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Philogen
innovating targeting

Philogen publishes a new study on OncoFAP in Clinical Cancer Research

The study shows excellent tumor uptake of the novel OncoFAP-MMAE Small Molecule-Drug Conjugates (SMDCs) with high and selective release of the cytotoxic MMAE payload at the tumor site.
OncoFAP-based pro-drugs are currently being developed for the imaging and therapy of cancer

Siena, Italy, October 19th, 2022 - Philogen S.p.A., a clinical-stage biotechnology company focused on the development of innovative medicines based on tumor targeting antibodies and small molecule ligands, announces the publication of a study in the peer-reviewed journal "Clinical Cancer Research" describing the development and the *in vitro*/*vivo* characterization of novel OncoFAP-based Small Molecule-Drug Conjugates (SMDCs). The study was conducted by scientists at Philochem AG, the wholly-owned Swiss subsidiary company of Philogen. The paper can be accessed from the Clinical Cancer Research website under the following link.

Fibroblast Activation Protein (FAP) has recently emerged as a tumor-associated antigen with abundant and selective expression in the majority of human solid malignancies. OncoFAP is an ultra-high affinity small organic ligand with a picomolar dissociation constant. The targeting potential of OncoFAP has been validated in human patients with different types of cancers (e.g., esophageal, breast, hepatocellular, pancreatic) showing excellent selectivity for the tumor and low kidney uptake. OncoFAP was used as a modular component for generating SMDCs equipped with the cytotoxic payload Monomethyl Auristatin E (MMAE) and novel cleavable linkers that are rapidly and selectively cleaved by FAP. Different linkers were compared *in vitro* and *in vivo* for their kinetics of payload release using an advanced mass spectrometry-based quantification technology. OncoFAP-Gly-Pro-MMAE emerged as best-in-class product for the selective and prolonged release of MMAE payload to FAP-positive tumor lesions. OncoFAP-Gly-Pro-MMAE displayed excellent therapeutic performance in preclinical models of cancer even with a single administration. The results presented in the Clinical Cancer Research paper support clinical development of OncoFAP-Gly-Pro-MMAE.

Dario Neri, Chief Executive Officer of Philogen commented: "The study demonstrates the impressive tumor-targeting and therapeutic performance of our novel Small Molecule Drug Conjugates targeting FAP. These novel products also benefit from the excellent imaging data collected so far with the OncoFAP ligand, which has been already administered to more than 60 cancer patients. We look forward to growing our small molecule clinical pipeline based on the OncoFAP delivery platform."

Samuele Cazzamalli, Head of Small Molecule Therapeutics of Philochem AG commented: "Our aim is to make OncoFAP-based therapies available to cancer patients. Companion diagnostics based on OncoFAP will allow us to select individuals that will most likely benefit from therapies based on FAP-targeted Small Molecule Therapeutics. We look forward to progressing the development of this important technology with the potential of benefitting millions of patients."

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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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