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 5 July 2022 (study termination date)
Trial Locations 	France, Spain, Belgium
We do research to improve patient care. This trial helped us to answer important questions about treatment of cancer.	

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?	The objective of this trial was 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 was the first time this treatment was tested in humans. There were 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 were the objectives and how were they evaluated?	The main objective of the trial was 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 was determined by testing increasing doses on different groups of participants (dose level) until the highest dose with acceptable side effects was found. In addition, the trial allowed: - 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 was the trial conducted?	In Phase I, 2 dosing schedules were planned to be tested successively in 2 groups of participants (called cohorts): - 20 participants were included in the first cohort (A1) - 14 participants were included in the second cohort (A2) Second part of the trial (Phase II) was designed when Phase I results were available.

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

The study enrolled participants who were diagnosed with advanced tumors, a condition where cancer has progressed and is challenging to treat. The participants were divided into two cohorts, Cohort A1 and Cohort A2, based on the treatment schedule they received.

Cohort A1: This group consisted of 26 individuals who were screened, and 21 of them were enrolled in the study. The majority of these participants were under the age of 65, predominantly White, and non-Hispanic or Latino. There was a higher number of females compared to males in this cohort.

Cohort A2: In this cohort, 23 individuals were screened, and 14 were enrolled. Similar to Cohort A1, most participants were under 65 years of age, White, and non-Hispanic or Latino. The gender distribution was more balanced in this group, with a similar number of females and males.

For both cohorts, the participants had an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1, indicating that they were fully active or restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature.

Most subjects in both cohorts presented with Stage IV disease, indicating that cancer had spread to other parts of the body. Breast cancer was the most frequently reported primary tumor type in both cohorts. Additionally, a subset of participants tested positive for overexpression of IGF-1R, a protein that can be involved in tumor growth.

Efficacy

Unfortunately, none of the participants in Cohort A1 and A2 achieved a complete or partial response to the treatment. Some participants experienced stable disease, meaning their tumors did not grow, but the majority had progressive disease, indicating that their tumors continued to grow.

Safety

Most participants experienced at least one treatment-related side effect. The most common side effects included blood and lymphatic system disorders such as thrombocytopenia (low platelet count) and increased levels of liver enzymes. Some side effects were serious, requiring careful monitoring and management.

Conclusion

The new treatment did not result in tumor shrinkage for the participants in this study. While the treatment was associated with some side effects, these were consistent with expectations for a trial of this nature. Further research may be needed to understand the potential benefits and risks of the treatment better.

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

Clinical Trial identification

Protocol Number	W00101IV101
Protocol	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

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 W00101IV101 Clinical Trial Protocol Lay Synopsis

Glossary	
Metastatic	Metastatic 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