



Oncodesign Precision Medicine and Navigo Proteins GmbH sign a strategic collaboration agreement for the research and development of new systemic radiotherapy agents

Dijon (France), May 15, 2024, at 6:00pm CEST— Oncodesign Precision Medicine (OPM) (ISIN: FR001400CM63; Mnemonic: ALOPM), a biopharmaceutical company specializing in precision medicine for the treatment of resistant and metastatic cancers, and Navigo Proteins GmbH (Halle, Germany), a biopharmaceutical company specializing in the discovery and development of Precision Medicine applications based on the Affilin® technology platform, announce the signature of a strategic collaboration agreement for the discovery and development of new systemic radiotheranostic agents.

OPM operates three technological platforms dedicated to precision medicine. OncoSNIPER is a technology using AI to select and validate new therapeutic targets involved in resistant and metastatic cancers, in particular kinases and targets expressed specifically on the tumor cell surface. The aim is to discover and develop new kinase inhibitors based on the Nanocyclix® technology platform and new radioligand therapy agents from its 3rd technology platform, Promethe®.

The construction of radiotheranostics is based on the identification of a specific target on the cancer cells' surface (surface antigen), and on small molecule, peptide, antibody or small protein (like Affilin®) targeting molecules that are highly specific for the identified target, enabling radioactivity (emitters a, β +- or γ) to be delivered to the tumor cell and thus triggering its detection and destruction. This therapeutic approach has already been clinically proven in the treatment of metastatic prostate cancer (Pluvicto®; Novartis) and inoperable or metastatic gastroenteropancreatic neuroendocrine tumors (Lutathera®; Novartis).

OPM has chosen Affilins®, a proprietary technology from Navigo Proteins GmbH, as biological targeting molecules to support its Promethe® platform.

Affilins® are small proteins derived from human ubiquitin, a protein naturally present in all cells. A huge number of ubiquitin variants are available in large libraries where each variant is modified in a slightly different way on its surface and has lost its natural biological functions but potentially binds to a given target structure. Phage display selection and screening is applied to identify Affilins® that bind selectively and with high affinity to the targeted surface antigen, like antibodies. The molecular weight of Affilins® is 1/15th of an antibody improving the pharmacokinetics, particularly the distribution and route of elimination which is predominantly through the kidney. Unlike antibodies, Affilins® are resistant to proteases, acids and bases and are highly thermostable facilitating their radiolabeling. Because they are human derived, Affilins® have a low immunogenicity risk (unwanted immune reaction after injection). The molecules have no post-translational modification like antibodies which allows their production in simple bacterial systems. Affilins® are highly engineerable and can be combined with other functional elements, enabling a modular design of molecules, adapted to clinical needs. For all these reasons, Affilin® molecules are ideal for use as radiotheranostic targeting molecules.

Navigo Proteins GmbH, a protein engineering company based in Halle, Germany, is headed by a strong and experienced team committed to leveraging Affilin® technology in multiple areas. This collaboration will enable OPM and Navigo to build a first-class entity in the field of radioligand therapy based on the complementary strengths of the two companies. Navigo's Board is composed of leading professors and scientists in the field of radioligand therapy, such as Oliver Buck (co-founder of ITM and member of the board of directors of Telix Pharmaceuticals).

Under the terms of the agreement, research will initially focus on two different targets in the field of oncology, particularly in resistant and metastatic digestive tract tumors, and molecules will be developed to the stage of drug candidates. Oncodesign Precision Medicine will fund this program over the next 3 years. This agreement is a first step towards a strong strategic alliance between OPM and Navigo Proteins GmbH with the vision to expand the partnership to additional targets.

Philippe GENNE, Co-founder, Chairman and CEO of Oncodesign Precision Medicine, said: "This strategic alliance will provide OPM with the opportunity to rapidly develop its portfolio of radiotheranostics and leverage its extensive knowledge and expertise in the discovery of next generation radioligand therapies. This is a promising therapeutic area that will revolutionize the treatment of inoperable and metastatic tumors. We are proud and delighted to benefit from the technology developed by Navigo, our partner in this collaboration, which in addition to its expertise in terms of Affilin® engineering, is also a bio-industrial company with the ability to support innovative bioprocessing of Biologics, often a delicate stage in the development of such molecules. Our objective is to build a world-class player in the field of radioligand therapies in the near future."

Jan HOFLACK, Co-Founder and Chief Scientific Officer of Oncodesign Precision Medicine added: "Our Promethe® technology represents the 3rd key element in our fight against cancers without therapeutic solution. It is highly complementary to our other technologies, Oncosniper and Nanocyclix®. These 3 approaches enable us to position ourselves on metastatic and resistant cancers, using immuno-oncology and radiotheranostics. These methods could be used in synergy in the future. Navigo's Affilins® give us access to a cutting-edge platform in terms of targeting vectors. The strengths and expertise of OPM and Navigo are highly complementary, which is the main reason for our alliance. Despite the logistical challenges associated with these radioligand therapy molecules, their potential to act both as imaging diagnostics at low doses and with an appropriate radioisotope, and as therapeutics at higher doses and with an isotope able to annihilate cancer cells, make them tremendous tools to fight cancers without a solution for the benefit of patients."

