Press Release

iOnctura clinical expansion positions lead PI3Kδ inhibitor IOA-244 for potential registration studies in metastatic uveal melanoma

- **Expansion of DIONE-01 supports subsequent transition to registration studies in metastatic uveal melanoma**
- **DIONE-01 trial design expanded with multiple cohorts including solid and hematologic malignancies**
- **DIONE-01 Part A data to be presented at ESMO IO in December 2021**
- **Interim DIONE-01 Part B data expected H1 2022**

Geneva, Switzerland, 8 November, 2021: iOnctura SA, a clinical stage oncology company targeting core resistance and relapse mechanisms at the tumor-stroma-immune interface, announces it has fully enrolled the metastatic uveal melanoma expansion cohort of the DIONE-01 study evaluating iOnctura´s lead compound, the selective PI3Kδ inhibitor IOA-244.

The DIONE-01 study entitled "A Study to Assess a PI3Kδ Inhibitor (IOA-244) in Patients with Metastatic Cancers" (NCT04328844) consists of two parts, A and B. In Part A, now complete, the objective was to determine the safety, tolerability, and dosage of IOA-244 in cancer patients to determine the predicted biologically effective dose range. Safety, PK and PD data from Part A will be presented as a poster (#405) at ESMO IO in Geneva between December 8-11, 2021.

Part B of the DIONE-01 study consists of expansion cohorts of patients with different tumor types, including patients with metastatic uveal melanoma. It will include the assessment of whether IOA-244 can increase the anti-tumor immune response in patients both as monotherapy and in combination with pemetrexed/cisplatin and an immune checkpoint inhibitor. The study will enroll up to 182 patients with uveal melanoma, cutaneous melanoma, NSCLC, mesothelioma, myelofibrosis, and NHL.

Within Part B, up to 26 patients with metastatic uveal melanoma will be recruited to determine the monotherapy activity of IOA-244. Patients with metastatic uveal melanoma currently have no approved treatment options. Positive outcome from this part of the trial is expected to support transition to subsequent registration studies for metastatic uveal melanoma. Interim data is expected in Q2 2022 with final top-line data scheduled for Q4 2022.

"iOnctura is entering a highly exciting phase as it progresses two tumor-stroma-immune interface targeting programs through clinical development. IOA-244 continues to demonstrate an unprecedented clinical profile among PI3Kδ inhibitors," said **Catherine Pickering, CEO of iOnctura**. "iOnctura is moving rapidly in the use of IOA-244 to treat a range of solid tumor types including metastatic uveal melanoma, an underserved cancer with no currently approved drug treatments and poor patient outcomes. We look forward to releasing early data from our preclinical and clinical evaluations of this exceptional molecule at ESMO IO."

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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 hematologic malignancies to address tumor and stroma induced immune suppression. IOA-244 is currently in a Phase 1 study which will support transition to subsequent registration studies. 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 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.

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.