# Updated clinical safety and efficacy data for iOnctura's roginolisib presented at ESMO Immuno-Oncology Congress 2023

- ***Updated safety and clinical efficacy data presented at leading immuno-oncology conference***
- ***Exploratory studies suggest roginolisib boosts antitumoral immunity, whilst simultaneously disrupting tumor survival mechanisms***
- ***Data suggest the potential of radiomics to assess changes in lesions over time, adding value above RECIST (Response Evaluation Criteria in Solid Tumors)***

**Geneva, Switzerland and Amsterdam, The Netherlands, 8 December 2023** - iOnctura, a clinical-stage biotech developing selective cancer therapies against targets that play critical roles in multiple tumor survival pathways, today announces clinical results for roginolisib, a first-in-class oral allosteric modulator of PI3Kδ, presented at the ESMO Immuno-Oncology Congress 2023 in Geneva.

Roginolisib is in development for solid and hematologic malignancies including uveal melanoma, a rare cancer of the eye. The poster presentation titled 'Safety and clinical efficacy of Roginolisib (IOA-244), the first oral allosteric modulator of phosphoinositide 3-kinase inhibitor delta (PI3Kδ)' demonstrated that roginolisib continues to be well tolerated over long periods of treatment and continues to show a favourable trend in overall survival exceeding the overall survival previously reported with immune checkpoint inhibitors.

Mass cytometry data showed treatment with roginolisib led to an increase in activated anti-cancer CD8+ T-cells and natural killer (NK) cells, increased interferon signalling and a decrease in cancer-promoting Regulatory T-cells. This shifts the balance of the immune system enabling a more-effective attack on cancer. Boosting of antitumoral immunity was observed in patients with long-term disease control after roginolisib treatment but not patients with progressive disease.

An exploratory analysis from a patient with uveal melanoma outlined the potential of radiomics, an advanced AI driven analysis of imaging data, as a way of tracking changes in cancer lesions over time in addition to standard RECIST measurements.

Overall, these findings are consistent with prior studies in pre-clinical models and support the development of roginolisib in uveal melanoma and other malignancies with immune suppressed conditions.

**Catherine Pickering, Chief Executive Officer of iOnctura, said:** *"These safety and clinical efficacy data demonstrate iOnctura's progression of roginolisib. Our first-in-class allosteric modulator of PI3Kδ continues to show a favourable trend in overall survival and is well tolerated over very long periods of treatment, now up to 38 months in patients with uveal melanoma. An exploratory readout also shows that patients who respond well to roginolisib, with prolonged stabilisation of their disease, exhibit signs of an activated immune system better able to fight the tumor. We eagerly anticipate a final clinical readout in 2024."*

**ENDS**

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**About iOnctura**

iOnctura is a clinical-stage biotech developing selective cancer therapies against targets that play critical roles in multiple tumor survival pathways such as cellular proliferation; escape from immune detection; and drug resistance. iOnctura's pioneering approach to drug development is expected to offer significant clinical benefits over the traditional approach of targeting a single pathway alone. iOnctura has progressed two therapeutic candidates into mid-stage clinical development: Roginolisib (IOA-244), an allosteric modulator of PI3Kδ; and IOA-289, a highly selective, non-competitive autotaxin (ATX) inhibitor. IOA-359, a TGF-β pathway inhibitor is also undergoing an extensive pre-clinical program in preparation for first-in-human studies. iOnctura is backed by specialist institutional investors including M Ventures, Inkef Capital, VI Partners, Schroders Capital, and 3B Future Health Fund. iOnctura BV is headquartered in Amsterdam, The Netherlands with its wholly owned Swiss subsidiary, iOnctura SA, located in Geneva, Switzerland.

**About roginolisib**

Roginolisib (IOA-244) is a first-in-class small molecule allosteric modulator of PI3Kδ. Its unique structural and selectivity features drive a unique way of inhibiting PI3Kδ which translates into a highly beneficial tolerability and clinical benefit profile. PI3Kδ over-expression stimulates multiple cancer mechanisms and has an oncogenic role in many tumor types. Roginolisib has a multi-modal effect on cancer; directly preventing cancer cell proliferation, harnessing an anti-tumor immune response via an effect on regulatory T-cells and cytotoxic T cells and potentiating the effect of immunotherapy. Roginolisib is currently in the extension phase of the DIONE-01 trial, a two-part, first-in-human dose study evaluating the drug in advanced cancers and as a combination partner for conventional and immune-therapies (NCT04328844).