LTS17789 ATLANTIS is a clinical study for adults and adolescents (>12y.o) diagnosed with moderate to severe Atopic Dermatitis, currently experiencing only minimal to no improvement with their current local (topical) therapy

Atopic Dermatitis (AD) also known as atopic eczema, is a severe skin disorder that makes you itch and leaves red blotches, usually on your face, arms and legs.

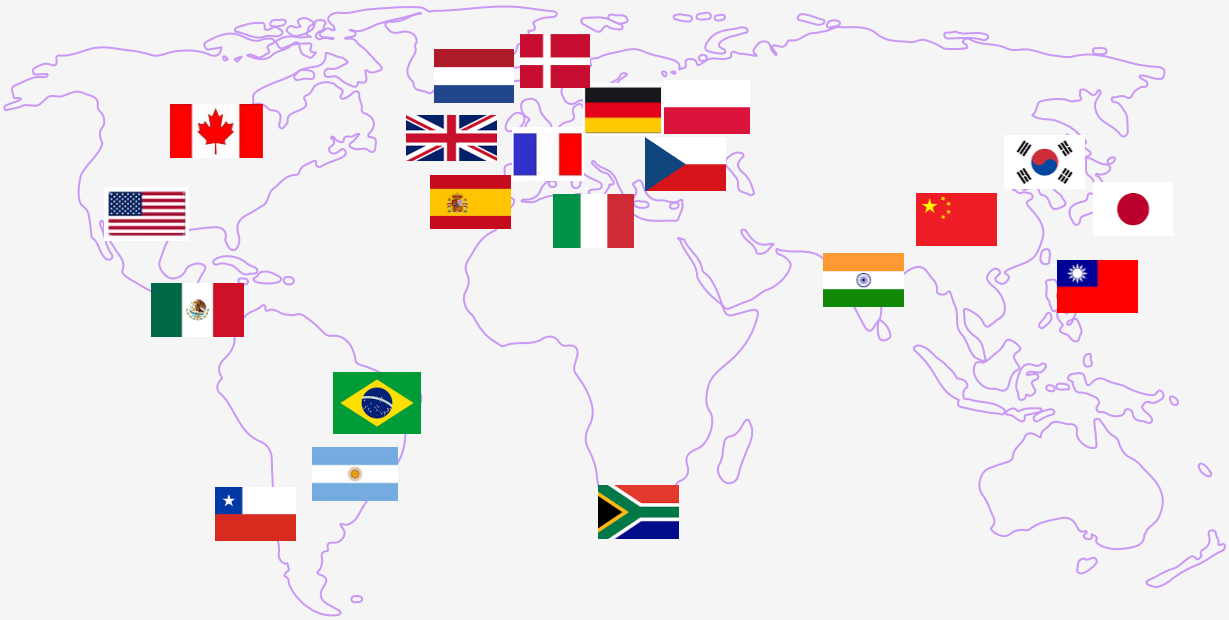
The goal of the ATLANTIS study is to assess the safety of a study medication called amlitelimab in treating AD when given under the skin (subcutaneously). The safety of the study participants will be measured through any side effects, related to the treatment they experience, and through the assessment of blood or urine samples. The effect of amlitelimab on the treatment of AD will be measured for all study participants.

Why this study?

The Atlantis Study is a clinical research study being conducted by Dermatologists to determine if this new study medication is safe and effective in the treatment of moderate to severe Atopic Dermatitis. Participants in this study will receive the treatment for at least 3 years.

The study medication (not yet approved by the health authority) is an injectable medication that could be used in association with local skin treatments generally used to treat AD.

This medication may represent a new treatment for AD patients who experience no improvement with their current therapy.



- **21 countries: Taiwan (Province of China), South Korea, Mainland China, India, South Africa, Japan, United Kingdom, Netherlands, Denmark, Germany, Czech Republic, Poland, Italy, France, Spain, United States, Canada, Brazil, Mexico, Chile, Argentina**
- **Up to 901 Participants, including approximately 330 adolescents**

All study exams and visits are fully covered by Sanofi.

Study periods

Screening period	Baseline visit	Treatment period	Post treatment follow up visit
			
Up to 28 days with a minimum of 14 days	You receive the 1st dose of amlitelimab	First year: visits to site every 4 weeks Second and third years: visit at site every 12 weeks and injection every 4 weeks, you may self-inject at home between visits or go to sites	No injection One visit 20 weeks after the last dose of amlitelimab

Study treatments

In the ATLANTIS study, all participants are receiving amlitelimab subcutaneously with a first loading dose followed by a dose every 4 weeks for 160 weeks (approx. 3 year).

During the study you can continue to use your local skin treatments. If your symptoms worsen despite the study treatment, you may receive oral corticosteroids as rescue medication.

