Press release

OPM announces positive interim results of its Phase 1 study evaluating OPM-101 in healthy volunteers

- **Completion of the single-dose administration (SDA) part of the Phase 1 healthy volunteers study of OPM-101 and transition to the multiple-dose escalation administration (MDA)**
- **A new mechanism of action normalizing TNF-alpha secretion and targeting chronic inflammatory bowel disease (IBD)**
- **Excellent tolerability with no adverse events observed and excellent safety range**
- **Significant target engagement over 24 hours, even at moderate doses**
- **Favorable pharmacokinetic profile with once-daily oral administration**
- **ANSM approval to start the multiple-dose administration (MDA) part in Q4 2023**

Dijon, France, October 2, 2023, at 6:00 pm CEST - Oncodesign Precision Medicine (OPM) (ISIN: FR001400CM63; Mnemonic: ALOPM), a biopharmaceutical company specializing in precision medicine for the treatment of resistant and metastatic cancer, announces positive interim results at the end of the first part of the Phase 1 single-ascending-dose oral administration (SAD) study of its drug candidate OPM-101 in healthy volunteers.

This first part of the Phase 1 trial was completed in 7 months. 72 healthy volunteers were randomized and OPM-101 was evaluated against placebo using single oral administration at escalating doses (SDA). This study demonstrated that OPM-101 had a significant safety range, as doses tested varied from 5 to 1000 mg, and the maximum tolerated dose was not reached.

Moreover OPM-101 demonstrated significant target engagement over a 24-hour period, starting with low doses. At the end of the SAD, OPM-101 demonstrated excellent tolerability in all cohorts. After a single-dose oral administration of OPM-101 (at doses from 5 to 1000 mg), target engagement was observed at low doses as early as 1 h after administration and maintained at a very significant level over 24 h.

No serious or severe adverse events or dose-limiting toxicities leading to study discontinuation were observed during the SAD part of the study. The few adverse events possibly related to the product were mainly minor, allowing repeated oral administration to be envisaged with confidence.

OPM capitalized on the analysis of OPM-101 data obtained during the SAD to optimize preparation of the second part of the study, scheduled to start in Q4 2023, following ANSM approval:

- OPM-101 is rapidly absorbed orally, with an estimated half-life elimination of 12 to 15 hours, enabling once-daily administration with target engagement above 80%.

- Taking a fat-rich breakfast increased peak concentrations (Cmax) and total exposure (AUC0-t) to the product. Administering OPM-101 after breakfast therefore offers the possibility of administrating lower doses to achieve equivalent levels of target inhibition.

- A dedicated cohort was also used to assess the gender effect, in preparation for the second part of the study, which will focus on repeated administration for 14 days. At the end of each of the seven dose-escalation cohorts, a data review committee agreed to proceed to the next cohort with a higher dose.

Jan Hoflack, Chief Scientific Officer of OPM, said: *« OPM-101 was very well tolerated and demonstrated significant target engagement over a 24-hour period, even at low doses. These arguments are in favor of a significant therapeutic range. The Data Review Committee (DRC) reviewed and analyzed all the data obtained during the SDA part of the study and recommended the start of the MDA (repeated administration) part of the study. In this part of the study, OPM-101 will be administered twice a day at doses designed to maintain target engagement above 80%. The MDA part is scheduled to start in early Q4-2023. The completion of this Phase 1 SDA - 9 cohorts in just 7 months highlights the quality of our OPM-101 product and of our preclinical and clinical teams. »*

Philippe GENNE, President and Chief Executive Officer of Oncodesign Precision Medicine, added: *« We are very pleased with the progress of this clinical trial at this stage. OPM-101 is a molecule with an ideal pharmacological profile, a perfect drug candidate that will enable us to fully test the therapeutic potential of RIPK2 kinase inhibition in chronic inflammatory bowel diseases with patients. These results reinforce our lead over our main competitors identified today and are very impressive to the world's leading key opinion leaders with whom we are working to build the Phase 2 clinical trial. »*

About OPM-101

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

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) Promethe 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. OPM-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 I. Finally, OPM has a significant portfolio of early-stage projects with Nanocyclix® and Promethe 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 info at: oncodesign.com

Contacts:

OPM
Karine Lignel
Deputy General Manager
Tel: +33 (0)3 80 78 41 93
investisseurs@oncodesign.com

NewCap
Investor Relations
Mathilde Bohin / Alban Dufumier
Tel: +33 (0)1 44 71 94 95
oncodesign@newcap.eu

NewCap
Media Relations
Arthur Rouillé
Tel: +33 (0)1 44 71 00 15
oncodesign@newcap.eu