Trial title	A trial to investigate the safety of encorafenib in Chinese mainland participants with *BRAF*^{V600E} advanced solid tumors OCEAN[1] Multicenter Open-label, phase1 study investigating the safety and tolerability of enCoraf/Enb monotherapy in BRAF V600E mutated chinese patients with AdvaNced metastatic solid tumors
Disease	Advanced solid tumors: skin cancer (melanoma) or lung cancer (non-small cell lung cancer)
Treatment	Encorafenib (BRAFTOVI®)
Participants	Mainland adult Chinese participants with advanced solid tumors carrying a specific mutation in BRAF gene (BRAF V600E)
Trial dates	From 15 September 2021 (First participant first visit) to 06 May 2022 (End of trial)
Trial Locations	China

We do research to improve patient care. This trial helped us to answer important questions about treatment of advanced solid tumors.

This document is a summary of trial results and conclusions written for the general public and people who took part in the trial.

This summary was finalized in August 2024. The information in this summary does not include additional information available after this date.

To people who took part in the trial, Pierre Fabre Pharmaceutical group would like to say

THANK YOU

We hope this document helps you understand and feel proud of your key role in medical research. If you have questions about the results, please speak with the doctor or staff at your study site.

To learn about the trial and its conduct:

- What was the purpose of the trial?
- What were the objectives and how were they evaluated?
- How was the trial conducted?

To get a summary of trial results:

- What were the results of the trial?

THE TRIAL	
What was the purpose of the trial?	Encorafenib is a marketed drug (Braftovi®) approved to treat patients with certain skin cancer (melanoma) and certain colorectal cancer in several countries (European Union, USA, Australia, Japan, Switzerland…). At the time of the trial conduct, limited clinical information of encorafenib used as a single drug (monotherapy) or in combination with other drugs were available specifically in Chinese patients whose tumor has a specific mutation in the BRAF gene (*BRAF*^{V600E} mutation). The purpose of this trial was to investigate the safety of encorafenib in Chinese participants with *BRAF*^{V600E} solid tumors.
What were the objectives and how were they evaluated?	The main objective of the trial was: • To investigate the safety (side effects) of encorafenib 300 mg during the first 28 days of treatment (first cycle). This was assessed by measuring the number of Chinese participants with major unacceptable side effects during the first 28 days of treatment (first cycle). In addition, the trial allowed: • To describe the safety of encorafenib 300 mg during the total treatment period and how the treatment entered the body, circulated in the bloodstream and was finally eliminated, evaluating the number, frequency and type of side effects that occurred in participants until 30 days after the last dose of treatment.
How was the trial conducted?	This trial was an open-label "Phase 1" trial in Chinese mainland population. This trial took place at 1 center in China. Only Chinese mainland participants aged 18 years or older with metastatic skin cancer (melanoma) or lung cancer (non-small cell lung cancer) took part in the trial. Their cancer needed to have a specific genetic mutation called *BRAF*^{V600E} mutation. The participants had been previously treated for their metastatic cancer but the previous treatment didn't work.

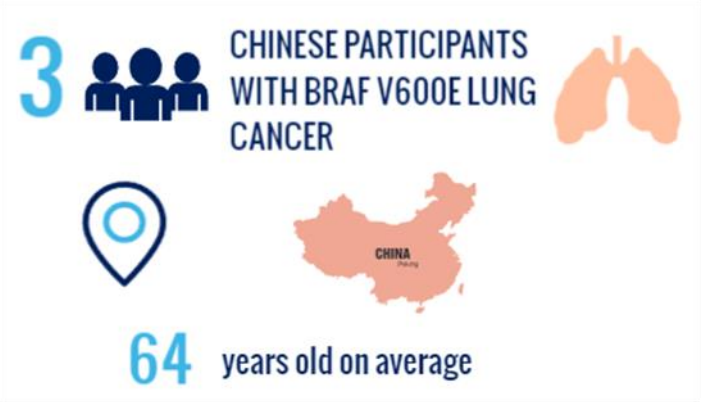
	All participants received the same treatment called encorafenib. All participants received 4 capsules of encorafenib once a day in the morning for 28-day periods (cycles). The total daily dose of encorafenib was 300 mg. After 28 days (one cycle) of treatment for the first 3 participants, an analysis was performed to investigate the safety of encorafenib and to determine whether participants had any major unacceptable side effect. After this analysis, if encorafenib was considered sufficiently safe, all participants could continue to receive encorafenib as long as they benefited from the treatment.

