Lay Summary of Study results

Lay language title:	Understanding the treatments commonly used and quality of life in adults living with metastatic non-small cell lung cancer with a *BRAF*^{V600E} mutation – OCTOPUS study
Full study title:	An ambispective observational study describing diagnosis and treatment patterns in adults with metastatic non-small cell lung cancer with *BRAF*^{V600E} mutation in clinical practice, to assess treatment effectiveness and quality of life – OCTOPUS study
Registry Number:	NCT05546905
Therapeutic area	Oncology
Disease	Non-small cell lung cancer
Study Phase	Real-Word-Evidence study
Final version	26 August 2026

This document is a summary of study results and conclusions written for the public and people who took part in the study. This summary was finalized on 26 August 2026.

Pierre Fabre Pharmaceutical Group extends its sincere gratitude to everyone who participated in the study. Your involvement is greatly appreciated.

THANK YOU

We hope this document helps you better understand your key role in medical research.
If you have any questions or would like more information about the results, please do not hesitate to reach out to your doctor or the staff at your study site.

Please note that:

- These are the results from all the participants combined. The individual results of each participant might be different and are not in this summary.
- This summary reflects the results of one single study and other studies may show different results.

Specific terms used in this lay summary may be found in the Glossary of Pierre Fabre

You can click below to find the following information:

1 What was the reason for the study?

Non-small cell lung cancer (NSCLC) is the most common type of lung cancer, making up about 80% to 85% of all cases. A small number of people with this cancer, around 1-2%, have a change in their DNA called a *BRAF*^{V600E} mutation. When the *BRAF gene* is mutated, it produces an over-active BRAF protein that tells the cells to continuously grow and divide, leading to cancer.

There is still limited information about how people with this rare form of NSCLC are diagnosed and treated in everyday clinical practice. Learning from the experience of patients who already have this condition can help to improve care for future patients.

This study aimed to better understand how people living with metastatic* NSCLC with a *BRAF*^{V600E} mutation were treated in routine medical practice. It described the treatments commonly used, how these treatments work, and when information was available, how they may affected people's quality of life.

* Metastatic means the cancer has spread from the lungs to other parts of the body. It is also called Stage IV lung cancer.

The main objective of this study was to describe how doctors usually treat adults living with metastatic NSCLC with a *BRAF*^{V600E} mutation. In particular, the study looked at the treatments received after diagnosis of the metastatic disease and the treatments given in case of progression of the disease or in case of low tolerability.

The study also aimed to:

- look at all the treatments received in case of progression** of the cancer or in case of low tolerability
- describe the characteristics of people (such as age, sex, and medical details)
- assess how long people lived after the start of the treatments
- assess whether their quality of life changed during treatment, using questionnaires in some patients
- describe any side effects during treatment. Side effects are unwanted medical events that may or may not be caused by treatment used
- explain how and when doctors tested for the *BRAF* mutation.

** in case of the cancer has grown despite treatment.

2 How was the study conducted?

This was an observational study. This means doctors observed what happened as part of normal care, without changing or influencing treatment choices.

This study took place in France, Germany, Italy, Spain and the United Kingdom.

Adults with metastatic NSCLC, with a *BRAF*^{V600E} mutation, who started their first treatments from December 2017, were invited to participate. People followed their usual care. Some of them filled out quality of life questionnaires during the study.

No extra tests or visits were required for the study.

3 When and where was the study conducted?

The study took place in France, Germany, Italy, Spain and the United Kingdom.

Participants were included in the study between June 2022 and January 2025.

Overall, 206 people participated in the study.

Country	Number of participants
France	69
Germany	33
Italy*	54
Spain	37
United Kingdom	13

* Due to local regulation in Italy, people who had died before the study started, could not be included in the analysis. As a result, only people who were still alive when the study began were included. This may have made the treatments appear more effective than they actually were, because the analysis included only people who had survived long enough be part of the study.
To better understand the results, additional analysis were carried out without including participants from Italy.

4 Who took part in the study?

Which participants took part in the trial?

- Participants aged 18 years or older at the start of the first treatment for metastatic NSCLC With a *BRAF*^{V600E} mutation confirmed by adequate testing
- Starting their first treatment for metastatic NSCLC, with a *BRAF*^{V600E} mutation, from December 2017
- Agreed to participate and allow their data to be used according to local regulations
- Not participating in another study for metastatic NSCLC.

How many participants took part in the study?

A total of 206 people participated in the study, and 184 were included in the main analysis. An additional analysis was conducted excluding participants from Italy. In this analysis, 134 of the 152 non-Italian participants were included.

How old were the participants?

At initial diagnosis, participants' average age was 68 years old.

5 What were the study treatments?

The researchers did not assign or require any specific or experimental treatment.

Doctors chose the most appropriate treatment as part of usual medical practice.

The study collected information from medical records in hospitals about the chosen treatment and about what happened after the treatment initiation.

6 What were the adverse events?

As discussed in the section 3, the original analysis may have been affected by bias related to data collected in one of the participating countries.
To better understand the results, additional analyses were carried out without including data from Italy.

What adverse events did participants have?

