iOnctura awarded UK's MHRA Innovation Passport for entry into innovative licensing and access pathway (ILAP)

Geneva, Switzerland and Amsterdam, The Netherlands, 28 March - iOnctura, a clinical stage biotechnology company developing breakthrough therapies for patients suffering with cancer, today announces that the innovative medicine designation, the Innovation Passport, has been awarded for roginolisib, for the treatment of metastatic uveal melanoma by the Medicines & Healthcare products Regulatory Agency (MHRA).

The Innovation Passport is the entry point to the Innovative Licensing and Access Pathway (ILAP) which aims to accelerate time to market and thereby patient access to novel treatments in the UK. Reserved for innovative therapies for life-threatening or seriously debilitating conditions, ILAP provides applicants with a toolkit to support all stages of the design, development, and approval process.

Roginolisib is a first-in-class, non-ATP-competitive, allosteric modulator of PI3Kδ which prevents tumor proliferation and breaks immune tolerance in patients with solid and hematological tumors.

Catherine Pickering, Chief Executive Officer of iOnctura, said: "The Innovation Passport is an exciting step in the clinical development programme for roginolisib, a drug with a game-changing clinical safety and activity profile. Being awarded this passport will allow us to work closely with the MHRA and its partner agencies to chart out a roadmap for regulatory and key development milestones with the primary goal of achieving early patient access to roginolisib."

PI3Kδ inhibition in solid tumors has recently emerged as a novel approach to treating cancer because of its potential in targeting multiple tumor survival pathways. First-generation PI3Kδ inhibitors are used to treat hematological tumors, but safety concerns and limited target selectivity have curbed their clinical usefulness. These concerns are even more aggravated in patients with solid malignancies where rapid onset of toxicities have been observed. In contrast, roginolisib has a favorable toxicity profile with less than 5% Grade 3/4 toxicities at the biologically effective dose in clinical studies. Importantly, these toxicities have to-date been transient in nature without the need for dose reductions.

Clinical activity, including partial and complete responses, are being seen in patients with both solid and hematologic malignancies. Further details on clinical responses will be released at a future international clinical conference in 2023. Fourteen of 43 patients (including 12 of 28 uveal melanoma patients) are still on treatment, with two patients having been on treatment for more than two years. The one-year OS rate is currently 70%; median OS has not been reached.

A research paper recently published in Cancer Research Communications highlights that roginolisib has immune-modulatory properties that can be exploited in solid tumors and further reinforced the conclusion that roginolisib inhibits regulatory T cell proliferation while having limited anti-proliferative effects on conventional CD4+ T cells and no effect on CD8+ T cells; both immune cell types key to a robust immune response to tumors. You can access the link to the paper here.

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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: IOA-244 (proposed name roginolisib), a first-in-class allosteric modulator of PI3Kδ; and IOA-289, a highly selective, non-competitive autotaxin (ATX) inhibitor. 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 is a first-in-class non-ATP competitive, small molecule, allosteric PI3Kδ modulator. 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 cohort expansion phase of the DIONE-01 trial, a two-part, first-in-human dose study evaluating roginolisib in advanced cancers and as a combination partner for conventional and immune- therapies (NCT04328844).

About uveal melanoma

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 for metastatic patients refractory to immunotherapy, the population included in the DIONE-01 trial, is approximately seven months.

About Innovation Passport

The Innovation Passport is the entry point to the Innovative Licensing and Access Pathway (ILAP) which aims to accelerate time to market, facilitating patient access. This designation is linked to a portfolio of activities through the product specific creation of the Target Development Profile (TDP). For more information, please visit www.gov.uk/guidance/innovative-licensing-and-access-pathway