

iOnctura announces first patient dosed in a phase I clinical study of its novel highly selective PI3K δ inhibitor, IOA-244 for solid tumours

Geneva, Switzerland, 26 February 2020: iOnctura SA., a clinical stage biopharmaceutical company, developing a pipeline of next generation molecules targeting cancer and fibrosis, announces it has dosed the first patient in a first-in-human dose escalation and expansion study evaluating the safety and preliminary efficacy of its lead programme IOA-244, which is being developed as a novel targeted therapy for solid tumours.

The phase I study will enrol approximately 60 patients with solid tumours that overexpress PI3K δ and are burdened by immune cells of the suppressor phenotype that are sensitive to PI3K δ inhibition. The dose escalation part of the study will evaluate the safety, tolerability and pharmacokinetic profile of IOA-244 and is being led by principal investigators Professor Evans from the Beatson West of Scotland Cancer Centre and University of Glasgow, and Professor Maio from the University Hospital of Siena. Results from the phase I study are expected in early 2021.

Michael Lahn, Chief Medical Officer of iOnctura, commented: “Our mission is to achieve true precision medicine that optimally treats patients according to the root causes of their disease. The start of this trial represents an important milestone for iOnctura to clinically demonstrate that highly selective PI3K δ inhibition not only drives an immune-mediated response but also a direct anti-tumoural effect in a stratified patient population across multiple solid tumour indications. This study will generate important insights into IOA-244, and its potential to provide meaningful and lasting clinical benefit for patients with cancer. We are very pleased to collaborate with Professor Evans and Professor Maio on this significant first-in-human dose escalation study. We look forward to continuing our evolution into a leading biopharmaceutical company with a diverse and sustainable pipeline in cancer and fibrosis.”

Professor Maio, Department of Medical Oncology, University Hospital of Siena, Italy said: “We are excited to participate in iOnctura’s first-in-human study. iOnctura’s innovative and differentiated approach has the potential to offer new, advanced treatment options to cancer patients and we are looking forward to evaluating this promising and unique target.”

Commenting on the study, recently appointed Clinical Advisory Board member, Dr. Jordi Rodón Ahnert, Clinical co-director, MD Anderson Cancer Center, added: “The design of the clinical trial is novel because it is going to investigate patients with expected high PI3K δ expression and immune suppression both of which are underlying causes of treatment resistance in many solid tumours. iOnctura’s novel compound, IOA-244, could be critically important for the treatment of solid tumours that are burdened with an immune-suppressive tumour microenvironment.”

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NOTES TO EDITORS

About IOA-244

IOA-244 is a next generation PI3K δ inhibitor with a unique chemical structure, exquisite selectivity, excellent drug-like properties and an expected best-in-class safety profile. It is being developed as a novel targeted therapy for solid tumours that over express PI3K δ and are burdened by immune-suppressive subtypes sensitive to PI3K δ inhibition.

About iOnctura

iOnctura SA, headquartered in Geneva, Switzerland, was founded in June 2017 as a spin out from Merck. It is a clinical stage biopharmaceutical company developing a pipeline of next generation, differentiated molecules that are at the forefront of pioneering new therapies for the treatment of cancer. Each of iOnctura's programmes harness the combined effect of immune-mediated and direct anti-tumour activity and aim to deliver molecules with superior clinical efficacy and safety in oncology.

The company's lead programme, IOA-244, entered the clinic in Q1 2020. The study is aimed to clinically demonstrate for the first time that a highly selective PI3K δ inhibition not only drives an immune-mediated response but also a direct anti-tumoural effect in a stratified patient population across multiple solid tumour indications. The company's second molecule is a novel autotaxin (ATX) inhibitor at IND stage for patients with solid tumours burdened with cancer-associated fibrosis. For more information, please visit www.ionctura.com

About the Beatson West of Scotland Cancer Centre, UK

The Beatson West of Scotland Cancer Centre is the largest cancer centre in Scotland and serves a population of 2.6 million and has clinical links with all hospitals in the West of Scotland.

The Beatson is renowned for being the lead centre for delivering non-surgical cancer care. There are approximately 150 innovative clinical trials ongoing at any one time, offering cutting-edge technologies, equipment and access to new cancer treatments. www.beatson.scot.nhs.uk

Professor Jeff Evans

Professor Jeff Evans is Professor of Translational Cancer Research and Clinical Lead of the Institute of Cancer Sciences, University of Glasgow. He is also Honorary Consultant in Medical Oncology at the Beatson West of Scotland Cancer Centre, and Lead of the Glasgow Experimental Cancer Medicine Centre (ECMC). His clinical research interests are in clinical development of novel anti-cancer agents including molecular targeted therapies, immunotherapy, and advanced cellular therapies. He leads a multiple number of Phase I clinical trials of innovative anti-cancer agents, including the development of novel therapies for gastro-oesophageal and hepato-biliary-pancreatic cancers and melanoma.

About University Hospital of Siena, Italy

The University Hospital of Siena is a centre of reference for clinical research in the field of immune oncology. The centre is involved in some of the most important global immunotherapy trials in solid tumours, with the main purpose of making the latest therapeutic treatments available to patients.

Since 2017, the University Hospital of Siena established a multidisciplinary entity, the Centre for Immuno-Oncology (CIO), allowing a complete and successful integration of clinical research services. The CIO has four integrated units, including the clinical facilities of Medical Oncology and Immunotherapy, the Clinical Research unit for clinical trials and the Translational and Pre-Clinical research laboratories. www.toscanalifesciences.org/en/bioincubator/research-groups/center-for-immuno-oncology-university-hospital-of-siena/

Dr. Michele Maio

Dr. Michele Maio is full professor of Oncology at the University of Siena, Director of the Center for Immuno-Oncology, of the Division of Medical Oncology and Immunotherapy, and of the Department



of Medical Oncology at the University Hospital of Siena, Italy. His clinical research interests include cancer immunobiology and epigenetics, as well as bioimmunotherapy of solid tumours. Dr. Maio is/has been Principal Investigator and National Coordinator of more than 100 Phase I-III clinical trials.