

iOmx Therapeutics Announces Dosing of First Patient with SIK Inhibitor OMX-0407 in Phase I Clinical Trial

- *First-in-human trial to test safety and tolerability of a novel immune-protective kinase inhibitor in multiple solid tumors.*
- *First iOTarg platform-derived product candidate in the clinic.*

Martinsried / Munich, Germany, 04 April 2023 - iOmx Therapeutics AG, a biopharmaceutical company developing next-generation targeted cancer immunotherapy treatments, today announced the dosing of the first patient in a Phase I dose escalation study evaluating OMX-0407, a first-in-class oral SIK (salt-inducible kinase) inhibitor.

The study is a single-arm, open-label, multicenter, Phase I clinical trial assessing the safety and tolerability of OMX-0407 as monotherapy in patients with previously treated unresectable solid tumors. The clinical trial has been approved by regulators in Spain and Belgium.

“With an exciting novel mode of action OMX-0407 holds the potential to address multiple solid tumors that are not responsive to conventional immune checkpoint inhibitors. Our research has shown that inhibition of SIK with OMX-0407 potentiates tumor cell apoptosis by un-leashing intra-tumoral death receptor signaling resulting in anti-tumor efficacy in pre-clinical models resistant to conventional immune checkpoint blockade,” said **Dr. Murray Yule, Chief Medical Officer of iOmx**. “We would like to express our gratitude to the investigators, their teams and the patient community for their support and trust in our treatment approach with OMX-0407.”

Dr. Apollon Papadimitriou, CEO of iOmx added: “We are proud to bring our first iOTarg platform-derived product candidate into the clinic. This is a significant milestone for iOmx as we pursue our goal to deliver better medical options for patients failing current cancer immunotherapy treatments.”

SIK family member SIK3 was identified as a novel immune-protective kinase by using iOmx’s systematic screening platform, iOTarg™. Inhibition of SIK3 with OMX-0407 targets a novel immune evasion biology by sensitizing tumors to immune-derived ligands of the TNF superfamily. In preclinical studies OMX-0407 showed strong monotherapy effects reshaping the immune compartment and accelerating tumor cell death.

About OMX-0407

OMX-0407 is an oral spectrum-selective salt-inducible kinase (SIK) inhibitor. The SIK family member SIK3 is known for regulating the NF-κB driven gene landscape

through phosphorylation of class IIa histone deacetylases (HDACs) and CREB-regulated transcriptional coactivators causing the tumor to evade death receptor-mediated killing. Downregulation of this pathway with OMX-0407 potentiates apoptosis by death receptor ligands, such as tumor necrosis factor (TNF) and TNF-related apoptosis-inducing ligand (TRAIL) in preclinical studies.

About the study

The study is a first-in-human, dose-escalation trial of OMX-0407 monotherapy in patients with previously treated unresectable solid tumors. The Phase I trial is designed to characterize the safety, tolerability and pharmacodynamic activity of OMX-0407. The dose escalation scheme is established on the 3+3 design to determine the maximum tolerated dose (MTD).

About iOmx Therapeutics

iOmx Therapeutics (www.iomx.com) is a biopharmaceutical company focused on developing first-in-class cancer immuno-therapeutics addressing novel immune checkpoints hijacked by cancer cells. Utilizing its iOTarg™ high-throughput screening platform, iOmx has identified a number of proprietary tumor-associated next-generation immune checkpoints and is advancing a preclinical stage pipeline of promising drug candidates that have the potential to address cancers that are resistant to current immunotherapies. The company's lead compound OMX-0407 targets SIK, an immune protective kinase family in multiple solid tumors. Founded in 2016 based on the work of its scientific founders Philipp Beckhove, MD, and Nisit Khandelwal, Ph.D., conducted at the German Cancer Research Center, iOmx is backed by international venture capital investors, such as Wellington Partners, Sofinnova Partners and M Ventures as well as MIG Capital and Athos Biopharma. iOmx is based in Martinsried/Munich, Germany.

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