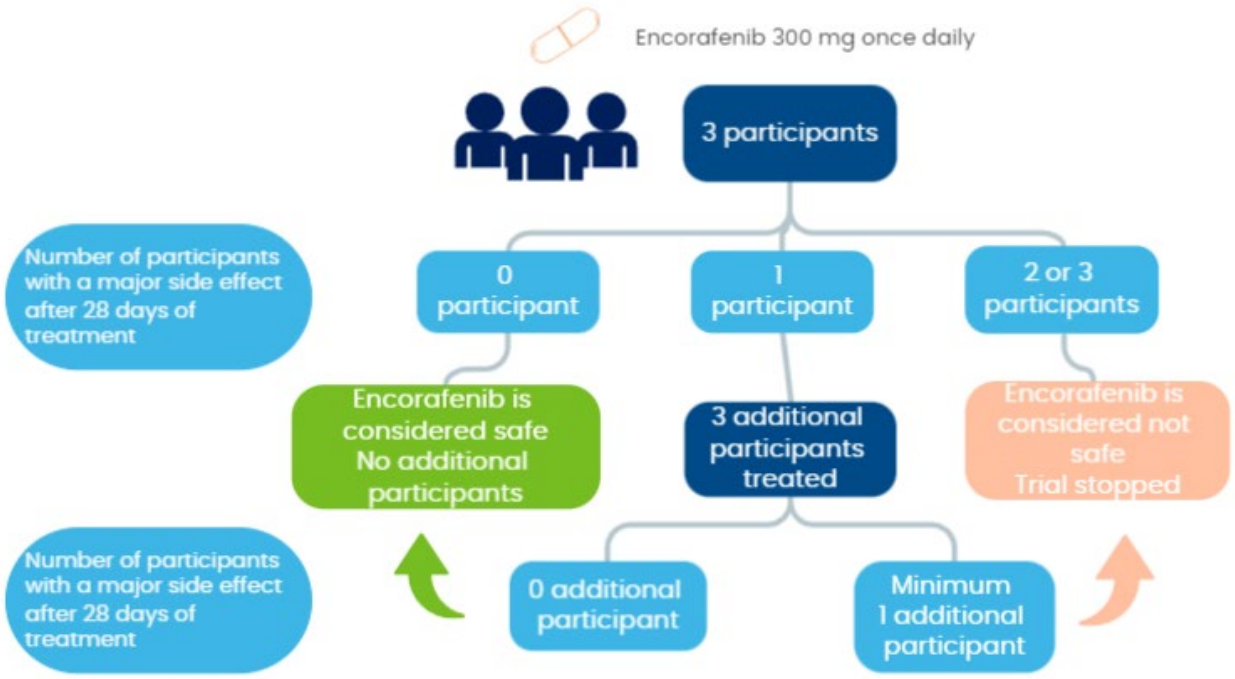
Trial title	A trial to investigate the safety of encorafenib in Chinese mainland participants with *BRAF*^{V600E} advanced solid tumors OCEAN Multicenter Open-label, phase I study investigating the safety and tolerability of enCorafEnib monotherapy in BRAF V600E mutated chinese patients with AdvaNced 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 will help us to answer important questions about treatment of advanced solid tumors	

This document is a brief summary of a clinical trial protocol. It is written in plain language for the general public, providing answers to the following questions:

- What is the purpose of the trial?
- What are the objectives of the trial and how are they evaluated?
- How is the trial conducted?
- Who can take part in the trial?
- What are the trial treatments and how are they administered?
- What are the possible benefits and risks in taking part in the trial?

What is 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…). Limited clinical information of encorafenib used as a single drug (monotherapy) or in combination with other drugs are available specifically in Chinese patients whose tumor has a specific mutation in the *BRAF* gene (*BRAF*^{V600E} mutation). The purpose of this trial is to investigate the safety of encorafenib in Chinese participants with *BRAF* V600E solid tumors.
What are the objectives of the trial and how are they evaluated?	The main objective of the trial is: • To investigate the safety (side effects) of encorafenib 300 mg during the first 28 days of treatment (first cycle). This is 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 allows : • To describe the safety of encorafenib 300 mg during the total treatment period and how the treatment enters the body, circulates in the bloodstream and is 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 is the trial conducted?	This trial is an open-label "Phase 1" trial in Chinese mainland population. A maximum of 6 adult Chinese participants (18 years and older) are in this trial. Three participants first take part in the trial and are treated with encorafenib. After 28 days (one cycle) of treatment for the first three participants, an analysis is performed to investigate the safety of encorafenib: -If no participant has a major unacceptable side effect, no further participants take part in the trial. -If one participant has a major unacceptable side effect, three (3) additional participants are treated with encorafenib to investigate the safety of the treatment. -If two (2) or three (3) participants have a major unacceptable side effect, encorafenib is not safe and the trial is stopped. Encorafenib is considered sufficiently safe if there is no more than 1 participant with observed major unacceptable side effects . If sufficiently safe, all participants are treated with encorafenib as long as they benefit from the treatment. That means until the tumor grows or the cancer spreads (disease progression). The schema summarizes the information presented above:



Who can take part in the trial?	To be part of the trial, participant must fulfill several conditions including the following: • Chinese mainland participants, aged 18 years or older with skin cancer (melanoma) or lung cancer (non-small cell lung cancer) and whose cancer has spread to other places of the body (metastatic). • The tumor has a specific genetic mutation called *BRAF*^{V600E} mutation • Participants have been treated for their metastatic cancer but the previous treatment didn't work • Participants have never been treated for their metastatic disease with a treatment targeting the *BRAF* mutation • Participants are not pregnant, lactating or breast-feeding women
What are the trial treatments and how are they administered ?	Participants receive 4 capsules of encorafenib once a day in the morning. The total daily dose of encorafenib is 300 mg.

What are the possible benefits and risks in taking part in the trial?	Previous clinical studies in the non-Chinese population have shown that encorafenib is effective to treat patients with certain melanoma. Previous clinical studies also indicate that other treatment that targets the *BRAF* mutation is effective to treat certain metastatic lung cancer. Therefore, it is expected (but not guaranteed) that encorafenib may have a beneficial effect on Chinese participants and improve their disease. If so, other Chinese patients with the same disease may have the opportunity to benefit from this treatment in the future. The trial may have potential discomforts and constraints for the participants requiring regular visits at hospital, blood sampling and imaging examinations. Encorafenib can cause side effects for which participants are informed by trial doctors at study entry and are closely monitors for all the duration of the trial.

Cinical 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 .

Glossary	
Advanced tumor	Tumor that is unlikely to be cured or controlled with treatment
BRAFV600E	All humans have a gene called *BRAF*. The *BRAF* gene makes a protein that helps control cell growth. In some patients with colorectal cancer, this gene mutates (V600E mutation) and makes the tumor grow faster.
Disease Progression	Cancer that continues to grow or spread.
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.
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