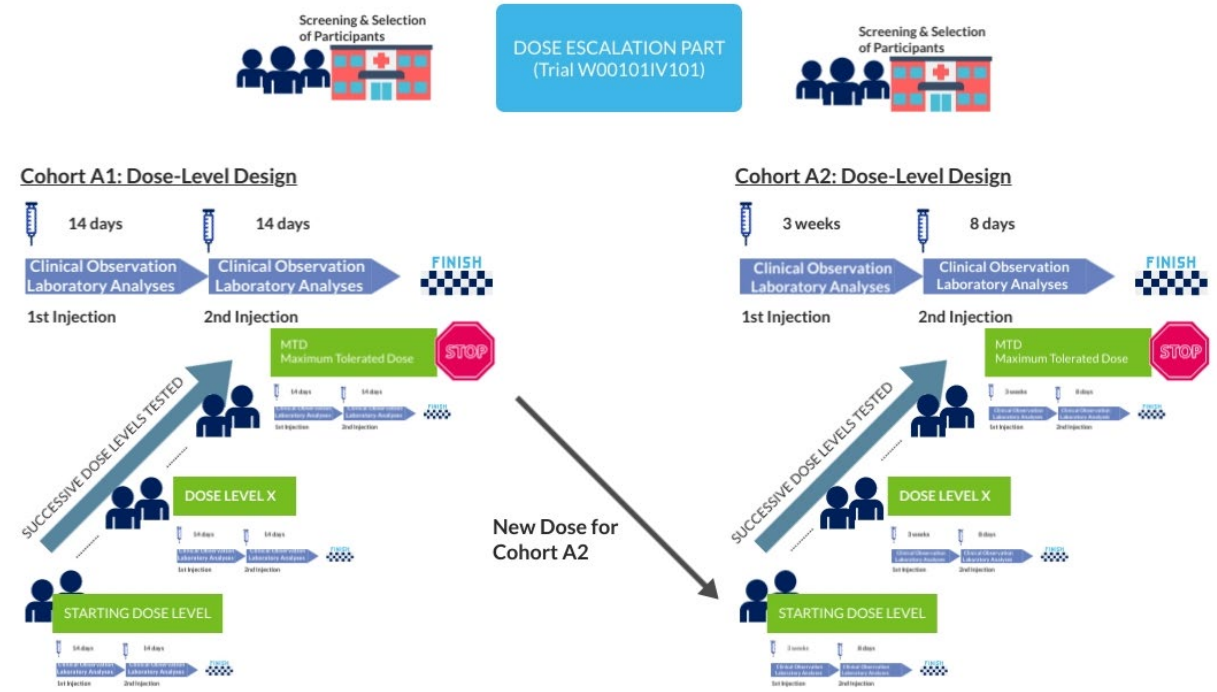
Trial title	A Trial of a new drug to Treat Patients with Advanced or Metastatic Solid Cancer Tumors (Ulysse)
Disease 	Advanced or metastatic solid cancer tumors
Treatment 	W0101 (lonigutamab ugodotin) administered by intravenous route (infusion)
Participants 	Male or female adults with confirmed advanced or metastatic solid cancer tumors
Trial dates 	24 November 2017 (consent of the first participant) to 4 October 2021 (last participant last visit)
Trial Locations 	France, Spain
We do research to improve patient care. This trial will help us to answer important questions about treatment of cancer.	

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?	The objective of this trial is to evaluate the tolerance and the activity of an experimental treatment (called W0101) against solid cancer tumors at an advanced stage of disease or which have spread to distant organs beyond the tumor's initial site (metastases). This is the first time this treatment is tested in humans. There are two parts in this trial: - Part /Phase I (dose escalation): to determine the best-tolerated dose as well as the most adequate administration schedule - Part/Phase II: to assess the treatment activity at the selected dose and schedule, which has been determined during phase I
What are the objectives of the trial and how are they evaluated?	The main objective of the trial is to determine the Maximum Tolerated Dose (MTD) that is to say the highest dose of W0101 that

	can be administered without exposing participant to an unacceptable health risk. The MTD is determined by testing increasing doses on different groups of participants (dose level) until the highest dose with acceptable side effects is found. In addition, the trial will allow: - To describe the safety of W0101 by evaluating the number and type of side effects - To describe how the treatment is taken into, move around and eliminated from the body - To provide preliminary data on the activity of W0101 against cancer tumors
How is the trial conducted?	In Phase I, 2 dosing schedules are planned to be tested successively in 2 groups of participants (called cohorts): - 20 participants will be included in the first cohort (A1) - 14 participants will be included in the second cohort (A2) Second part of the trial (Phase II) will be designed when Phase I results will be available. 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: • Adult participants with confirmed advanced or metastatic solid cancer tumors. According to cohort A1 and A2, participants with some specific types of cancer are preferentially selected.
What are the trial treatments and how are they administered ?	W0101 (lonigutamab ugodotin), is an Antibody Drug Conjugate (ADC). An ADC is composed of two main parts: an antibody and a cancer- fighting agent (cytotoxic agent) attached to it. An antibody is a molecule pertaining to the immune system that can specifically recognize a particular receptor expressed on the surface of tumour cell (here IGF-1R) and bind to it. Once bound, the cancer fighting agent has the capacity to kill the cancer cell effectively while sparing the body's healthy cells and thus limit the adverse effects of chemotherapy. This treatment will be administered by intravenous route (infusion) in 2 different administration schedules: - Cohort A1: administered every 2 weeks

	- Cohort A2: administered every 3 weeks Participants may receive W0101 as long as they benefit from it that means as long as the tumors do not worsen and the W0101 is well tolerated.
What are the possible benefits and risks in taking part in the trial?	W0101 is an experimental treatment against cancer. It has been previously tested in laboratory and animal studies. This is the first time it is tested on human (First in Human trial). In animals, W0101 as demonstrated encouraging data in term of cancer tumors growth inhibition with good tolerability. The potential benefits for participants are the reduction or the stabilization of the tumors' size that would delay cancer progression. The trial may have potential discomforts and constraints for the participants requiring notably regular visits to hospital, and serial blood samplings. W0101 can cause side effects for which participants are closely monitored for all the duration of the trial.

Cinical Trial identification

Protocol Number	W00101IV101
Protocol Version	11.0 dated 12 July 2021
Full trial title	Phase I/II open label dose escalation and dose expansion study of intravenous infusion of W0101, an antibody-drug conjugate, in patients with advanced or metastatic solid tumors. International, multicenter, open label study.
Registry ID	ClinicalTrials.gov: NCT03316638 ULYSSE Trial - ClinicalTrials.gov EudraCT Number: 2017-001842-82 ULYSSE Trial - Clinicaltrialsregister.eu

Who sponsors this trial?

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

Additional Information

Glossary	
Metastatic	Metastasic means that cancer has spread to a different part of the body than where it started
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.
Antibody	An antibody is a molecule pertaining to the immune system that can specifically recognize a particular receptor expressed on the surface of tumour cell and bind to it
Advanced tumor	Tumor that is unlikely to be cured or controlled with treatment
Solid tumor	A type of tumor that is an abnormal mass of tissue that usually does not contain liquid areas