FDA Approves OCTIMET's Investigational New Drug Application to evaluate OMO-1 in patients

Visit the Octimet website

OCTIMET Oncology NV, a Belgian clinical-stage biotech company, is pleased to announce that the U.S. Food and Drug Administration (FDA) has granted its approval for the company's Investigational New Drug (IND) Application to initiate its Phase I/II trial of OMO-1 in US.

Beerse (Belgium), 29th January 2019 – OCTIMET Oncology NV, a translational accelerator with a focus on the development of highly specific and differentiated oral MET kinase inhibitors, announces the approval of the IND application for its modular, multi-arm, multi-centre, Phase I/II clinical trial (NCT03138083) evaluating OMO-1, the company's lead asset. This first-in-patient trial is primarily evaluating the safety, tolerability, pharmacokinetics, pharmacodynamics and preliminary efficacy of the MET kinase inhibitor OMO-1 alone and in combination with anti-cancer treatments. OCTIMET is excited to have the opportunity of extending the ongoing European Phase I/II trial to biomarker selected US patients with MET-mutated/amplified locally advanced, metastatic or unresectable solid tumours. The first US study site is currently being initiated and further sites are being recruited.

Timothy Perera, CEO of OCTIMET Oncology NV: "Since there is still a high unmet need for targeted therapies that can give significant benefit to biomarker selected patients with cancer, we are pleased to have received FDA acceptance for our first IND application evaluating our lead asset, OMO-1. Receiving this approval is testament to the quality and efficiency of our team. We look forward to expanding our ongoing clinical study in US sites, thereby increasing significantly the potential to enrolling patients with MET-mutated/amplified solid tumors. The opening of the US IND also opens the path for OCTIMET to further expand to additional global trial sites".

About OCTIMET

OCTIMET Oncology NV acts as a translational accelerator, focusing on creating value for patients and investors by providing rapid clinical proof of concept for cancer therapies through innovative clinical development strategies and patient centred biomarker approaches. OCTIMET was set-up in 2016 and is backed by leading national and international life sciences investors. OCTIMET licensed three patent families related to highly selective MET kinase inhibitors from Janssen Pharmaceutical companies of Johnson and Johnson in January 2017. OCTIMET is based at the JLABS@BE facility in Beerse (Belgium). The current focus is on its clinical stage lead asset OMO-1, a highly selective small molecule MET kinase inhibitor that is developed using specific patient selection biomarkers.

Media Contacts:

Dr Timothy Perera, CEO, OCTIMET Oncology NV
Telephone: +32 (0)473 558 353 – E-Mail: – www.octimet.com