

Oncodesign Precision Medicine announces the initiation of Phase I of its RIPK2 inhibitor ODS-101, a new therapeutic agent for IBD

● First-in-Man study of ODS-101 in healthy volunteers

Dijon (France), February 9, 2023, at 05:45pm CET– Oncodesign Precision Medicine (OPM) (ISIN: FR001400CM63; Mnemonic: ALOPM), a clinical stage biopharmaceutical company specializing in precision medicine for the treatment of resistant and metastatic cancers, announces the clinical entry of its drug candidate ODS-101 with the first subject dosing in Phase 1 clinical trial in healthy volunteers.

Philippe Genne, Chairman and CEO of OPM, commented: *"This is a very important milestone for Oncodesign Precision Medicine. After the entry into the clinic of our first drug candidate against Parkinson's disease in partnership with Servier last September, it is now time for ODS-101 to start its clinical development. This molecule is based on our Nanocyclix® technology and our strategy is to finance the development ourselves until proof of concept in Phase 2a in 2024. Before that, we will determine the most appropriate clinical indication for the continuation of this phase I and finally, we will seek a pharmaceutical licensing partner. We have already demonstrated that we have the capacity to sign this type of international pharmaceutical partnership, and numerous contacts have already been established since the selection of ODS-101. IBD affects over 200,000 people in France and 40% of patients worldwide are non-responders to existing treatments. We will do our best to bring an effective therapeutic alternative to patients suffering from these diseases."*

Inflammatory Bowel Disease (IBD) includes conditions such as ulcerative colitis (UC) and Crohn's disease (CD). The number of patients concerned has been estimated at 10 million worldwide with a prevalence of 1% ([EFCCA](#) analysis), which is constantly increasing, mainly in developed countries. The combined global 8MM (8 major markets) UC and CD market accounted for \$14.2 billion in 2019 with growth forecast to 2029 at \$24.9 billion (GlobalData 2020 Reports).

RIPK2 plays a key role in modulating the innate immune response, making this kinase particularly relevant to address the need for safer and more effective therapies for patients who often experience significant side effects with current therapies. Furthermore, the current knowledge about this target, associated with the favorable profile of ODS-101, opens up the possibility to realize combinations with first-line treatment therapies, particularly those based on anti-TNF α antibodies.

ODS-101 is a macrocyclic molecule from OPM's proprietary Nanocyclix® platform. It is a highly potent Type 1 inhibitor (inhibitor in the active cavity of the kinase), selective against other kinases and orally bioavailable. In pharmacology studies, ODS-101 has demonstrated good efficacy in several preclinical models of colitis. Its safety profile in preclinical studies meets a quality standard recognized by the pharmaceutical industry and compatible with chronic administration to treat diseases such as IBD. OPM's intellectual property strategy is effective in protecting the value of this asset and its use in a wide range of therapeutic indications.

The announced "First-in-human" clinical study is a randomised, double-blind, placebo-controlled, healthy volunteer study with a single administration phase (SAD – single ascending dose) and a multiple administration phase (MAD - multiple ascending dose) design to study the safety, tolerability, pharmacokinetic and pharmacodynamic profile of ODS-101. This Phase 1 also includes the study of the food effect and the study of the gender effect in order to prepare as well as possible the future clinical development of the molecule.

Jan Hoflack, Chief Scientific Officer of OPM added: *"The regulatory approval of the CTA submission allows us to initiate a Phase 1 clinical trial in healthy volunteers with our second Nanocyclix® compound in less than 6 months. These results materialize the potential of our Nanocyclix® program by getting closer to clinical validation of our products in order to deliver a new generation of therapeutic agents. This represents another important step in OPM's development as it establishes itself as a clinical stage biotech with multiple programs in the clinic. This program, which began in 2012 within Oncodesign with the selection of ODS-101 at the end of 2019, demonstrates the potential and expertise developed by the OPM team that continues to investigate new kinase targets in Oncology."*

About the Nanocyclix® technology

The Nanocyclix® technology is based on small macrocyclic molecules designed to inhibit the human kinome (the family of kinases that has more than 500 members), which plays a role in more than 400 diseases. These molecules represent an extraordinary opportunity thanks to their physicochemical properties (low molecular weight, cell membrane crossing, selectivity) to target with high potency and selectivity little explored or notoriously difficult kinases and to obtain drug candidates that meet the specifications compatible with our ambition to deliver therapeutic agents in precision medicine.

About Oncodesign Precision Medicine (OPM)

Oncodesign Precision Medicine (OPM), the result of the transfer of Oncodesign's Biotech and AI activities, is a biopharmaceutical company specializing in precision medicine to treat resistant and metastatic cancers.

OPM's innovative technologies are (i) OncoSNIPER for the selection of therapeutic targets using artificial intelligence; (ii) Nanocyclix® for the design and selection of macrocyclic small molecule kinase inhibitors and (iii) Theranostics for the design and selection of radiolabeled biological molecules for systemic radiotherapy.

From these technologies, OPM has built a portfolio of therapeutic products. A first drug candidate based on the Nanocyclix® technology entered the clinical phase in 2022, in partnership with SERVIER (which exercised its option for an exclusive worldwide license on the program) to treat Parkinson's disease. ODS 101 is OPM's second candidate to enter the clinic, in the treatment of chronic immuno-inflammatory diseases. Finally, OPM is also collaborating with Servier to discover new therapeutic targets for the treatment of pancreatic adenocarcinoma based on its OncoSNIPER technology. In addition, OPM is seeking a partner for Florepizol, a radiotracer specific for the mutated EGFR target, which has successfully completed Phase 1. Two projects are in early partnership phase with TIUMBIO (pulmonary fibrosis) and SEngine in oncology. Finally, OPM has a significant portfolio of early-stage projects with Nanocyclix® and Theranostics in oncology. With this portfolio of molecules and diversified therapeutic targets, OPM's mission is to discover effective therapies to treat resistant and advanced cancers. Based in Dijon, at the heart of the university and hospital cluster, OPM has 25 employees.

More information: oncodesign.com



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