The last dose of treatment will be injected at week 156. For the first 52 weeks, amlitelimab will need to be given to you at the study site. However, after that, with the agreement of your study doctor, and after an appropriate training, you may be given the study drug at home.

You could self-inject yourself or be injected by a caregiver or a qualified/trained family member. If you prefer you could go to the study site to receive your injections. Above diagram explaining study periods and durations.

Study visits, Tests and procedures in this study

- Most visits will last a half day or less depending on the procedures required by the study protocol.
- The first study treatment visit may last longer, to observe whether any allergic reaction may occur.
- You will make regular visits to your site for medical exams, questionnaires, urine and blood samples.
- You will be fully and regularly monitored during the whole study from screening to follow-up period with regular blood draws, visits to your doctor, and exams, plus you will have a diary to report your experience of Atopic Dermatitis within this study.

If you decide to enroll in this study (with the consent of your legally authorized representative if you are <18 years) and are eligible to participate, you will continue to receive medical care and necessary treatment you need for your condition. Your doctor will give you all the information to help you make an informed decision, including the potential risks and benefits of study participation as well as your rights and duties as a participant.

You will find more information in your Informed Consent Form.

	Screening period	TREATMENT PERIOD - first 52 weeks (approx. first year)						TREATMENT PERIOD - from week 64 to week 160 (approx. second and third years)			Safety Follow-up Period
Frequencies of visits at study site		Visits every 2 weeks			Visits every 4 weeks			Visits every 3 months (12 weeks)			20 weeks after the last dose of amlitelimab
Study visits	Visit 1	Visit 2 Baseline	Visit 3 Week 2	Visit 4 Week 4	Visit 5 Week 8	10 visits (every month/ 4 weeks)	Visit 16 Week 52	Visit 17 Week 64	7 visits (every 3 months)	Visit 25 Week 160*	Visit 26 Week 176 (EOS: End of Study)
Informed consent form (ICF) signature	X										
Electrocardiogram (ECG)						Only at V7, V9 and V13			Only visit 21		
Vital signs and physical examination											
Amlitelimab administration and check of local skin reaction		Every 4 weeks At study site	Every 4 weeks At study site	Every 4 weeks At study site	Every 4 weeks At study site	Every 4 weeks At study site	Every 4 weeks At study site	Every 4 weeks At study site	Every 4 weeks at study site or at home	Last injection done week 156	
Blood and urine sampling						Except V10,V12 and V14					
Questionnaires/scales electronically completed by patients						Only at V7 and V9					
Daily e-diary on itch, skin pain and sleep disturbance	Start diary	Daily diary until week 24					7d prior to visit		7d prior toV18, V20 and V22	7d prior to visit	7 d prior to visit
Paper diary completion for amlitelimab injections								Paper diary of injections only for home injections			

For details and optional investigations, please refer to the Informed Consent Form

Frequently asked questions (FAQs)

Why are clinical studies (or trials) conducted?
Clinical studies are essential to the development of new drugs that help people to live longer and with less pain or disability. They help researchers to understand what does and doesn't work in humans that cannot be learned in the laboratory or in animals. Clinical studies are also required by the health agencies for new drugs prior to being prescribed and used by healthcare professionals for treatment of patients.

How do clinical studies work?
Clinical studies must adhere to a set of rules called "Good Clinical Practices (GCP)", rigid standards that clearly state what is allowed by medical professionals during a clinical study.
Clinical studies follow rigid drug testing procedures designed to help researchers determine the safety and effectiveness of the investigational drug or medical treatment being studied.

Who can participate in a clinical study?
Every clinical trial has a set of criteria that participants must meet to participate, including agreeing to follow all study procedures and recommendation and signing an informed consent form. Individuals younger between 12 and 18 years can participate if their legally authorized representative consents.

Are study-related medical care expenses covered in association with the studies?
If you participate, there will be no cost for study-related exams, the investigational study drugs, and other study-related medical care.

Will I receive the investigational study drug if I participate?
In this study, all participants will receive the active treatment of amlitelimab injected under the skin (subcutaneously) once every 4 weeks.

What about clinical trials participation during COVID-19?
This study requires in-person visits to the study site. Precautions are being taken to reduce the on-site risks of exposure to COVID-19. To ensure treatment continuity and safety of patients participating in our clinical trials during this worldwide pandemic, several alternative solutions have been put in place according to local rules.

Who is sponsoring these trials?
Sanofi is the sponsor of this trial.

Your rights: Information about this study is provided in the informed consent form (ICF). The ICF is very detailed and will explain all the steps and procedures *in* this study. If you *decide* to participate, your doctor will ask you to sign these documents. **You are completely free to accept or refuse to participate.** If you decide to take part in this study, please know that you can leave the study at any time. It will not affect your regular medical care.