Participants can have unwanted health issues while receiving treatment during the study. These health issues may or may not be caused by the treatments. They are called adverse events.

Adverse events are described below in the overall people as well as in people excluding those from Italy.

Participants	**Total (out of 184 participants)**	**Total (out of 134 participants) Without participants included in Italy**
Participants who had adverse events	99 (54%)	67 (50%)
Participants who had serious* adverse events	58 (32%)	47 (35%)
Participants who had at least one adverse event of special interest	91 (50%)	61 (46%)

= participants

* An adverse event is serious when:
- It results in death,
- It puts life in danger,
- It results in hospitalisation or prolongs it,
- It causes lasting problems,
- It results in health problems in babies or foetus, or,
- It is considered medically important.

99/184 (54%) participants had at least one adverse event, 58 (32%) had at least one serious* adverse event. Of the patients with at least one serious adverse event, 29% died.

91 (50%) had at least one adverse event of special interest, which are events that lead to switching to a different treatment, changing the dose of the treatment, stopping the treatment permanently or temporarily, hospitalisation or prolongation of hospitalisation.

The table below show the most frequent adverse events reported in at least 6 patients (≥ 3%) of the total participants.

Adverse event	**Total (out of 184 participants)**
Fever	17 (9%)
Fatigue	16 (9%)
Nausea	16 (9%)
Diarrhoea	13 (7%)
Shortness of breath	11 (6%)
Low level of white blood cells	11 (6%)
Itchy skin	10 (5%)
Decreased appetite	9 (5%)
Oedema peripheral	9 (5%)
General physical health deterioration	8 (4%)
Joint pain	7 (4%)
Vomiting	7 (4%)
Anaemia	6 (3%)
Constipation	6 (3%)
Rash	6 (3%)
Urinary tract infection	6 (3%)

= participants

7 What were the study results?

How and when doctors test for the *BRAF* mutation?

To check for specific genetic changes, tests were done using two methods:

- Next Generation Sequencing: used in 61% of cases, this method reads large amounts of DNA quickly to find genetic changes.
- Polymerase Chain Reaction: used in 30% of cases, this method copies small amounts of DNA to make them easier to study.

The average time from NSCLC diagnosis to $BRAF^{V600E}$ testing was around 1.5 months.

Participants characteristics at initial diagnosis of the metastatic NSCLC

99/184 participants (54%) were male.

124/173 participants (72%) were previous or current smokers.

Comorbidities were reported for 124 participants. Comorbidity refers to the simultaneous presence of two or more medical conditions in a participant. The most frequent comorbidities were high arterial blood pressure (39%), diabetes (16%) and heart disease (13%).

Most participants (86%) had metastatic disease (stage IV) at initial diagnosis.

At initial diagnosis, 58% of participants had visceral metastases, 67% had non-visceral metastases, and 20% had brain metastases.

Most of the participants had an ECOG* of 0 (fully active) or 1 (restricted in physical activity) at first line treatments (80%) and at second line treatments (64%).

* ECOG (Eastern Cooperative Oncology Group) is a performance status.

How was the analysis done?

Due to local regulation in Italy, people who had died before the study started, could not be included in the analysis. As a result, only people who were still alive when the study began were included. This may have made the treatments appear more effective than they actually were, because the analysis included only people who had survived long enough to enter in the study.
To better understand the results, an additional analysis was carried out, with 134 participants, excluding the ones from Italy.

How doctors treat patients with NSCLC after the first treatments in additional analysis?

When excluding the participants from Italy, all (100%) the participants received first line treatments and 73/134 (54%) received second line treatments.

For both first- and second-lines treatments, the most common therapy was dabrafenib + trametinib combination therapy* with 37% of participants receiving this therapy in first line and 52% in second line.

* Dabrafenib and trametinib are marketed drugs, and both of which are targeted therapies. Targeted therapy is a drug treatment that inhibits specific targets such as BRAF proteins to stop cancer cells from growing and spreading (oral treatment).

The table below shows the treatments participants received.

Treatments	First line treatment Total (out of 134 participants)	Second line treatment Total (out of 73 participants)
Dabrafenib + trametinib combination therapy	50 (37%)	38 (52%)
Chemotherapy alone	27 (20%)	11 (15%)
Pembrolizumab + chemotherapy	24 (18%)	8 (11%)
Pembrolizumab alone	13 (10%)	2 (3%)
Other treatments	20 (15%)	14 (19%)

= participants

How well the treatments work in NSCLC in additional analysis?

Overall survival refers to how long a person lives after starting their first line treatments for NSCLC, regardless of the cause of death.

When excluding the participants from Italy, the median* overall survival time was 20 months.

When excluding the participants from Italy, after dabrafenib + trametinib as first line treatment, the median overall survival time was 24 months.

When excluding the participants from Italy, after dabrafenib + trametinib as second line treatment, the median overall survival time was 28 months.

* The median is the middle value when results are placed in order. Half of the results are at or below the median, and half are at or above it.

8 Further information

Are there plans for further studies?

No further studies are planned.

Where can you learn more about this study?

You can find more information about this study on this website:www.ClinicalTrials.gov