

Press release

October 23, 2023

ESMO 2023/A new effective, innovative and personalized treatment for patients with a rare form of lung cancer

For the first time a brand-new targeted therapy demonstrates its effectiveness in treating a rare form of lung cancer¹. This innovative drug is a bispecific antibody (amivantamab) which, combined with chemotherapy, increases survival and reduces the risk of the diseases spreading by 60% in patients who until now had no therapeutic options.

This is shown by the results of the PAPILLON phase III study whose results were presented in the presidential session on October 21, 2023, at the ESMO meeting by Prof. Nicolas Girard, respiratory oncologist, head of the Medical Oncology department at Institut Curie and principal investigator on the trial. This work was also published at the same time in the *New England Journal of Medicine*.



"The very positive results of the PAPILLON study represent a real breakthrough for patients suffering from a rare form of lung cancer that affects between 500 and 600 patients each year in France. This is the first time that a trial has demonstrated effectiveness of a treatment for these patients, and we hope that in light of these data, health authorities will be able to approve authorization to access this innovative molecule for patients" explains Prof. Nicolas Girard, respiratory oncologist, head of the Medical Oncology department at Institut Curie and principal investigator on the PAPILLON study.

With 52,777 new cases in France in 2023², lung cancer is the second most common cancer in men and the third in women, with a sharp increase in cases in women. It is the leading cause of death from cancer in France, with a survival rate of just 20%. Although immunotherapy is now part of the therapeutic strategy against lung cancer, it is not always effective and for patients who don't respond, or have limited response, it is vital to identify new targets and develop innovative therapeutic strategies.

PAPILLON: an international phase III study assessing a bispecific antibody in lung cancer for the first time

Within this context, the PAPILLON international study (phase III, randomized) was conducted with 308 patients suffering from a rare form of advanced lung cancer: non-small cell lung cancer (NSCLC) with mutation of epidermal growth factor (EGFR) by Exon 20 insertion. This form of the disease carries a poor prognosis and accounts for 1% of lung cancer cases (or 500 to 600 patients each year in France).

Through this study launched in 2021, a bispecific antibody - amivantamab - was tested for the first time in lung cancer. By recognizing two sites on cancerous cells (EGFR and c-MET, two receptors frequently expressed in the lung), amivantamab acts on the intracellular signaling pathways and facilitates the destruction of tumor cells.

The PAPILLON study assessed the first-line effectiveness of amivantamab in combination with chemotherapy, compared with chemotherapy alone. The results show that with amivantamab, the duration of the effectiveness of treatment is increased almost twofold. Survival without progression was significantly improved (by 11.4 months with amivantamab + chemotherapy

¹Non-small cell lung cancer (NSCLC) with mutation of epidermal growth factor (EGFR) by Exon 20 insertion.

²Source INCa panorama of cancers 2023

compared with 6.7 months with chemotherapy alone). **In addition, with amivantamab, the risk of the disease progressing is reduced by more than 60%.**

Treatment with amivantamab shows effectiveness better than the current standard, with a positive innocuity profile, for first-line treatment of patients with NSCLC with mutation of EGFR by Exon 20 insertion.

New therapeutic strategies in lung cancer addressed at ESMO 2023

In addition to the PAPILLON study coordinated by Prof. Nicolas Girard, Institut Curie is heavily involved in other studies whose results are also being presented at the ESMO meeting, including the **MARIPOSA AND MARIPOSA 2 studies**. These two phase III trials have been conducted in patients with advanced lung cancer with EGFR mutation (which is present in 15% of patients with lung cancer).

These two trials have established a clinical benefit for patients of the combination of amivantamab with targeted therapy, including patient survival improved by more than 6 months in first-line treatment (MARIPOSA).

All of these data will help us redefine treatments for patients with EGFR+ lung cancer with increased effectiveness and improved survival with these combinations.

Furthermore, another study: TROPION-Lung01 positively assessed a new innovative class of molecule for the first time in lung cancer: antibody-drug conjugate (Datopotamab deruxtecan) - which enables us to deliver chemotherapy specifically into the core of tumor cells - with positive results.

“The work presented in lung cancer in this 2023 edition of the ESMO meeting is proof of the dynamism of European research with the announcement of major breakthroughs and original therapeutic solutions. And Institut Curie is fully engaged in this innovative momentum which will improve treatment of our patients”, concludes **Prof. Nicolas Girard**.

Presidential session Saturday October 21, 2023:

Amivantamab plus chemotherapy vs chemotherapy as first-line treatment in EGFR Exon 20 insertion-mutated advanced non-small cell lung cancer (NSCLC): Primary results from PAPILLON, a randomized phase III global study.

Amivantamab plus Chemotherapy in NSCLC with EGFR Exon 20 Insertions, New England Journal of Medicine. Caicun Zhou, M.D. (...) and Nicolas Girard, M.D., Ph.D. 21 octobre 2023 DOI: 10.1056/NEJMoa2306441

Presidential session Monday October 23, 2023:

> Datopotamab deruxtecan (Dato-DXd) vs docetaxel in previously treated advanced/metastatic (adv/met) non-small cell lung cancer (NSCLC): Results of the randomized phase III study TROPION-Lung01

> Amivantamab plus lazertinib vs osimertinib as first-line treatment in patients with EGFR-mutated, advanced non-small cell lung cancer (NSCLC): Primary results from MARIPOSA, a phase III, global, randomized, controlled trial

> Amivantamab plus chemotherapy (with or without lazertinib) vs chemotherapy in EGFR-mutated advanced NSCLC after progression on osimertinib: MARIPOSA-2, a phase III, global, randomized, controlled trial

Presidential sessions



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Institut Curie, France's leading cancer center, combines an internationally-renowned research center with a cutting-edge hospital group, treating all types of cancer, including the rarest. Founded in 1909 by Marie Curie, Institut Curie employs 3,700 researchers, physicians, and health professionals across three sites (Paris, Saint-Cloud, and Orsay), all of whom contribute to its three missions of treatment, teaching, and research. A foundation with public utility status, Institut Curie is authorized to accept donations and bequests, and thanks to the support of its donors, is able to accelerate discoveries and improve patient treatment and quality of life.

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