new centers to speed-up recruitment and collect clinical information in different types of patients, thus facilitating future planning of pivotal trials
  - Ability of Nidlegy™ to induce a rapid necrosis of the injected lesion, with very good tolerability and excellent cosmetic outcome
  - Presentation of initial clinical results at the World Melanoma Congress 2021 (April 14-17, 2021)

- **US Phase II trial for the treatment of Stage IV melanoma**
  - Completed submission of a Phase II trial for the treatment of patients with Stage IV melanoma who no longer respond to PD-1 blockade, as previously planned in a Type C meeting with the U.S. Food and Drug Administration (FDA).
  - The study foresees three different treatment groups, all in combination with PD-1 blockade

Fibromun

- **European Phase III trial for the treatment of first line advanced/metastatic Soft Tissue Sarcoma**
  - The study is being conducted at German centers, comparing Fibromun and doxorubicin against doxorubicin alone
  - Additional centers are being opened in Germany
  - Opening of centers in Poland, Spain and Italy is currently being planned
  - The ongoing trial is expected to read out by the end of 2023

- **US Phase IIb trial for the treatment of first line metastatic Leiomyosarcoma**
  - The study is being conducted at eight centers in the United States
  - Additional centers are being opened in the United States

- **European Phase II trial for the treatment of pretreated advanced/metastatic Soft Tissue Sarcoma**
  - The study is being conducted at German centers, involving third and later line patients with advanced Soft Tissue Sarcoma, comparing Fibromun plus dacarbazine against dacarbazine alone
  - The study foresees an initial non-randomized run-in part (in which all patients receive Fibromun plus dacarbazine), followed by a randomized part with two groups of treatment (43 patients per group)
  - Start of the randomized part of the trial expected in Summer 2021
  - Trial has the potential to read out by the end of 2023

- **European Phase I/II trial for the treatment of IDH wildtype WHO Grade III-IV High-Grade Glioma at first recurrence/relapse (monotherapy)**

- Completed recruitment in December 2020 for a Phase I/II trial for the treatment of high-grade glioma patients at first recurrence/relapse, involving monotherapy treatment with Fibromun,
- Patients are being monitored for survival, with promising interim results compared to historical controls
- Preliminary data published in *Science Translational Medicine*, with clinical data confirming the pharmacodynamic effects observed in orthotopic animal models of the disease [Weiss et al. (2020) Sci. Transl. Med., 12, eabb2311]
- Rapid induction of tumor necrosis evidenced by Magnetic Resonance Imaging (MRI).
- Interim survival reports expected in June 2021 and in December 2021
- Observed preclinical and clinical data (activity and tolerability) have supported the initiation of clinical trials in first and second line, in combination with the corresponding standards of care

- **European Phase I/II trial for the treatment of Glioblastoma at first recurrence/relapse (in combination with Lomustine)**
  - Execution of the trial strongly supported by curative activity observed in orthotopic and immunocompetent mouse models of glioma
  - Trial started in Switzerland, opening of additional centers in other countries planned for the randomized Phase II part of the study
  - Ongoing harmonized regulatory dialogue with European Medicines Agency (EMA) and FDA

- **European Phase I/II/IIb trial for the treatment of newly diagnosed Glioblastoma (in combination with Radiotherapy and Chemotherapy)**
  - Execution of the trial strongly supported by curative activity observed in orthotopic and immunocompetent mouse models of glioma
  - Trial started in Switzerland, opening of additional centers in other countries planned for the randomized Phase IIb part of the study
  - On-going harmonized regulatory dialogue with European Medicinal Agency (EMA) and FDA

