

iOnctura announces expansion of roginolisib clinical trial program to NSCLC

- Phase II study in non-small-cell-lung-cancer (NSCLC) to be run in collaboration with the ETOP IBCSG Partners Foundation across sites in Europe
- Study will investigate dostarlimab + roginolisib +/- docetaxel in patients with NSCLC resistant to first-line checkpoint inhibitor therapy

Geneva, Switzerland and Amsterdam, The Netherlands, 9 July 2024 - iOnctura, a clinical-stage biopharmaceutical company combating neglected and hard-to-treat cancers, today announces expansion of the clinical trial program for lead pipeline asset, roginolisib. Via clinical collaboration agreements with the ETOP IBCSG Partners Foundation and GSK, roginolisib will be evaluated in combination with dostarlimab in NSCLC.

Roginolisib is an allosteric modulator of PI3K δ , widely recognized as a 'master switch' of cancer. Inhibition of PI3K δ unleashes a multi-pronged anti-tumor and immune response to combat the tumor¹. Roginolisib has demonstrated an unprecedented clinical profile in solid and liquid cancers², with 44 patients treated to date.

Emerging clinical and translational biomarker data supports the hypothesis that combining roginolisib with a programmed death receptor-1 (PD-1) targeting agent, with or without docetaxel, may prevent or reverse drug resistance in NSCLC and may show synergistic anti-tumor immune activity without significant addition of toxicity³.

Dostarlimab is a PD-1-blocking antibody approved for certain patients with endometrial cancer, which has also demonstrated clinical activity in combination with chemotherapy in NSCLC⁴. Under the terms of the agreement with iOnctura, GSK will supply dostarlimab for use in a randomized Phase II clinical trial in NSCLC patients resistant to first-line checkpoint inhibitor therapy, with or without docetaxel. iOnctura will retain worldwide rights to roginolisib.

The ETOP IBCSG Partners Foundation is a leading organization performing international clinical and translational research in thoracic malignancies and breast cancer. Through the clinical collaboration, iOnctura will be provided access to a network of highly experienced investigators for the Phase II study. Professor

¹ [AACR Volume 3, Issue 4, April 2023, Poster presentation, SITC 2022](#)

² [Poster presentation, ESMO-IO 2023](#)

³ [Poster presentation, ESMO-IO 2023, Poster presentation EACR 2023](#)

⁴ [Lim, S.M. et al., Nat Commun 14, 7301 \(2023\)](#)

Solange Peters, MD, PhD, Chair of Medical Oncology and the Thoracic Malignancies Programme in the Department of Oncology at the University Hospital of Lausanne will be the primary coordinating investigator of the study.

Catherine Pickering, Chief Executive Officer of iOnctura, said: “As iOnctura moves into the next phase of clinical development, we are thrilled to be able to assess the effectiveness of roginolisib in combination with dostarlimab for the treatment of NSCLC. The successful uveal melanoma data reported so far, combined with a rich preclinical data package, support the rationale to expand our development program with potentially synergistic combinations in NSCLC.”

Solange Peters, Professor and Chair of Medical Oncology & Thoracic Malignancies Programme in the Department of Oncology at the University Hospital of Lausanne in Lausanne, Switzerland, commented: “On behalf of the ETOP IBCSG Partners Foundation, we are intrigued by the benefit/risk profile of roginolisib. In patients who no longer respond to current therapies, we wish to investigate whether roginolisib in combination with dostarlimab provides a novel treatment option. ETOP IBCSG Partners Foundation is committed to investigate novel treatment options to help our patients.”

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About iOnctura

iOnctura is a clinical-stage biopharmaceutical company combating neglected and hard-to-treat cancers with precision oral small molecules that target cancers in novel ways. The bold new treatments extend lives and improve healthspans, changing the outlook for patients and their families. Two therapeutic candidates have progressed into mid-stage clinical development: roginolisib is the first allosteric modulator of PI3K δ and cambrtaxestat is the only autotaxin inhibitor in clinical development to treat cancer. iOnctura BV is headquartered in Amsterdam, The Netherlands with its wholly owned Swiss subsidiary, iOnctura SA, located in Geneva, Switzerland. iOnctura is backed by specialist institutional investors including Syncona, EIC Fund, M Ventures, Inkef Capital, VI Partners and Schroders Capital.

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About roginolisib

Roginolisib is the first allosteric modulator of PI3K δ with a unique chemical structure and binding mode. The PI3K signalling pathway is one of the most commonly dysregulated pathways in cancer and the precise targeting of the PI3K δ isoform delivers substantial anti-tumor effects with a low-toxicity profile. Clinical data have demonstrated roginolisib's excellent safety profile and sustained clinical activity in uveal melanoma (UM), a rare eye cancer with few available treatments. Randomized Phase II trials are planned to start in late 2024 in UM and other cancers, including non-small cell lung cancer and primary myelofibrosis.

About the ETOP IBCSG Partners Foundation

The ETOP IBCSG Partners Foundation was established through the merger of the European Thoracic Oncology Platform (ETOP) and the International Breast Cancer Study Group (IBCSG) (ETOP IBCSG Partners Foundation). The foundation, with its legal seat in Bern, Switzerland, has become a leading organization in performing international clinical research in thoracic malignancies and breast cancer. The ETOP IBCSG Partners Foundation is sponsoring and managing an increasing number of clinical trials and translational research projects in Europe and beyond.

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