

Press Release

The PIONeeR Project to Present Late-Breaking Results from its Phase Ib/IIa umbrella study at the ESMO Congress 2024

- The Presidential Symposium "Eyes to the future" will feature the first-ever presentation of the clinical trial portion of the PIONeeR Project (Precision Immuno-Oncology for advanced Non-Small Cell Lung Cancer Patients with PD-(L)1 ICI Resistance).
- PIONeeR is a major international hospital-university research (RHU) project addressing the critical challenge of resistance to PD-1(L1) immune checkpoint inhibitors (ICIs) in patients with advanced non-small cell lung cancer (NSCLC), including a biomarker program (> 400 biomarkers) and an umbrella clinical trial (4 ICI combinations).
- The PIONeeR trial used an innovative and adaptive design for trial reporting and decision making, to identify signals of efficacy for novel ICI combinations in advanced NSCLC patients progressing after PD-(L)1 inhibitors.

Marseille, France, Sept 12, 2024 – The PIONeeR Project consortium today announced that Pr Pascale Tomasini, Principal investigator of the PIONeeR early phase randomized umbrella trial, will present the first data from the PIONeeR Project's clinical trial at the upcoming ESMO Congress 2024, to be held September 13-17 in Barcelona, Spain, and virtually, during the Presidential Symposium III: Eyes to the future.

"The PIONeeR trial is a collaborative success, fighting on multiple fronts at once, with all the artillery at our disposal, to explore how to overcome resistance to sequential or concurrent PD-(L)1 inhibitors in advanced NSCLC. The clinical trial is now complete, and we are conducting extensive biomarker analyses that we hope will shed light on the path on how to address this major challenge," said Prof. Fabrice BARLESI, coordinator of the PIONeeR Project, General Director at Gustave Roussy and Professor at Paris-Saclay University. "I would like to highlight this incredible act of selflessness by our more than 450 patients enrolled in our biomarker part of the PIONeeR Project, and our more than 150 patients being screened for inclusion in the clinical trial portion of the study. We are grateful for the dedication of our patients, which has taken us a giant step forward in advancing this study."

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Details on the abstract accepted for presentation at ESMO Congress 2024 include:

Presidential Symposium III: Eyes to the future

- Title: *Precision Immuno-Oncology for advanced Non-small cell lung cancer (NSCLC) patients with PD-(L)1 inhibitors Resistance (PIONeeR): a phase Ib/IIa clinical trial targeting identified resistance pathways*
- Presentation Number: LBA8.
- Presenter: Pr Pascale Tomasini, Aix Marseille Université, AP-HM, Early Phase Clinical Trials in Oncology Unit, Principal investigator of the PIONeeR early phase randomized clinical trial
- Presentation Time: Monday September 16, 2024, 4:30 - 6:15 pm CEST

Abstract will be available on the ESMO website: [ESMO Congress 2024 - Conference Calendar](#). All accepted abstracts will be published in the ESMO Congress 2024 Abstract Book, a supplement to the official ESMO journal, *Annals of Oncology*.

About the PIONeeR Project

Winner of the 3rd University-Hospital Research in Health call for projects in the "Investments for the Future program", the PIONeeR Project gathers over 100 scientists across 3 different countries, 8 research labs, and 16 hospitals, all committed to the scientific, medical and human adventure that it represents. The project has recruited 450+ patients to its biomarker program and 114 patients to the PIONeeR Phase Ib/IIa clinical trial. The clinical trial is now complete and extensive biomarker analyses are ongoing. The partners of the PIONeeR Project are Marseille Immunopôle (MI), Aix Marseille Université (amU), Inserm, CNRS, 4 research & technology centers (CIML, CRCM, CIPHE, MImAbs), Assistance Publique-Hôpitaux de Marseille (AP-HM), the Paoli-Calmettes Institute, the Léon-Bérard Center, Gustave Roussy Institute, and industrial partners AstraZeneca, ImCheck Therapeutics, Innate Pharma and Veracyte. This 7-year project¹ has been granted a French public funding (ANR-17-RHUS-0007).

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¹ Initially a 5-year project. Extension period granted, notably linked to the Covid crisis.