Henning Afflerbach, CEO of Navigo Proteins GmbH, concludes: "Our collaboration with Oncodesign Precision Medicine provides us with the ideal opportunity to advance our platform in radiotheranostics towards clinical application. Our proprietary Affilin® technology offers unparalleled modularity combined with exceptional biodistribution properties making Affilins® invaluable tools in our quest to revolutionize cancer treatment. By leveraging OPM's expertise in preclinical development, targeted oncology and bioindustrial capabilities, we are keen to tackle together key challenges in targeted therapeutics development. Our alliance with OPM underscores the synergy between our strengths and expertise, aiming to deliver innovative solutions that benefit patients worldwide."

About radiotheranostics

This is a radiotherapy technique used in nuclear medicine in the field of oncology. Unlike external radiotherapy, irradiation is targeted by molecules able to bind to tumors. These are radiolabeled and administered intravenously, in the same way as chemotherapy or other targeted therapy. External radiotherapy is currently used in more than 50% of clinical protocols in oncology, but it is only feasible in the case of a single tumor or a limited number of tumors (oligometastases). Radioligand therapies, on the other hand, are well suited for the treatment of disseminated metastases.

Technologically, radioligand therapies are based on the administration of a targeting molecule containing a radioactive isotope (= radiopharmaceutical) aimed at specifically destroying tumors. Its effectiveness comes from the highly localized energy released in radioactive decay, which results in cell death preferentially of tumor cells, while not damaging adjacent healthy tissue. These particle-emitting radioisotopes are directed at targets over-expressed by tumor cells, using highly specific targeting molecules capable of recognizing and attaching to them. The specificity of the targeting molecule for a tumor marker enables healthy tissue to be spared and guarantees greater efficacy while limiting side effects, a strategy that is particularly well suited to disseminated diseases.

One of the advantages of radioligand therapies is the potential to create a theranostic agent, i.e. a radiopharmaceutical which, depending on the nature of the radiation from the chosen isotope, enables diagnostic imaging (prediction/therapeutic monitoring, β + or γ emitters) or patient therapy (β -, α , auger emitters).

About Oncodesign Precision Medicine (OPM)

Oncodesign Precision Medicine (OPM), founded in 2022, is a biopharmaceutical company specializing in precision medicine, dedicated to the discovery of treatments for resistant and metastatic cancers.

OPM currently has two kinase inhibitors in clinical trials: OPM-101, for the treatment of chronic immuno-inflammatory digestive diseases, which demonstrated a significant therapeutic margin and lack of toxicity in phase I trials with healthy volunteers, with a phase II trials in cancer patients with severe colitis induced by treatment with immuno checkpoint inhibitors (CUII) scheduled to start at the end of 2024. OPM-201, licensed to Servier for the treatment of Parkinson's disease, completed its phase I trial in healthy volunteers this year, with phase II scheduled to start in 2025. Finally, a third kinase inhibitor, OPM-102, targeting oncology, is in preclinical development.

These three molecules come from the Nanocyclix® technology platform, which enables the design and selection of small macrocyclic kinase inhibitors that are highly effective and selective. We now have 12,000 such molecules in our library and will be using Al to accelerate the discovery of drug candidates while reducing the cost of this phase.

OPM's two other technology platforms are:

- OncoSNIPER, for the selection of therapeutic targets using artificial intelligence, in partnership with Servier for the search of targets in pancreatic cancer,
- (ii) PROMETHE® for the design and selection of radiolabeled biological molecules for systemic radioligand therapies, for which we are currently discussing partnerships with vectorization companies. The current agreement is a result of these discussions.

OPM, co-founded by Philippe Genne, Jan Hoflack and Karine Lignel, is based in Dijon, in the heart of the university and hospital cluster, and has 22 employees.

Further information: oncodesign.com







About Navigo Proteins GmbH

Navigo Proteins is a fast-growing biopharmaceutical company focused on Precision Medicine and particularly next generation radiotheranostics based on its proprietary Affilin® platform. Affilins® are novel target-binding proteins, combining the advantages of antibodies and peptides. Easily customizable as mono-, bi-, or multi-specific ligands, Affilins® can be coupled to radioactive isotopes and cytotoxic payloads for potent anti-cancer therapeutics against Tumor Associated Antigens (TAAs) and immuno-oncology (I/O) targets. The high modularity of the Navigo platform allows faster innovation cycles building on proven and tested components.

Our growing Affilin® portfolio, backed by unique pre-clinical data, tackles key challenges in targeted therapeutics, achieving exceptional tumor-specific accumulation and favorable biodistribution. Collaborations in the Radiopharmaceutical industry with strong partners like ITM as well as in-house programs drive the development of Affilins® for targeted radioligand therapy and imaging.

Our ultimate aim at Navigo Proteins is to deliver best-in-class therapies and life saving products to patients faster.

Further information: https://www.navigo-proteins.com/



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