Clinical Study Results

MedImmune
A member of the AstraZeneca Group

Research Sponsor: MedImmune LLC, a wholly owned subsidiary of AstraZeneca

Drug Studied: MEDI1873

Study Title: A study to find out about the safety of MEDI1873 in participants with advanced solid tumors

Thank you

Thank you for taking part in the clinical study for the study drug MEDI1873.

MedImmune LLC sponsored this study and believes it is important to share the results. An independent non-profit organization called CISCRP helped prepare this summary of the study results for you.

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

Who took part in the study?

The researchers asked for the help of men and women with advanced solid tumors. The participants in this study were 32 to 81 years old when they joined and had already tried at least 1 treatment for their tumors.

The participants in this study had 1 of 3 types of advanced solid tumors:

- Squamous cell carcinoma of the head and neck, also called SCCHN
- Non-small cell lung cancer, also called NSCLC
- Colorectal cancer, also called CRC

The study included 40 participants in the United States.

Why was the research needed?

Researchers are looking for a better way to treat advanced solid tumors. Before a drug can be approved for people to take, researchers do clinical studies to find out how safe it is and how it works.

A solid tumor is a type of cancer that starts in an organ of the body. “Advanced” usually means that the cancer keeps growing even with treatment. The cancer may also be “metastatic”. This means that it has spread to other parts of the body or has grown beyond the organ where it started. In people with advanced solid tumors, certain proteins cause the tumor to grow. The study drug, MEDI1873, was designed to stop 1 of these proteins from letting the tumor grow and to cause tumor cells to die.

In this study, the researchers wanted to find out about the safety of MEDI1873 in participants with advanced solid tumors.

What was the purpose of this study?

The main questions the researchers wanted to answer in this study were:

- What signs and symptoms did the participants have during the study?
- What medical problems did the participants have during the study?

The answers to these questions are important to know before other studies can be done that help find out if MEDI1873 improves the health of people with advanced solid tumors.

What treatments did the participants take?

This was an “open-label” study. This means the participants, researchers, study doctors, and other study staff knew what each participant was getting.

All of the participants got MEDI1873 through a needle into a vein, also known as an IV infusion. They got MEDI1873 every 2 weeks for 1 year. Some participants may have continued getting MEDI1873 after 1 year, if the study doctors thought it was helping their cancer.

There were 8 treatment groups in this study, and each group got a different dose of MEDI1873. The doses were measured in milligrams, also called mg.

The participants in Groups 1 and 2 started the study first. After these participants got at least 2 doses of MEDI1873, the study doctors looked at the results. Then, the researchers decided whether to increase the dose of MEDI1873 in the next group. Each group of participants got at least 2 doses of MEDI1873 before the next group started the study.

The table below shows the 8 different treatment groups and doses in the study.

Group number (number of participants out of 40 participants)	Treatment
Group 1 (1 participant)	1.5 mg of MEDI1873
Group 2 (1 participant)	3 mg of MEDI1873
Group 3 (3 participants)	7.5 mg of MEDI1873
Group 4 (3 participants)	25 mg of MEDI1873
Group 5 (9 participants)	75 mg of MEDI1873
Group 6 (15 participants)	250 mg of MEDI1873
Group 7 (7 participants)	500 mg of MEDI1873
Group 8 (1 participant)	750 mg of MEDI1873

What happened during the study?

The study started in November 2015 and ended in December 2018. The researchers stopped the study early because they did not think that MEDI1873 was helping the participants' cancer.

Before the participants got study treatment, they visited their study site 1 time. At this visit, the study doctors checked the health of the participants to make sure they could join the study. This part of the study lasted up to 4 weeks. The study doctors:

- did a physical exam and asked about the participants' medications and any medical problems they were having
- checked the participants' heart health using an electrocardiogram, also called an ECG
- took pictures of each participant's tumors and their brain using CT or MRI scans
- used surgery for some participants to take a sample of the tumor called a biopsy
- took blood and urine samples

The study doctors also did these tests and measurements throughout the study.

While the participants were getting study treatment, they visited their study site 33 times. The participants got their infusion of MEDI1873 every 2 weeks. This part of the study lasted for 1 year.

After the participants got study treatment, they visited their study site 3 times in the first 3 months. Then, they visited every 3 months after that. This part of the study lasted for 1 year.

After the second year of visits, the participants could keep visiting their study site for the study doctors to check their health. This could keep happening every 6 months until the participants' cancer got worse or they decided to leave the study.

What were the results of the study?

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.

Researchers look at the results of many studies to decide which treatments work best and are safest. Other studies may provide new information or different results. Always talk to a doctor before making any treatment change.

The websites listed at the end of this summary may have a full report of the study results.

What signs and symptoms did the participants have during the study?

To answer this question, the study doctors did tests and measurements before and after the participants took study treatment. The doctors did physical exams and tested the participants' blood and urine samples to check their overall health. They also did ECGs to check the participants' heart health. Overall, the researchers found that there were some small changes in the results of these tests and measurements. But, the researchers did not consider these to be significant.