THE RESULTS

This is a summary of the main results and conclusions of the trial. 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 outcome of one single trial and that other trials may show other results or other outcomes.

Participants



Three (3) participants were enrolled in the trial and received the treatment encorafenib: they were all Chinese men aged 64 years with a metastatic *BRAF*^{V600E} non-small cell lung cancer.

All participants received encorafenib for 17 weeks to 32 weeks and then stopped taking the treatment: two participants because their cancer got worse and one because he no longer wanted to participate in the trial.

Side effects

Like all medicines, encorafenib can cause side effects although not everybody gets them.

Major side effects

To learn more about the safety of encorafenib, the trial doctors looked at the number of certain side effects during the first 28 days of treatment.

After 28 days of treatment, no participant had a major unacceptable side effect. All participants could, therefore, continue to receive encorafenib, no additional participants were enrolled in the trial and the trial went on.

Other side effects

All participants had a side effect considered related to the treatment encorafenib. The most common side effects – those reported by at least 2 participants - were nausea, vomiting and hyperkeratosis and occurred in two participants. The other side effects were reported by less than two participants and are not presented in this summary.

Conclusion

The results of this trial showed that the side effects observed in Chinese participants are similar to those already observed in previous trials with encorafenib in non-Chinese participants.

These results encourage further study of encorafenib in the Chinese population. A trial exploring the combination of encorafenib and binimetinib in *BRAF*^{V600E} lung cancer (non-small cell lung cancer) is ongoing in China.

For more information on the results, see the **Additional information** section on the next page.

Clinical Trial identification

Protocol Number	W00090GE102
Protocol	3.0 dated 30 September 2021
Full trial title	A multicenter, open-label, phase 1 study investigating the safety and tolerability of encorafenib monotherapy in *BRAF*^{V600E}–mutated Chinese patients with advanced metastatic solid tumors
Registry ID	ClinicalTrials.gov: NCT05003622 Ocean I - ClinicalTrials.gov

Who sponsors this trial?

Name and contact details of the sponsor	Pierre Fabre Médicament Les Cauquillous 81500 Lavaur-France

Additional information

This summary of the clinical trial results is available online at Pierre Fabre's Clinical Trials Website.

For more information:

- on this clinical trial, please visit: Pierre Fabre's Clinical Trials Website
- on the summary of the trial's protocol, please visit Ocean I Clinical Trial Protocol Lay Synopsis
- on the results of the trial, please visit Ocean I - ClinicalTrials.gov

Glossary	
Advanced tumor	Tumor that is unlikely to be cured or controlled with treatment.
BRAF^{V600E}	All humans have a gene called BRAF. The BRAF gene makes a protein that helps control cell growth. In some patients, this gene mutates (V600E mutation) and makes the tumor grow faster.
Hyperkeratosis	Increased thickness of the stratum corneum, the outer layer of the skin.
Metastatic	Metastatic means that cancer has spread to a different part of the body than where it started.
Non-small cell lung cancer	A group of lung cancers named for the kinds of cells found in the cancer and how the cells look under a microscope.
Open-label	A type of trial in which both the doctors and the participants are aware of the treatment being given.
Phase I trials	Phase I trials test an experimental drug, vaccine or device in a small group of people to evaluate safety, identify side effects and determine safe dosages.
Serious side effect	A side effect is serious when: • The patient needs to be hospitalized. • The patient's life is in danger. • It causes permanent damage or death.
Side effects	Side effects are unwanted medical events (such as headache) that happen during the trial and that are related or possibly related to trial treatment.
Solid tumor	A type of tumor that is an abnormal mass of tissue that usually does not contain liquid areas.