Darleukin

- **European Phase II trial sponsored by the University of Maastricht for the treatment of limited metastatic non-small cell lung cancer (in combination with anti-PD(L)1 and Stereotactic Ablative Radiotherapy)**
  - Strong preclinical rationale for the use of Darleukin (L19IL2) in combination with radiation therapy, established and published for multiple immunocompetent mouse models of cancer
  - On-going randomized Phase II clinical trial in patients with non-small cell lung cancer in combination with stereotactic ablative radiotherapy and PD-(L)1 blockade, following encouraging Phase I results [Van Limbergen et al. (2020) Int J Radiat Oncol Biol Phy 109, 1421]
  - EU funded trial (www.immunosabr.org), sponsored by the University of Maastricht (The Netherlands), currently involving 10 centers in The Netherlands, Belgium, and France.
  - Planned the opening of three additional centers in new countries

Dekavil

- The product has been licensed to Pfizer
- Philogen is involved in the clinical development program in Rheumatoid Arthritis
- Communication activities are to be performed in agreement between the two companies

Dodekin

- The product is developed in collaboration with a large pharmaceutical company
- A Phase I/II monotherapy trial in patients with multiple types of cancer, who no longer respond to immunotherapy, is currently being conducted in Italy, Switzerland, and Germany, with Philogen acting as Sponsor
- Communication activities are to be performed in agreement between the two companies

OncoFAP

- **FAP-targeting platform for the delivery of radionuclide-conjugates, drug-conjugates, bispecific immunomodulators, universal CAR-T cells**
  - Radionuclide-conjugates: First-in-human data exhibiting an extremely efficient and selective targeting of both primary and metastatic lesions in cancer patients, with very rapid clearance through the kidney and no apparent normal organ liability
  - Quantitative biodistribution data published in the *Proceedings of the National Academy of Sciences* [Millul et al. (2021) Proc. Natl. Acad. Sci. U.S.A., 118, e2101852118]
  - Collaboration with Senn Chemical AG for the large-scale GMP production of OncoFAP-DOTAGA, in preparation for larger clinical studies
  - Curative results in murine models of cancer obtained with OncoFAP coupled to monomethyl auristatin E, supporting the development of FAP-targeted small molecule-drug conjugates (SMDCs) as an alternative to antibody-drug conjugates (ADCs)
  - Potentiation of ADCs and SMDCs by Darleukin

OncoIX

- **CAIX-targeting platform for the delivery of radionuclide-conjugates, drug-conjugates, bispecific immunomodulators, universal CAR-T cells**
  - Rationale for the use of the OncoIX platform not only for radionuclide delivery and for drug delivery, but also for the creation of small molecule bispecifics and adaptors for universal CAR-T cell therapy [Pellegrino et al. (2020) *Bioconj. Chem.*, 31,1775]

Tripokin

- **IND-enabling studies progressing**
  - Clinical development program supported by excellent tumor targeting performance data and by therapy results in preclinical models of cancer [De Luca et al. (2017) Mol Cancer Ther, 16, 2442; De Luca et al., (2018) Cancer Immunol Immunother, 67, 1381].

- The incorporation of potency-matched cytokine moieties in the same product promises to be useful for the treatment of multiple tumor types, alone or in combination with other therapeutic modalities, exploiting the function of interleukin-2 and of tumor necrosis factor
- Stable cell line development completed
- GMP production schedule to start in Q2 2021
- Start of clinical trials expected in 2022

Additional preclinical programs

- **Antibody-based candidates**
  - Breakthrough results in the antibody-based delivery of interferon-gamma, after many years of research in the field (patent pending).
  - Advances in research on antibody-cytokine fusion proteins with "activity-on-demand"
- **Small molecule-based candidates**
  - Ligands against undisclosed tumor-associated antigens have been discovered and are currently being optimized
  - Ligands against immune cell markers have been discovered and are being optimized, with the plan to develop fully synthetic small molecule bispecific

Potentiation of the Manufacturing facilities

- **Rosia**
  - Completion of the construction of a second GMP production facility on-track (expected by the end of May 2021).
  - Validation activities and production of engineering lots are planned prior to the inspection by the relevant authorities, expected in 2022
- **Montarioso**
  - Planned upgrade of the existing facility, with purchase of additional equipment
  - Manufacturing activities both for in-house product development and for third parties

