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innovating chemistry

PRESS RELEASE

Philochem AG (a company of the Philogen group) announces the completion of central radiolabeling activities for the therapeutic use of OncoFAP-23

Zürich, Switzerland, December 4, 2023 – Philochem AG, a wholly owned subsidiary of Philogen S.p.A., focused on the discovery and development of small molecule pharmaceuticals for the imaging and therapy of cancer and other serious conditions, announces the completion of the central radiolabeling activities of its therapeutic product OncoFAP-23.

These activities have been conducted in partnership with Seibersdorf Laboratories (Austria), a specialist in the industrial manufacturing of Radiolabeled Pharmaceuticals for therapeutic purposes.

Philochem has developed and patented high-affinity targeting agents, with best-in-class potential, specific to Fibroblast Activation Protein (FAP, a tumor-associated target expressed in the majority of solid malignancies). OncoFAP-23, labeled with the therapeutic radionuclide lutetium-177, allows the delivery of sterilizing radiation to the site of disease, helping spare normal tissues. Other lutetium-177-based products, which recognize different targets, are routinely used in the clinical practice for the treatment of neuroendocrine tumors and prostate cancer. OncoFAP-23 has the potential to be used in a broader variety of patients, who do not have a therapeutic option.

Radiolabeled small molecules, which preferentially localize to tumors, have the potential to be used in a "theranostic" manner. Confirmation of tumor uptake by imaging technologies potentially opens the way for therapeutic intervention, using radioactive payloads such as lutetium-177.

Philochem retains all rights for the therapeutic use of its OncoFAP platform. The completion of logistical and radiolabeling activities for ^{177}Lu-OncoFAP-23 allows the submission of a clinical trial application, which is planned for December 2023. The corresponding multicenter international clinical trial will foresee the treatment of patients, who have exhausted available therapeutic options and who are suitable for OncoFAP-23-based pharmacodelivery strategies.

In a consistent number of preclinical studies, ^{177}Lu-OncoFAP-23 was shown to eradicate cancer in "difficult-to-treat" mouse models of cancer, at extremely low levels of radioactivity (5 Megabecquerel per mouse). Said promising results provide a rationale for the clinical translation activities, which are now possible following the successful completion of GMP manufacturing process and of central radiolabeling procedures.

Prof. Dr. Dario Neri, Member of the Board of Philochem and CEO of the Philogen Group, commented "From the first FAP ligand published in 2021, Philochem has undertaken great efforts to optimise OncoFAP derivatives for the delivery of therapeutic radionuclides. We are impressed by the potent activity of ^{177}Lu-OncoFAP-23 in preclinical models and are excited to move this promising candidate to clinical trials. We believe OncoFAP technology has potential to pave the way for a new approach to tumor therapy for patients suffering from various solid tumors."

Dr. Samuele Cazzamalli, Head of Small Molecule Therapeutics at Philochem AG, commented: "We are excited to move forward to the clinical stage with our lead candidate ^{177}Lu-OncoFAP. The OncoFAP

platform holds the potential for pan-tumoral applications, and we hope that ^{177}Lu-OncoFAP-23 will evolve as promising treatment option for patients with various types of cancer."

About Fibroblast Activation Protein (FAP) and FAP-targeted Technology

Fibroblast Activation Protein, or FAP, is a transmembrane protein that is overexpressed in cancer-associated-fibroblasts (CAFs) in the tumor microenvironment of most tumor types, but expressed at low levels in normal adult tissues. It is involved in a variety of tumor-promoting activities and is considered a promising target with diagnostic and theranostic potential in a variety of diseases. FAP is being investigated for use in diagnostic imaging and therapy in multiple tumor types, such as colon, breast, lung, pancreatic and esophageal cancers, among others. CAFs are also highly expressed in tissue remodeling, and FAP imaging may have applications in benign fibrotic conditions such as wound healing, as well as in chronic inflammation, cirrhosis, and cardiovascular and rheumatoid diseases.

Radiolabeled FAP ligands have demonstrated high binding affinity, rapid binding to FAP-expressing tumors and impressive lesion to background ratios in patients with a broad range of cancer types.

About Philochem and the Philogen Group

Philochem is a fully owned subsidiary of the Philogen Group, a Swiss-Italian, clinical-stage biotechnology company listed on the Italian Stock Exchange. Philogen is engaged in the discovery and development of novel pharmaceutical and biopharmaceutical products. Philogen's strategy is to selectively deliver bioactive agents (such as radionuclides, cytokines or drugs) to the site of disease using antibodies or small organic ligands. 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.

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