WHAT ELSE SHOULD I KNOW?

Taking part in a clinical research study is entirely voluntary. Participation can be withdrawn at any time for any reason.

- Study-related therapies and assessments are provided at no cost.
- Participants are not paid to take part in this study, however, reasonable study related expenses will be reimbursed, such as meals and parking.
- Travel arrangements may be provided with no out-of-pocket expenses for the participant.
- To participate in the study, participants will be asked to carefully review and sign the informed consent* document.
- Since this investigational drug has never been studied in adult patients with bullous pemphigoid, it's important that potential benefits and risks of the study be discussed with your doctor.
- Applicable COVID-19 precautions will be carried out throughout the duration of the study.

** Informed consent is the process of providing participants with key information about a research study before they decide whether to agree to take part and continue throughout the study. The study team provides an informed consent document that includes details about the study, such as its purpose, how long it's expected to last, tests or procedures that will be done as part of the research, and who to contact for further information. The informed consent document also explains risks and potential benefits.*

ballad
Bullous Pemphigoid Study

FIND OUT MORE ABOUT THE STUDY:

To learn more about the ballad study or to find out if the study is right for you or someone you know *, please contact

[Site Specific Contact Email]

For more information

please visit clinicaltrials.gov

[Study NCT Number]

Or visit **[Study Specific Website]**

Additional Resources:

To learn more about the sponsor of this study, please visit: www.argenx.com

*Eligibility Criteria Apply

The investigational study drug has not been approved for use in bullous pemphigoid by any regulatory agency as efficacy and safety have not been established.

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Bullous Pemphigoid Study

Bullous Pemphigoid Study

A guide to a clinical research study for **Bullous Pemphigoid**

Version 1.2 MAY 2022

MED-US-EFG-2100221

LIVING WITH BULLOUS PEMPHIGOID

We are conducting this study in an effort to explore if this investigational study drug is safe and effective for the treatment of bullous pemphigoid.

ABOUT CLINICAL RESEARCH

Clinical research studies, also called clinical trials, like this one look for ways to treat a disease. The trial will carefully monitor all risks as well as potential benefits and will keep the well-being of the patient as the primary focus. Even if patients don't directly benefit from the results of the clinical trial, the information gathered can help others and add to scientific knowledge. People who take part in clinical trials are vital to the process of improving medical care.

There are security measures to protect personal information. This is to avoid personal information from being lost, used, altered, disclosed, or accessed in any unauthorized way. To protect the identity of the participant, personal study information will be coded (e.g., unique study numbers are assigned to each patient). More information about privacy maintenance will be shared with those who choose to participate in the study.

Version 1.2 MAY 2022

ballad
Bullous Pemphigoid Study

A CLINICAL TRIAL FOR THE TREATMENT OF ADULTS WITH BULLOUS PEMPHIGOID

The ballad study is designed to assess the safety and effectiveness of the investigational study drug* compared to a placebo**, for the treatment of adults living with bullous pemphigoid.

Patients enrolled in the study will be randomly assigned by a computer to either receive the investigational study drug* or placebo**. Half of the patients will be assigned to receive the investigational study drug and half will receive placebo.

The study is blinded, meaning that neither the study participant nor the study team will know if the study participant is receiving the investigational study drug or placebo.

** The investigational study drug has not been approved for use in bullous pemphigoid by any regulatory agency as efficacy and safety have not been established.*

*** A placebo has no active ingredient and is used to compare the effects of the investigational study drug. The placebo will look exactly like the investigational study drug and will be administered the same way to make sure that no one, not even the study doctor, will know which drug has been assigned to whom. In the event of an emergency, the participant will receive medical care and, if deemed in their best interest, the treating doctor will quickly be able to determine whether a patient was given the investigational study drug or placebo.*

THE BALLAD STUDY

STUDY DESIGN

The study will last for up to 45 weeks and during this period study participants might need to visit the trial site up to 40 times. The study will consist of a screening period, a treatment period of 36 weeks where the participant will receive the investigational study drug or placebo on a weekly basis and an optional 7-week follow-up period. During the study treatment period, some on-site visits can be replaced by home visits (where a study nurse can visit the participants' home) if the disease status allows it.
All participants will receive oral corticosteroids.
After the treatment period, participants will have the opportunity to enter the open-label extension study where they will continue to receive the investigational study drug.

As part of the safety measures in the trial, all enrolled participants will be monitored and supported by the study team. Part of this process will include a series of health questions, physical examinations, and blood and urine tests.

WHO IS ELIGIBLE TO PARTICIPATE?

To join, you or someone you know must:

- Have been diagnosed with bullous pemphigoid.
- Not be pregnant, or actively trying to get pregnant.
- 18+ Be at least 18 years old.
- Meet additional criteria that the study staff will discuss.