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Philogen
innovating targeting

Philogen Announces R&D Program Update

Fibromun shows activity in pretreated glioma and sarcoma patients; OncoFAP targets tumor lesions in cancer patients; a new product partnered with AbbVie entered clinical studies

Siena (Italy), 2 July, 2021 – (Globe Newswire) – Philogen S.p.A. (BIT:PHIL), a clinical-stage biotechnology company focused on the development of innovative medicines based on tumor targeting antibodies and small molecule ligands, is pleased to provide an update on three R&D programs: Fibromun, OncoFAP and ABBV-022. A full pipeline update will be made to the market on 28 September, 2021, in the Company's Half Year results announcement.

Prof. Dr. Dario Neri, Co-Founder, Chief Executive Officer and Chief Scientific Officer of Philogen S.p.A., said: *"We are extremely pleased to see that our technology has been delivering exciting product candidates of diverse nature, both by our partners such as AbbVie and under our ownership, across a variety of clinical trials. The early signs of activity support our ambition to bring innovative treatment options to patients with serious unmet medical need."*

Fibromun

Fibromun (L19TNF), wholly-owned by Philogen, is a fully-human immunomodulatory product consisting of the L19 antibody and TNF (a strong pro-inflammatory cytokine). Recombinant TNF has so far been approved only for certain loco-regional clinical applications.

- Promising interim survival benefits have been demonstrated in the European Phase I/II trial, investigating Fibromun as a monotherapy for the treatment of IDH wildtype WHO Grade III-IV High-Grade Glioma at first recurrence/relapse. Data on progression free survival at six months are being finalized, while the overall survival data will be consolidated by the end of 2021, with expected publication in a peer-reviewed scientific journal in 2022.
- In the European Phase I/II trial, in which Fibromun is combined with lomustine for the treatment of Glioblastoma at first recurrence/relapse, a partial response has been observed already in the first patient treated in the study. The historical overall response rate for this patient population is 4.3% (Wick et al., J Clin Oncol 2010, 28,1168)
- A Parallel Scientific Advice (PSA) with the European Medicines Agency and the US Food and Drug Administration has been completed in June 2021. The development plan for the treatment of glioblastoma and the proposed strategy for marketing authorization have been discussed and agreed with competent authorities. Philogen will follow the recommendations that were provided during the PSA.
- In the European Phase II trial, in which Fibromun is combined with dacarbazine for the treatment of pretreated advanced/metastatic Soft Tissue Sarcoma ($\geq 3^{rd}$ line), the second patient treated in the study enjoyed a partial response. The historical overall response rate for this patient population is 4.0% (Garcia-del-Muro et al., J Clin Oncol 2011, 29,2528). After the run-in part of the trial, the trial progresses to a randomized part.
- Fibromun is investigated in six clinical trials, of which five have a pivotal potential. In Soft Tissue Sarcoma, the European Phase III trial in 1^{st} line and the Phase II trial in $\geq 3^{rd}$ line are expected to read out by the end of 2023.

OncoFAP

OncoFAP is a small molecule radiotracer, wholly-owned by Philogen, with ultra-high affinity for Fibroblast Activation Protein (FAP). The product is suitable for the non-invasive detection of a variety of metastatic solid tumors, as FAP is overexpressed in more than 90% of epithelial cancers (e.g., malignant breast, colorectal, ovarian, lung, skin, prostate, and pancreatic cancers, as well as in some soft tissue and bone sarcomas)

- Clinicians from the Department of Nuclear Medicine at the University Hospital of Münster have employed a OncoFAP-based radionuclide conjugate (OncoFAP-^{68}Ga) in clinical scanning of patients with various FAP-positive cancer types and have shown excellent tumor uptake in both primary and metastatic lesions with low uptake in healthy organs (including kidneys) after intravenous injection.
- These clinical results also support the investigation of OncoFAP-^{177}Lu for Radionuclide Ligand Therapy (RLT).
- Philogen is currently planning international, exploratory, clinical trials to investigate OncoFAP in a variety of cancer indications. The results from these studies will provide the basis for a pivotal clinical program in selected cancer types.

ABBV-022

ABBV-022, a product out-licensed by Philogen to AbbVie, consists of an IL-22 payload fused to a targeting antibody. The cytokine, selectively delivered to the epithelial surface of damaged gut mucosa, promotes survival of intestinal stem cells, improves goblet cell function and epithelial barrier, thereby reducing inflammation.

- ABBV-022 has started a Phase I clinical trial for the treatment of Ulcerative Colitis. The original collaboration between Philogen and AbbVie began in 2014.

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.

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 development of the share price. Philogen provides no guarantee of any kind that the capital invested will increase in value or maintain its value. In light of these given risks, we strongly advise you to seek professional advice before making any investment decision. The material contained on the website does not relieve the user from having to make his own decisions. This press release may contain links to external websites of third parties (external links) the content of which is outside the sphere of influence of Philogen. Visiting and using such websites that are accessible via such links are subject to the conditions of the data protection policy of these websites and the liability of the respective operators. Philogen accepts no responsibility and offers no guarantee of any kind for the content or websites of third parties and gives no assurances of any kind in this regard. Philogen accepts no responsibility for the data protection policy and customer information of websites of third parties and shall not be liable for the content or web pages of third parties which are linked to the Philogen website, or which display the Philogen website in frames.

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