iOnctura Shows No Dose-limiting Toxicity and Reduced Tregs In Solid Tumor Study Of PI3Kδ Inhibitor IOA-244 Presented At ESMO-IO

Geneva, Switzerland, 9 December 2021: iOnctura SA, a clinical stage oncology company targeting core resistance and relapse mechanisms at the tumor-stroma-immune interface, is presenting clinical data on its lead pipeline asset, the PI3Kδ inhibitor IOA-244, showing no dose-limiting toxicity and a reduction in T regulatory (Treg) cells. The data is being presented as a poster at the European Society of Medical Oncology’s Immuno-Oncology Congress (ESMO-IO) taking place on December 8–11, 2021 as a virtual meeting.

The data demonstrates there were no dose-limiting toxicities in patients with solid tumors treated with IOA-244, including patients who were treated for up to 1 year duration. The PK profile of IOA-244 showed low intra- and inter-patient variability with no clinically relevant reactive metabolites detected. Mesothelioma, cutaneous and uveal melanoma – tumor types being treated with IOA-244 - are known to have a high burden of T regulatory cells. IOA-244 administration was associated with a reduction in Treg counts in the peripheral blood of patients with uveal melanoma, as measured using cytometry by time of flight (CyTOF). These data strengthen the rationale for treating patients with IOA-244 and expanding the DIONE-01 study, a two-part, first-in-human dose study evaluating IOA-244 in solid tumors and hematologic malignancies.

The poster at ESMO-IO presents data from the first part (Part A) of the DIONE-01 study and is entitled “First-in-human (FIH), pharmacokinetic (PK) and pharmacodynamic (PD) study of IOA-244, a phosphoinositide 3-kinase delta (PI3Kδ) inhibitor, in patients with advanced metastatic mesothelioma, uveal and cutaneous melanoma” (P139).

The e-poster presentation is available on the ESMO-IO virtual meeting platform and iOnctura’s website.

IOA-244 is a novel phosphoinositide 3-kinase delta (PI3Kδ) inhibitor with an unprecedented preclinical and clinical profile, currently being investigated in Part B of the DIONE-01 trial.

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iOnctura SA is clinical stage oncology company targeting core resistance and relapse mechanisms at the tumor-stroma-immune interface. iOnctura’s best-in-class drug development programs combine immune-mediated and direct anti-tumor activity to deliver molecules with superior clinical efficacy and safety in oncology. Its lead program, IOA-244 is the only semi-allosteric PI3Kδ specific, orally dosed, small molecule inhibitor that is being developed in
solid and hematological malignancies to address tumor and stroma induced immune suppression. IOA-244 is currently in Part B of a Phase 1 study. iOnctura’s second program, IOA-289, is an oral small molecule that inhibits the cross-talk between the tumor and its stroma and is in a Phase 1 clinical study. iOnctura is backed by blue chip investors including M Ventures, Inkef Capital, VI Partners, Schroders Capital, and 3B Future Health Fund. For more information, please visit www.ionctura.com

**IOA-244** is a PI3Kδ specific, orally dosed, small molecule inhibitor that overcomes tumor and stroma induced immune suppression. Its unique chemistry, semi allosteric binding mode and mechanism of action contribute to its unprecedented clinical profile. IOA-244 is currently in the cohort expansion phase of the DIONE-01 trial, a two-part, first-in-human dose study evaluating IOA-244 in solid tumors and hematologic malignancies and as a combination partner for conventional and immune-therapies (ClinicalTrials.gov Identifier: NCT04328844).

**Uveal melanoma** (UM) is a rare malignancy arising within the uveal tract of the eye. There are approximately 7,000 newly diagnosed cases of uveal melanoma each year (around 2,000 in the United States). Over 50% of patients will progress to metastatic disease. Median overall survival is approximately 1 year for metastatic uveal melanoma and there are no approved therapies.