Financial Update

- Philogen successfully listed on the Italian Stock Exchange on March 3rd, 2021.
- Philogen is well capitalized, with cash & cash equivalents of about € 120 million
- The proceeds will boost late stage programs, expand the pipeline and potentiate in house manufacturing

About Philogen

Philogen is a Swiss-Italian clinical-stage biotechnology company listed on the Italian Stock Exchange. It is engaged in the discovery and development of novel pharmaceutical and biopharmaceutical products. Philogen's strategy is to deliver bioactive agents, for example cytokines or drugs, to the site of disease using antibodies and other ligands that specifically and efficiently target stromal antigens. This technology has generated a strong proprietary pipeline of clinical-stage products and preclinical compounds in an array of disease indications. Philogen is headquartered in Siena, Italy, and has research activities at its subsidiary company Philochem near Zurich, Switzerland. Philogen has signed

agreements with several major pharmaceutical companies. For more information, please visit www.philogen.com and www.philochem.com.

Forward-Looking Statements

The forward-looking statements contained in this press release may be identified by words such as "aims," "anticipates," "believes," "could," "estimates," "expects," "forecasts," "goal," "intends," "may," "plans," "possible," "potential," "seeks," "will" and variations of these words or similar expressions that are intended to identify forward-looking statements, although not all forward-looking statements contain these words. Forward-looking statements in this press release include, but are not limited to, statements regarding anticipated advancement of preclinical development efforts and initiation and progression of clinical trials; anticipated enrollment in and progression of Philogen's clinical trials; the availability of data from clinical trials and preclinical studies; anticipated regulatory filings; the therapeutic potential of Philogen's product candidates; Philogen's ability to achieve planned milestones. Philogen may not actually achieve the plans, intentions or expectations disclosed in these forward-looking statements, and you should not place undue reliance on these forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in these forward-looking statements as a result of various factors, including: risks to site initiation, clinical trial commencement, patient enrollment and follow-up, as well as to Philogen's and its partners' abilities to meet other anticipated deadlines and milestones, also due to the ongoing COVID-19 pandemic; uncertainties inherent in the initiation and completion of preclinical studies and clinical trials and clinical development of Philogen's product candidates by Philogen or its partners; the risk that Philogen may not realize the intended benefits of its technology; availability and timing of results from preclinical studies and clinical trials; whether the outcomes of preclinical studies will be predictive of clinical trial results; whether initial or interim results from a clinical trial will be predictive of the final results of the trial or the results of future trials; the risk that trials and studies may be delayed and may not have satisfactory outcomes; potential adverse effects arising from the testing or use of Philogen's product candidates; risks related to Philogen's ability to maintain existing collaborations and realize the benefits thereof; expectations for regulatory approvals to conduct trials or to market products; other factors which could cause our actual result to differ from those contained in the forward-looking statements, as also described in greater detail in the Risk Factors section in the prospectus drafted by Philogen and approved by Consob on February 17, 2021. Any forward-looking statements contained in this press release speak only as of the date hereof, and Philogen expressly disclaims any obligation to update any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise, except as otherwise required by law. The information and contents of this press release do not: (i) constitute an order or an offer to purchase or to sell financial products or financial services; (ii) relate to special investment goals or to the financial situation or particular requirements of specific users. All information presented, reports published and opinions expressed are intended purely for information purposes, and do not constitute an offer for the conclusion of a contract or other legal transaction. In particular, the content of the press release is not to be understood as an invitation or recommendation to buy or sell securities of Philogen, or as an advertisement for securities of Philogen. Neither does it constitute an offer to participate in any other transaction, including (but not restricted to) trading in derivatives. The mere use of the website does not give rise to any contractual relationship of any kind between the user and Philogen. Philogen expressly draws your attention to the fact that its share price is subject to fluctuation, and that the future development of the share price cannot be derived either from the previous price history or from the information and content shown on this website. Results achieved in the past provide no guarantee in regard to the future

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