

iOmx Therapeutics Initiates Phase Ib with OMX-0407

- *Data from the successful Phase Ia dose escalation study showed that OMX-0407 monotherapy demonstrated a favorable safety profile and signs of anti-tumor activity, with one durable complete response in a high-medical-need indication*
- *Phase Ib expansion phase in two priority indications opened*

Martinsried / Munich, Germany, August 22, 2024 – iOmx Therapeutics AG (iOmx), a clinical-stage biopharmaceutical company translating unexplored immune evasion biology into a growing pipeline of biomarker-enabled drug programs, today announced successful completion of the dose escalation segment of the Phase Ia/Ib clinical trial ([NCT05826600](https://clinicaltrials.gov/ct2/show/study/NCT05826600)) investigating OMX-0407, a first-in-class, spectrum-selective SIK (salt-inducible kinase) inhibitor, in patients with advanced solid tumors and opening of the expansion phase in kidney cancer and angiosarcoma.

Murray Yule, M.D., Chief Medical Officer of iOmx, said: “The completion of the dose escalation segment of our Phase Ia/Ib clinical trial is a significant step forward in the development of our lead candidate OMX-0407. I look forward to observing the positive effects OMX-0407 will have on larger patient populations in kidney cancer and angiosarcoma.”

Topline data from the 20-patient dose escalation segment showed that OMX-0407 monotherapy was safe and well-tolerated. Evidence of anti-cancer activity was observed in this heavily pretreated population of patients, suffering from a variety of solid tumors. Notably, one patient who was resistant to multiple previous chemotherapies achieved a durable complete response (CR) with disappearance of all tumor lesions. Furthermore, biomarker analyses showed evidence of substantial pharmacological activity in circulating blood cells.

Hannes Loferer, Ph.D., Chief Operations Officer of iOmx, said: “We are now focusing on generating efficacy data in the dose expansion segment of the study. The first two indications, kidney cancer and angiosarcoma, amongst other prioritized key solid tumor indications, have a high potential for objective response to OMX-0407 based on the results of the dose escalation and the preclinical data package.”

The expansion cohorts will be run in major oncology centers with expertise in kidney cancer and angiosarcoma. The study aims to further evaluate the single agent activity and the safety profile of OMX-0407 at the recommended dose as determined in the completed dose escalation segment. Backed by a robust translational data package the study will enroll patients with previously treated renal



cell carcinoma and angiosarcoma. The primary endpoint is objective response rate, with secondary objectives including duration of response and patient survival.

Apollon Papadimitriou, Ph.D., Chief Executive Officer of iOmx, concluded: "Kicking-off the Phase Ib segment of the OMX-0407 trial is a key development milestone for iOmx. The dose escalation data, including one long-lasting complete response in an indication of high medical need and additional signs of anti-tumor activity in other patients is very strong. We are confident that we are progressing towards providing a clinically meaningful, differentiated therapy for patients failing current cancer treatments and expect to report topline clinical proof-of-concept data by early 2026."

About the Phase Ia/Ib Clinical Trial

The Phase Ia/Ib clinical trial is investigating the effects of OMX-0407 monotherapy in patients with previously treated unresectable solid tumors. The dose escalation scheme utilized 3+3 design to characterize the safety profile of OMX-0407 and determine the maximum tolerated dose (MTD). The dose expansion phase will evaluate OMX-0407 in two tumor-specific cohorts, enrolling up to 86 patients with previously treated renal cell carcinoma or angiosarcoma.

About OMX-0407

OMX-0407 is an orally available and first-in-class spectrum-selective kinase inhibitor targeting key oncology-relevant tyrosine kinases and salt-inducible kinases (SIKs). OMX-0407 directly interferes with tumor cell proliferation through modulation of tyrosine kinase signaling. Complementary to this direct mode of action, OMX-0407 potentiates tumor cell apoptosis in response to death receptor ligands like tumor necrosis factor, reshaping the tumor micro-environment.

About iOmx Therapeutics

iOmx Therapeutics (www.iomx.com) is a clinical-stage company that harnesses deep tumor and myeloid biology insights, along with its proprietary iOTarg™ target screening platform, to generate novel treatments for the most prevalent solid tumor indications. The company is translating unexplored immune evasion biology into a growing pipeline of biomarker-enabled drug programs. Focused on developing drugs with single agent activity, iOmx is creating potential new backbone therapies in a modality-open fashion. By applying its comprehensive drug discovery & development expertise iOmx is committed to shaping the future of cancer therapy. The company's lead program, OMX-0407, is a proprietary first-in-class spectrum-selective kinase inhibitor targeting key oncology-relevant tyrosine kinases and salt-inducible kinases (SIKs) and is currently being investigated in a Phase Ia/Ib clinical trial in multiple solid tumors. The second program, IOMX-0675, a highly differentiated, LILRB1&2 cross-specific antibody is on track for CTA submission in



Q4 2024. iOmx is backed by international venture capital investors, such as Athos, Sofinnova Partners, Wellington Partners, MIG Capital and M Ventures. The Company is based in Martinsried/Munich, Germany.

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