The study doctors also kept track of the "adverse events" that the participants had. An adverse event is any sign or symptom that participants have during a study. Doctors keep track of all the adverse events that happen in studies, even if they do not think the adverse events might be related to the study treatment.

Later in this document, there will be a summary of the adverse events that the study doctors thought might be related to the study treatment. This section is a summary of all the adverse events, whether they might be related to the study treatment or not. An adverse event is considered "serious" when it is life-threatening, causes lasting problems, or the participant needs hospital care.

Adverse events may or may not be caused by the treatments in the study. A lot of research is needed to know whether a treatment causes an adverse event.

How many participants had adverse events?	97.5% (39 out of 40 participants)
How many participants had serious adverse events?	37.5% (15 out of 40 participants)
How many participants stopped taking study treatment because of adverse events?	7.5% (3 out of 40 participants)

The most common serious adverse events were nausea and vomiting. These were the only serious adverse events that happened in more than 1 participant.

The most common adverse events are shown below.

Most common adverse events during the study	
Adverse event	**Total (out of 40 participants)**
Nausea	40.0% (16)
Headache	37.5% (15)
Vomiting	35.0% (14)
Decreased appetite	32.5% (13)
Tiredness	30.0% (12)
Low numbers of red blood cells, also called anemia	27.5% (11)

The study doctors also counted the number of dose-limiting toxicities the participants had during the study. A dose-limiting toxicity is a medical problem that is severe enough to stop the study doctor from increasing the participant's dose of study treatment. A dose-limiting toxicity is also known as a DLT.

Counting the number of DLTs helps researchers determine the safety of different doses of a treatment. This helps them find the highest dose that the participants can take.

There were 18 participants who did not complete the DLT measurements. So, the DLT information was collected for 22 participants.

In this study, 9.1% of the participants had a DLT. This was 2 out of 22 participants.

What medical problems did participants have during the study?

This section is a summary of the medical problems the participants had during the study that the study doctors thought might be related to the study drug. These medical problems are called “adverse reactions”. An adverse reaction is considered “serious” when it is life-threatening, causes lasting problems, or requires hospital care.

These adverse reactions may or may not be caused by the study drug. A lot of research is needed to know whether a drug causes an adverse reaction. These adverse reactions have been, and will continue to be, reviewed together with all of the available data for the drug.

The websites listed at the end of this summary may have other information about adverse reactions or other medical problems that happened during this study.

How many participants had adverse reactions?	82.5% (33 out of 40 participants)
How many participants had serious adverse reactions?	12.5% (5 out of 40 participants)
How many participants stopped taking study treatment because of adverse reactions?	7.5% (3 out of 40 participants)

What serious adverse reactions happened during this study?

The table below shows the serious adverse reactions that happened in the study. It does not show the serious adverse reactions that happened in each group. Because there was a small number of participants in each group, leaving this information out helps protect their identities.

Serious adverse reactions that happened in the study	
Serious adverse reaction	**Total (out of 40 participants)**
Heart attack	2.5% (1)
Nausea	2.5% (1)
Vomiting	2.5% (1)
Heart failure	2.5% (1)
Pain	2.5% (1)
Inflammation of the lungs	2.5% (1)

What adverse reactions happened during this study?

The most common adverse reaction was headache.

The table below shows the most common adverse reactions that happened in 5 or more participants during the study. There were other adverse reactions, but these happened in fewer participants. The table does not show the adverse reactions that happened in each group. Because there was a small number of participants in each group, leaving this information out helps protect their identities.

Most common adverse reactions during the study	
Adverse reaction	**Total (out of 40 participants)**
Headache	25.0% (10)
Decreased appetite	17.5% (7)
Infusion site reaction	17.5% (7)
Tiredness	15.0% (6)
Nausea	15.0% (6)
Vomiting	15.0% (6)
Diarrhea	12.5% (5)

How has this study helped patients and researchers?

This study helped researchers learn more about the safety of MEDI1873 in participants with advanced solid tumors.

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 one study. Other studies may provide new information or different results.

Further clinical studies with MEDI1873 are not planned.

Where can I learn more about this study?

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

- www.clinicaltrials.gov. Once you are on the website, type **"NCT02583165"** into the **"Other Terms"** search box, and click **"Search"**.
- www.AstraZenecaClinicalTrials.com. Once you are on the website, type **"D6150C00001"** into the search box, and click **"Find a Study"**.

Full study title: A Phase 1 Study of MEDI1873 (GITR Agonist) in Adult Subjects With Select Advanced Solid Tumors

National Clinical Trials number: NCT02583165

MedImmune Protocol Number: D6150C00001

MedImmune LLC, a wholly owned subsidiary of AstraZeneca, sponsored this study and has its headquarters in Gaithersburg, Maryland, USA

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 patients.

CISCRP

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 participants for clinical studies, nor is it involved in conducting clinical studies.

CISCRP
One Liberty Square, Suite 1100
Boston, MA 02109
1-877-MED-HERO

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