Clinical Study Results

MedImmune
A member of the AstraZeneca Group

Research Sponsor: MedImmune

Drug Studied: Durvalumab and MEDI9090, a mixture of durvalumab and tremelimumab

Study Title: A study to learn about the safety of durvalumab and MEDI9090 in participants with advanced solid tumors

Thank you!

Thank you for taking part in the clinical study for the study drugs durvalumab and MEDI9090. MEDI9090 is a combination of the study drugs durvalumab and tremelimumab.

MedImmune 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 people with advanced solid tumors. The participants in this study were 28 to 78 years old when they joined.

The study included 42 participants in Japan and 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. Normally, cells in the immune system help stop tumors from growing. But in people with advanced solid tumors, the tumor cells can interact with certain proteins on the immune cells. This may stop the immune cells from recognizing the tumor cells and then attacking them.

The study drugs in MEDI9090, durvalumab and tremelimumab, were each designed to stop the tumor cells from interacting with some of these proteins. This lets the immune cells recognize and attack the tumor cells.

In this study, the researchers wanted to find out about the safety of both durvalumab on its own and MEDI9090 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:

- Did any of the participants have immune reactions to MEDI9090 within the first 30 days of getting treatment?
- 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 to find out if MEDI9090 helps improve the health of people with advanced solid tumors.

What treatments did the participants take?

All of the participants got MEDI9090, which is a combination of the study drugs durvalumab and tremelimumab. Some participants also got durvalumab by itself after they got MEDI9090. Durvalumab and MEDI9090 were each given through a needle into a vein, also known as an IV infusion.

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

The study had 2 treatment periods. In the first treatment period, all of the participants got an IV infusion of MEDI9090 once every 4 weeks. This treatment period lasted for 4 months.

In the next treatment period, some of the participants got an IV infusion of durvalumab every 4 weeks. The participants continued getting these infusions until any of these happened:

- their cancer got worse
- the study doctor decided that study drug was no longer helping the participants
- they left the study for other reasons

The table below shows the treatments the participants got during the study:

	Treatment period 1 MEDI9090 (42 participants)	Treatment period 2 Durvalumab (17 participants)
	• All of the participants got 4 IV infusions of MEDI9090	• All of the participants got IV infusions of durvalumab
	• Once every 4 weeks for 4 months	• Once every 4 weeks until the participants left the study

What happened during the study?

The study started in August 2016 and ended in January 2020.

Before the participants got study treatment, they visited their study site at least 1 time within the 4-week period before the start of study treatment. At this visit, the study doctors checked the health of the participants to make sure they could join the study. The study doctors took pictures of the participants' tumors using CT or MRI scans. These are also known as computed tomography and magnetic resonance imaging scans. They also:

- 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 blood and urine samples

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

While the participants got MEDI9090, they visited their study site 9 times. Every 4 weeks, the participants got an infusion of MEDI9090. The study doctors checked to see if the participants' tumors were shrinking about every 8 weeks.

While the participants got durvalumab, they visited their study site once every 4 weeks. At these visits, the participants got an infusion of durvalumab. The study doctors checked to see if the participants' tumors were shrinking about every 8 to 16 weeks.

After the participants stopped getting study treatment, they visited their study site once a month for 3 months. At these visits, the study doctors checked the participants' health and asked about the participants' medications and any medical problems they were having.

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.

The study doctors were not able to use the results from 3 of the participants. So, the results below include 39 out of 42 participants.

Did any of the participants have immune reactions to MEDI9090 within the first 30 days of getting treatment?

To answer this question, the study doctors counted how many participants had medical problems related to the infusion of the study drugs within the first 30 days of getting treatment. These were called “infusion-related reactions”.

The study doctors found that none of the participants had any infusion-related reactions within the first 30 days of getting treatment.

The study doctors also did blood tests to learn if any of the participants had immune reactions by developing antibodies against MEDI9090 within the first 30 days of getting treatment. Antibodies are proteins that the body’s immune system makes to protect against anything the immune system does not recognize as part of the body. The study doctors used the proportion of participants who had developed antibodies against MEDI9090 as a measurement of whether or not the participants had an immune reaction against MEDI9090.

Because MEDI9090 is a combination of durvalumab and tremelimumab, the study doctors looked for antibodies against each of these study drugs individually.

The study doctors found that there were some participants who developed antibodies against MEDI9090 within the first 30 days of getting treatment:

- 5.1% of the participants had antibodies against durvalumab. This was 2 out of 39 participants.
- 7.7% of the participants had antibodies against tremelimumab. This was 3 out of 39 participants.

Having these antibodies in the participants' blood did not seem to affect their health. Based on these results, the study doctors concluded that the participants did not have a strong immune reaction against MEDI9090.

What medical problems happened 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 drugs. 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 drugs. 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 study drugs.

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.

Did any adverse reactions happen during this study?	
How many participants had adverse reactions?	81.0% (34 out of 42 participants)
How many participants had serious adverse reactions?	2.4% (1 out of 42 participants)
How many participants stopped getting study treatment because of adverse reactions?	0.0% (0 out of 42 participants)

What serious adverse reactions happened during this study?

There was 1 serious adverse reaction that happened during this study. This was the low production of hormones by the adrenal glands. This happened in 2.4% of participants during the durvalumab treatment period of the study. This was 1 out of 42 participants.

None of the participants died due to serious adverse reactions.

What adverse reactions happened during this study?

The most common adverse reactions were fatigue and itching.

The table below shows the most common adverse reactions that happened in 4 or more participants during the study. There were other adverse reactions, but these happened in fewer participants.

Most common adverse reactions during the study

Adverse reaction	Durvalumab and MEDI9090 (out of 42 participants)
Fatigue	26.2% (11)
Itching	26.2% (11)
Diarrhea	14.3% (6)
Nausea	14.3% (6)
Chills	11.9% (5)

How has this study helped patients and researchers?

This study helped researchers learn more about immune reactions and the safety of durvalumab and MEDI9090 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 these study drugs 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 **"NCT02900157"** into the search box and click **"Search"**.
- www.AstraZenecaClinicalTrials.com. Once you are on the website, type **"D4190C00055"** into the search box, and click **"Find a Study"**.

Full Study Title: A Phase I Study to Evaluate the Safety and Pharmacokinetics of MEDI9090 in Subjects with Advanced Solid Tumors

AstraZeneca Protocol Number: D4190C00055

National Clinical Trials number: NCT02900157

MedImmune, a wholly owned subsidiary of AstraZeneca, sponsored this study and has its headquarters in Gaithersburg, MD, 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 • www.ciscrp.org