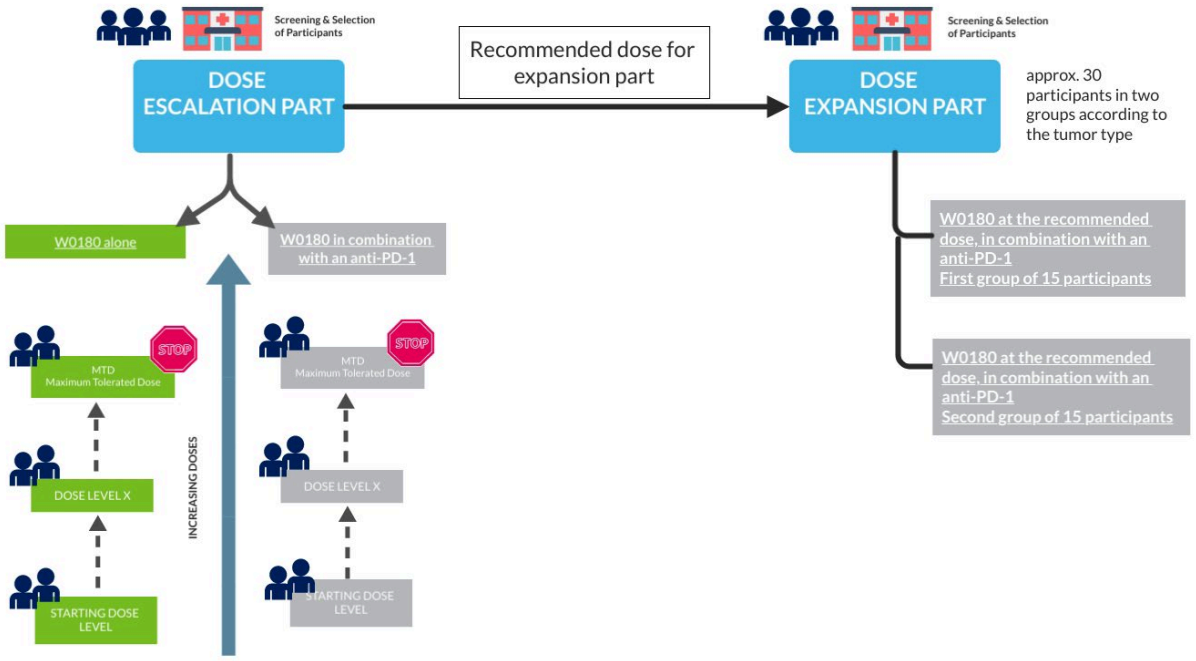
Trial title	A trial to test an antibody as an experimental treatment for Patients with Advanced or Metastatic Solid Tumors (VISTA)
Disease 	Locally advanced or metastatic solid cancer tumors
Treatment 	Monoclonal antibody W0180 administered by intravenous route
Participants 	Male of female adults with locally advanced or metastatic solid cancer tumors
Trial dates 	From 8 September 2020 (first participant entering the trial) to May 2024 (anticipated end of trial)
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 W0180), alone and in combination with an existing immunotherapy treatment (pembrolizumab) in patients with different advanced cancers (large local or distant spread of their tumor) excluding blood cancers. This is the first time that this treatment (W0180) is tested in humans. The trial includes 2 parts: - The dose escalation part to determine the best-tolerated dose - The dose expansion part to confirm the selected dose and provide additional information on tolerance and treatment activity
What are the objectives of the trial and how are they evaluated?	The main objective of the trial is to determine a best-tolerated dose that would be recommended for clinical development of W0180. This relies firstly on the identification of the Maximum Tolerated Dose (MTD) that is to say the highest dose of W0180 (alone and in combination with pembrolizumab) 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. Based on MTD evaluation and all others

	information available at the end of the escalation part, a dose of W0180 will be recommended for the expansion part (RDE). In addition, the trial will allow: - To describe the safety of W0180 (alone and in combination with pembrolizumab) by evaluating the number and type of side effects - To describe how the treatment enters the body, circulates in the bloodstream and is finally eliminated. - To provide preliminary data on activity of W0180 (alone and in combination with pembrolizumab) against cancer tumors
How is the trial conducted?	The Dose Escalation Part will include up to 39 participants either administered with increasing doses of W0180 alone or in combination with pembrolizumab. The Expansion Part will include up to 30 participants with specific tumor types, at the dose determined following the dose escalation part. The schema summarizes the study design:



Who can take part in the trial?	To be part of the trial, participants must fulfil several conditions, including the following: • Adult participants with locally advanced or metastatic solid tumors and following specificities according to trial part: • For the dose escalation in combination with pembrolizumab and the dose expansion only: Participants whose diseases are not responsive to a certain class of immunotherapies • For the expansion part only: Participants with tumor types expressing VISTA receptor • Participants unresponsive to standard treatment or for whom no standard treatment is available or appropriate
What are the trial treatments and how are they administered ?	W0180 is a therapeutic antibody. An antibody is a molecule pertaining to the immune system that can specifically recognize a particular receptor on the surface of cells and bind to it. Here the targeted receptor is called VISTA. By binding to it, W0180 should stimulate your own immune system to increase your own capacity to fight against cancer cells. This potential anti-tumor

	capacity could be improved when combined with other known therapeutic antibodies especially other immune treatment like pembrolizumab. Pembrolizumab is an existing immune treatment against cancer. Pembrolizumab is also a therapeutic antibody. Participants receiving W0180 alone will have one administration per week. Participants receiving W0180 in combination with pembrolizumab will have one administration of W0180 per week and one administration of pembrolizumab every 3 weeks. Both treatments will be started on the same day. All treatments are administered by intravenous route. Participants may receive the treatment as long as they benefit from it meaning that the tumor does not worsen and the treatment is well tolerated, with a limitation of 35 administrations maximum for pembrolizumab
What are the possible benefits and risks in taking part in the trial?	W0180 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, W0180 in combination with pembrolizumab has 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.

	W0180 can cause side effects for which participants are closely monitored for all the duration of the trial. Pembrolizumab is a therapeutic antibody approved as treatment for cancer; toxicities related to Pembrolizumab are well known and manageable by doctors.

Cinical Trial identification	
Protocol Number	W00180IV101
Protocol Version	6.0 dated 06 July 2022
Full trial title	Phase I dose escalation and dose expansion, international, multicenter study of W0180 as single agent and in combination with pembrolizumab (anti-PD-1) in adult participants with locally advanced or metastatic solid tumors.
Registry ID	ClinicalTrials.gov: NCT04564417 VISTA Trial - ClinicalTrials.gov

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
Immunotherapy	Treatment that improves ability of the immune system to fight disease
Locally advanced	A locally advanced cancer is a cancer that has grown to a specific size, may consist of multiple tumors, and/or may have spread to adjacent lymph nodes, organs or tissue but has not yet spread to others part of the body