# Combinations of iOnctura's roginolisib revert immune suppression in immunotherapy-resistant NSCLC

- Late breaking data from ongoing Phase I/II PULMO-01, the first clinical study of conformation-selective PI3Kδ inhibitor roginolisib in immunotherapy-resistant non-small cell lung cancer (NSCLC), presented at SITC
- Data demonstrated roginolisib-containing regimens were tolerable, reduced immunosuppressive activated regulatory T cells (Tregs) and expanded stem-like CD8+ T cells
- The 'chemo-free' (roginolisib plus dostarlimab) arm exhibited the most pronounced and sustained immune-cell changes and had the lowest rate of grade ≥3 adverse events; approximately half the rate of the other two 'chemo-containing' arms
- Clinical benefit was observed across all arms, and overall survival follow-up is ongoing

Geneva, Switzerland and Amsterdam, The Netherlands and Cambridge, Massachusetts, USA, November 6, 2026 – iOnctura, a clinical-stage precision oncology company combating neglected and hard-to-treat cancers, today presented late-breaking data from PULMO-01, evaluating combinations of roginolisib in patients with immunotherapy-resistant NSCLC, at the Society for Immunotherapy of Cancer (SITC) 2026 Annual Meeting.

Roginolisib is the first conformation-selective inhibitor of PI3Kδ that locks the enzyme in its inactive state. PI3Kδ signaling contributes to immune suppression, which can enable tumors to resist immune checkpoint inhibition (ICI), a standard-of-care therapy in NSCLC. Blocking PI3Kδ signaling is therefore a potentially powerful way to help restore anti-tumor immunity.

Overall, the data suggest roginolisib-containing regimens could help combat resistance to checkpoint inhibitors without the toxicity associated with chemotherapy.

"Resistance to immunotherapy remains one of the greatest challenges in the treatment of advanced NSCLC," said Catherine Pickering, CEO and co-founder of iOnctura. "These data show that roginolisib reduces immunosuppressive Tregs, which are linked to resistance in patients whose cancer no longer responds to checkpoint inhibitors. The strongest immune effects came with the 'chemo-free' regimen, which was also the most tolerable. These results support a potential future chemo-free treatment regimen for patients whose tumors have become resistant to checkpoint inhibitors."

## Immune and safety findings

PULMO-01 enrolled patients with advanced or metastatic non-squamous NSCLC who had experienced disease progression following ICI-based treatment. They were randomized to one of three regimens:

roginolisib, the ICI dostarlimab and chemotherapy docetaxel (the triplet arm, n=16), roginolisib and dostarlimab (the chemo-free arm, n=17), or dostarlimab and docetaxel (the control arm, n=16).

In both arms where patients received roginolisib, activated Tregs decreased and stem-like TCF1+ CD8+ central memory T cells increased. These changes are consistent with restored anti-tumor immunity. They were most pronounced and sustained in the chemo-free arm.

Roginolisib-containing regimens were also tolerable: The chemo-free arm showed the lowest rate of Grade ≥3 treatment-emergent adverse events at 35%, compared with 69% for the triplet combination and 75% for the control arm. No fatal adverse events were attributed to roginolisib.

### Clinical activity and survival follow-up

As expected in this treatment-refractory population, response rates were low across all arms. Confirmed partial responses were observed in one patient (6%) in the triplet arm, two patients (12%) in the chemo-free arm and two patients (13%) in the control arm.

Clinical benefit lasting at least six months was seen in 31%, 24% and 19% of patients, respectively.

Overall survival (OS) data remains immature. As of September 30, 2026, at a median follow-up of 6.4 months, six-month OS rates were 60.9% for the triplet arm, 74.8% for the chemo-free arm and 43.8% for the control arm. The study was not designed to compare survival between arms and follow-up continues.

### Poster presentation details

- Title: Roginolisib plus dostarlimab with or without docetaxel reverts immune suppression and shows clinical activity in immunotherapy-resistant non-small cell lung cancer (NSCLC)
- Session date: Friday, November 6, 2026
- Location: PCC-North Building-Lower Level-Exhibition Halls 4-5-6
- Abstract number: 1181

ENDS


### For more information contact:

**iOnctura**
Corporate Press Office:
press@iOnctura.com

**Optimum Strategic Communications**
Mary Clark / Stephen Adams / Henry Williams
Tel: +44 203 821 6420
Email: ionctura@optimumcomms.com

## About iOnctura

iOnctura is a clinical-stage precision oncology company combating neglected and hard-to-treat cancers with a pipeline of first-in-class small molecules. The bold new treatments extend lives and improve healthspans, changing the outlook for patients and their families. Lead asset, roginolisib, is the first conformation-selective inhibitor targeting the inactive form of PI3Kδ. This novel binding mode allows for precise inhibition of PI3Kδ, delivering clinical activity without the detrimental tolerability seen with previous generations of inhibitors. Roginolisib is being investigated in multiple randomized Phase II studies in solid and hematological malignancies. iOnctura is headquartered in Amsterdam, The Netherlands with subsidiaries located in Geneva, Switzerland and Cambridge, MA, USA. iOnctura is backed by specialist institutional investors including Syncona, M Ventures, Inkef Capital, EIC Fund, VI Partners, Schroders Capital and XGEN Venture.

## About roginolisib

Roginolisib is a non-ATP-competitive PI3Kδ inhibitor that stabilizes the catalytic C-terminal helix kα12, inducing an allosteric conformational shift that locks PI3Kδ in its inactive state and prevents ATP-mediated activation. This novel binding mode allows for precise inhibition of PI3Kδ, delivering clinical activity without the detrimental tolerability seen with previous generations of inhibitors. The PI3K signaling pathway is one of the most commonly dysregulated pathways across multiple cancer types. The potential of roginolisib has been validated by positive clinical signals in Phase I in solid tumor and hematological malignancies, including a doubling of overall survival compared to historical controls in rare eye cancer, uveal melanoma. The company has carefully designed its clinical portfolio to allow full development in uveal melanoma, while in parallel validating the program in larger market indications.

The randomized Phase II OCULE-01 study in uveal melanoma (NCT06717126) completed patient recruitment in January 2026, the PULMO-01 study in non-small cell lung cancer (NSCLC) (NCT06879717) completed recruitment in December 2025 and the HEMA-MED Phase I/II study (NCT06887803) in myelofibrosis began in October 2025 and recruitment is ongoing.

## About PULMO-01

PULMO-01 is an ongoing Phase I/II open-label, randomized, parallel-arm study (NCT06879717) evaluating roginolisib in combination with dostarlimab, with or without docetaxel. The study treated 49 patients whose disease progressed on standard-of-care immune checkpoint therapy. It is primarily investigating the safety of the combinations and the proportion of patients with a reduction in peripheral blood regulatory T cells in each arm. Secondary endpoints include objective response rate, clinical benefit rate, progression-free survival, overall survival and changes in immune cell subsets.