Dosing of First Patient with investigational agent OMO-1

OCTIMET Oncology NV, the Belgian life science company with a focus on the development of MET kinase inhibitory drug candidates having additional differentiating properties, is pleased to announce the dosing of OMO-1 to the first patient. The multicenter, Phase I/II clinical trial (NCT03138083) is primarily evaluating the safety, pharmacokinetics and tolerability, alone and in combination with anti-cancer treatments, in patients with locally advanced, unresectable or metastatic solid malignancies.

OMO-1 is a selective small molecule that has demonstrated potent single agent and combination activity in a range of preclinical models. OCTIMET obtained a worldwide exclusive license to OMO-1 from Janssen Pharmaceutica who had previously carried out a healthy volunteer trial where predicted efficacious exposures were reached without any significant adverse events.

The primary objective of this Phase I/II study is to demonstrate that OMO-1 has an acceptable safety and tolerability profile; secondary objectives include determination of pharmacokinetic (PK) characteristics, and indication of biological activity and clinical efficacy at doses and schedules at or below the maximum tolerated dose (MTD) or maximum feasible dose (MFD).

This adaptive study, with an innovative modular design, will be conducted in different countries including the United Kingdom, Belgium, The Netherlands and France. Approximately 50 adult patients with a diagnosis of advanced, unresectable or metastatic solid malignancies will be enrolled into the monotherapy module of the study, with preliminary top-line results expected in Q3 2018. In parallel preclinical studies are ongoing to further optimise the clinical strategy and to fine tune the biomarker strategy.

Timothy Perera, CEO of OCTIMET: “We are pleased to reach this important milestone within 7 months of obtaining funding. We look forward to accelerating the development of this agent so that we can bring another personalised therapeutic option for patients in areas of unmet medical need.”

Glen Clack, CMO of OCTIMET: “Despite the current perceived lack of clinical success in targeting the MET pathway in oncology, we have taken onboard the learnings from these previous clinical trials in designing our development program; namely cutting-edge study design, a more rational patient selection methodology and improved molecule selectivity and pharmacokinetics. We believe that these approaches will provide the differentiation required to ensure a successful clinical proof of concept for OMO-1.”

Sarah Blagden, Principal Investigator, University of Oxford : “OMO-1 was given to the first cancer patient in the world today in Oxford University’s Early Phase trials unit. We are proud to host this innovative clinical trial and have high expectations for its success.”

Ronald Openshaw, CEO, Simbec Orion : “Simbec-Orion are delighted that working alongside OCTIMET this first significant milestone was achieved so quickly. We look forward to recruiting the remaining subjects for this study in line with OCTIMET's protocol and developing a drug in an area with such high unmet medical need".

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About OMO-1

OMO-1 is a small molecule inhibitor of the enzymatic activity of the MET receptor tyrosine kinase (RTK). The MET gene has been shown to be responsible for some hereditary types of cancer. In addition, inappropriate MET activation has been shown in most types of solid tumours, often correlating with poor prognosis (Trusolino et al 2010, Gheradi et al 2012). The unique properties of OMO-1 have shown potent and differentiated activity in a range of preclinical models that if translated into the clinic would offer significant therapeutic benefit to patients in areas of unmet therapeutic need.

About OCTIMET

OCTIMET Oncology NV acts as a translational accelerator, focusing on creating value for investors and patients by providing rapid clinical proof of concept for cancer therapies through innovative clinical development strategies and patient centered biomarker approaches. OCTIMET was set-up in 2016 and is backed by leading national and international life sciences investors since January 2017. OCTIMET is based at the new JLINX facility in Beerse in Belgium. Within the JLINX model OCTIMET gets access to drug development expertise located within the Janssen site. The current focus is on its clinical stage asset OMO-1, a highly selective small molecule MET inhibitor that will be developed with specific biomarkers, whilst an additional late pre-clinical stage oncology asset 0MO-2 will also enter the portfolio. (www.octimet.com)

About Simbec-Orion

Simbec-Orion is an international, full service, boutique CRO, focused on a defined series of core therapeutic areas that delivers their clients' clinical development needs through close collaboration.