

PRESS RELEASE

Philochem and Blue Earth Diagnostics Announce First Three Patients Imaged in Phase 1 Clinical Trial of ⁶⁸Ga-OncoFAP (⁶⁸Ga-OncoFAP-DOTAGA) for Diagnostic Imaging in Solid Tumors

- *Novel ultra-high affinity ligand OncoFAP targets Fibroblast Activation Protein (FAP), associated with a variety of solid tumors*
- *Licensing agreement between Philochem and Blue Earth Diagnostics, one of the Bracco family of companies, encompasses applications of OncoFAP for diagnostic and medical imaging*
- *Philogen's Phase I clinical trial with investigational ⁶⁸Ga-OncoFAP is underway in Europe, with first three patients successfully imaged*
- *Blue Earth Diagnostics will assume further clinical development and future commercialization activities of OncoFAP for diagnostic or medical imaging purposes worldwide*

Zürich, Switzerland, Oxford, UK and Monroe Township, NJ, USA, December 4, 2023 – Philochem AG, a wholly owned subsidiary of Philogen S.p.A., and Blue Earth Diagnostics, a Bracco company and recognized leader in the development and commercialization of innovative PET radiopharmaceuticals, today provided additional information regarding a March 2022 licensing and collaboration agreement between Philochem and Blue Earth Diagnostics. The collaboration encompasses the development of OncoFAP, a proprietary, small organic ligand with ultra-high affinity to Fibroblast Activation Protein (FAP), for applications in the diagnostic imaging of solid tumors. Under the agreement, the Philogen Group is conducting a Phase 1 clinical study to evaluate the safety and dosimetry of ⁶⁸Ga-OncoFAP (⁶⁸Ga-OncoFAP-DOTAGA) in patients with solid tumors. The agreement provides Blue Earth Diagnostics rights to develop and commercialize ⁶⁸Ga-OncoFAP worldwide. FAP is a tumor-associated antigen which is expressed 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).

The Philogen Group has a Phase I clinical trial (called FAPrimo) underway in Europe to evaluate the safety and dosimetry of ⁶⁸Ga-OncoFAP in patients with solid tumors. The study is planned to enroll up to 20 patients who will undergo PET/CT imaging with ⁶⁸Ga-OncoFAP. The first three enrolled patients in the trial were imaged in November 2023 at the *National Cancer Institute of Milan* (INT). To date, ⁶⁸Ga-OncoFAP-DOTAGA has been used for PET imaging applications in approximately 100 patients with various solid tumors through Philochem's collaboration with the University of Münster, Germany.

Prof. Dr. Dario Neri, Member of the Board of Philochem and CEO of the Philogen Group, commented: "We are excited about the promising tumor-targeting performance of ⁶⁸Ga-OncoFAP in preclinical models and human patients to date. Philochem discovered and published the first paper on this important tumor targeting ligand in 2021. We believe OncoFAP technology has potential to pave the way for a new approach to tumor diagnosis, and significantly improve diagnosis and informed management for patients who have solid tumor cancers."

"We are delighted to announce this key milestone of the first three patients being dosed in the Phase 1 trial for ⁶⁸Ga-OncoFAP PET in the detection and localization of advanced solid tumors," **commented David Gauden, D.Phil., Chief Executive Officer of Blue Earth Diagnostics.** "⁶⁸Ga-OncoFAP is an innovative and promising addition to Blue Earth Diagnostics' robust portfolio of

precision PET radiopharmaceuticals. We are grateful for the support of our parent company, Bracco Imaging, S.p.A., in helping to advance innovation to shape the future of precision medicine and improve patients' lives worldwide with imaging technology such as OncoFAP. Based on preclinical studies and early clinical experience, ⁶⁸Ga-OncoFAP has demonstrated favorable radiochemical properties, rapid clearance from organs and soft tissues and avid tumor uptake. We look forward to continuing collaboration with Philochem throughout this Phase 1 trial and applying our deep expertise in radiopharmaceutical development and commercialization as we advance further, with the goal to help patients and address unmet needs in 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. They can be labeled with isotopes such as ⁶⁸Ga or ¹⁸F for diagnostic PET imaging, or with therapeutic radioisotopes such as ¹⁷⁷Lu or ²²⁵Ac for therapy.

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.

About Blue Earth Diagnostics

Blue Earth Diagnostics, an indirect subsidiary of Bracco Imaging S.p.A., is a growing international molecular imaging company focused on delivering innovative, well-differentiated diagnostic solutions that inform patient care. Formed in 2014, the Company's success is driven by its management expertise and supported by a demonstrated track record of rapid development and commercialization of positron emission tomography (PET) radiopharmaceuticals. Blue Earth Diagnostics' expanding oncology portfolio encompasses a variety of disease states, including prostate cancer and neuro-oncology. Blue Earth Diagnostics is committed to the timely development and commercialization of precision radiopharmaceuticals for potential use in imaging and therapy. For more information, please visit: www.blueearthdiagnostics.com.

About Bracco Imaging

Bracco Imaging S.p.A., part of the Bracco Group, is a world-leading diagnostic imaging provider. Headquartered in Milan, Italy, Bracco Imaging develops, manufactures and markets diagnostic

imaging agents and solutions. It offers a product and solution portfolio for all key diagnostic imaging modalities: X-ray imaging (including Computed Tomography-CT, Interventional Radiology, and Cardiac Catheterization), Magnetic Resonance Imaging (MRI), Contrast Enhanced Ultrasound (CEUS), and Nuclear Medicine through radioactive tracers and novel PET imaging agents to inform clinical management and guide care for cancer patients in areas of unmet medical need. Our continually evolving portfolio is completed by a range of medical devices, advanced administration systems and dose-management software. In 2019 Bracco Imaging enriched its product portfolio by expanding the range of oncology nuclear imaging solutions in the urology segment and other specialties with the acquisition of Blue Earth Diagnostics. In 2021, Bracco Imaging established Blue Earth Therapeutics as a separate, cutting-edge biotechnology vehicle to develop radiopharmaceutical therapies. Visit: www.braccoimaging.com.

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