Clinical Study Results

MedImmune
A member of the AstraZeneca Group

Research Sponsor: MedImmune, LLC

Drug Studied: MEDI9314

Short Study Title: A study to learn if MEDI9314 is safe to take for patients with atopic dermatitis

Thank you!

Thank you for taking part in the clinical trial for the study drug MEDI9314. The study started in February 2016 and ended in June 2017.

MedImmune, LLC sponsored this study and thinks it is important to share the results of the study with you and the public. An independent, nonprofit organization called CISCRP and a medical writing organization called Synchrogenix helped prepare this summary of the study results. We hope it helps you understand and feel proud of your important role in medical research.

If you have questions about the results, please speak with the doctor or staff at your study site.

Why was the research needed?

Researchers are looking for a better way to treat a type of eczema called atopic dermatitis, also known as AD. Before a treatment can be approved for patients to take, researchers do clinical studies to find out how it works and how safe it is.

In this study, the researchers wanted to find out if the participants had any medical problems during the study. This information is important to know before other studies can be done that help find out if MEDI9314 improves the health of people with AD.

What kind of study was this?

This was a “double-blind” study. This means none of the participants, doctors, or other study staff knew what treatment each participant got.

All of the participants in this study got either MEDI9314 or a placebo. A placebo looks like a drug but does not have any medicine in it. Researchers use a placebo to help make sure any of the effects they see in the participants who take the drug are actually caused by the drug.

A computer program was used to randomly choose the treatment each participant got. This helps make sure the groups are chosen fairly. Researchers do this so that comparing the results of each treatment is as accurate as possible.

What happened during the study?

To see if the participants could join the study, the study doctors did a physical examination and took blood and urine samples. They also checked the heart health of the participants using an electrocardiogram, also known as an ECG. The study doctors also asked about the medical history of the participants, how they felt, and what medicines they were taking.

All of the participants in this study got either MEDI9314 or the placebo. Different doses of MEDI9314 were given in the study.

During the study, the participants stayed at their study site for 6 days. On the second day, they got either MEDI9314 or the placebo as an injection or through a needle under the skin.

After the 6 days, the participants had 13 follow-up visits for about 8 months. During these visits, study doctors checked the health of the participants again.

What were the study results?

This is a summary of the main results from this study overall. The results each participant had might be different and are not in this summary. A full list of the questions researchers wanted to answer can be found on the website listed at the end of this summary. If a full report of the study results is available, it also can be found on this website.

The researchers wanted to learn if MEDI9314 is safe to take for patients with AD. So, they studied the medical problems that the participants had during the study. The researchers then compared the medical problems in the participants who got MEDI9314 to the medical problems in the participants who got the placebo.

What medical problems did participants have?

The medical problems participants have during clinical studies that the doctors think might be related to the study drugs are called “adverse reactions”. An adverse reaction is considered “serious” when it is life-threatening, causes lasting problems, or requires hospital care.

The adverse reactions that happen in a study may or may not be caused by the study drugs. A lot of research is needed to know whether a drug causes an adverse reaction.

The adverse reactions that happened in this study are not in this summary. Because there was a very small number of participants, leaving this information out helps protect their identities. The website listed at the end of this summary may have other information about medical problems that happened in this study.

How has this study helped patients and researchers?

This study helped researchers learn if MEDI9314 is safe to take for patients with AD.

Researchers look at the results of many studies to decide which treatments work best and are safest. This summary shows only the main results from this 1 study. Other studies may provide new information or different results. Always talk to a doctor before making any treatment changes.

Further clinical studies with MEDI9314 may be planned in the future.

Where can I learn more about this study?

You can find more information about this study on the website listed below. If a full report of the study results is available, it also can be found there.

- www.clinicaltrials.gov. Once you are on the website, type **"NCT02669667"** into the search box and click **"Search"**.

The full title of your study is: A Phase 1a Randomized, Blinded, Placebo-controlled, Single-ascending Dose Study to Evaluate the Safety and Tolerability of MEDI9314 in Healthy Adult Subjects

The protocol number of your study is: D4361C00002

MedImmune, LLC, a member of the AstraZeneca Group, sponsored this study and has its headquarters at 1800 Concord Pike, Wilmington, DE 19850.

The phone number for the AstraZeneca Information Center is 1-877-240-9479.

Thank you!

Clinical study participants belong to a large community of people who take part in clinical research around the world. They help researchers answer important health questions and find medical treatments for participants.

CISCRP
THE CENTER FOR INFORMATION & STUDY ON CLINICAL RESEARCH PARTICIPATION

The Center for Information & Study on Clinical Research Participation (CISCRP) is a non-profit organization focused on educating and informing the public about clinical research participation. CISCRP is not involved in recruiting patients for clinical studies, nor is it involved in conducting clinical studies.

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