NOVARTIS

Clinical Trial Results Summary

A clinical trial to learn more about the effects of DRB436 and TMT212 in Chinese adults with non-small cell lung cancer

Thank you!

Thank you to the participants who took part in the clinical trial for **non-small cell lung cancer (NSCLC)**. Every participant helped the researchers learn more about the trial drugs **DRB436**, also called **dabrafenib**, and **TMT212**, also called **trametinib**.

Novartis sponsored this trial and believes it is important to share what was learned from the results of this trial with the participants and the public.

We hope this helps the participants understand their important role in medical research.

Trial information

Trial number: CDRB436ECN01

Novartis drugs studied: **DRB436**, also called **dabrafenib**, and **TMT212**, also called **trametinib**.

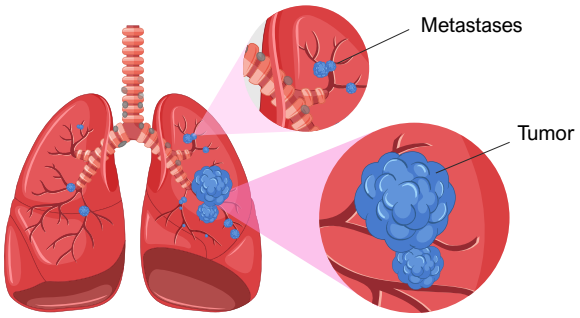
Sponsor: Novartis

If you were a participant and have any questions about the results, please talk to the doctor or staff at the trial site.

This summary only shows the results of a single clinical trial. Other clinical trials may have different findings.

What was the main purpose of this trial?

The main purpose of this trial was to learn about the effects of **DRB436** given with **TMT212** in Chinese adults with **non-small cell lung cancer (NSCLC).**



NSCLC

NSCLC is the most common type of lung cancer. It starts when healthy lung cells become damaged and begin to grow out of control and then form a tumor. When cancer spreads beyond its original site, this is called **metastasis**. As the tumor grows, it can block airways, irritate lung tissue, and affect breathing.

Common symptoms of **NSCLC** are:

- Continuous cough that worsens
- Coughing up blood or phlegm
- Chest pain or discomfort
- Shortness of breath
- Weight loss
- Weakness and loss of appetite

One cause of **NSCLC** is a change in certain genes, called a **mutation**. These mutations can affect how cells grow and divide. Some people with **NSCLC** have a mutation in a gene called **BRAF**.

Normally, the BRAF gene helps cells grow and function properly. But when this gene is mutated, it can create abnormal BRAF proteins, which may lead to uncontrolled cell growth and the spread of cancer.

When this trial started, there were no approved treatments in China that target BRAF mutations in people with **NSCLC**. That is why researchers were studying different treatments for this type of cancer.

The trial drug, **DRB436 (dabrafenib)**, blocks the activity of the abnormal BRAF proteins, which can help prevent the growth of cancer cells. It is given along with another cancer drug called **TMT212 (trametinib)**. This combination is already approved in many countries for other types of cancer.

Drug
dabrafenib

Pronounced as
duh-BRA-feh-nib

Drug
trametinib

Pronounced as
truh-MEH-tih-nib

TMT212 (trametinib) blocks the signals from the BRAF mutation and helps slow down cancer growth.

The trial's purpose was to answer these main questions:

- How many participants had their tumors shrink or disappear after treatment?
- What medical problems, also called adverse events, happened during this trial?
  - ↳ An **adverse event** is any sign or symptom that participants have during a trial. Adverse events **may** or **may not** be caused by treatments in the trial.

How long was this trial?

The trial began in August 2020 and ended in November 2024. The participants could receive trial treatments as long as they were benefiting from them.

When the trial ended, researchers created a report of the trial results. This summary is based on that report.

Who was in this trial?

40 participants from **China** with **NSCLC** received treatment in this trial. Participants' ages ranged from 46 to 77 years. Their average age was 62 years.

The number of participants by gender is shown below.

Gender

21	Women
19	Men

Participants **could take part** in this trial if they:

- Were at least 18 years old
- Had **NSCLC** with BRAF mutation
- Did not receive any treatments before, or
- Had received up to 3 treatments and did not respond or stopped responding to them.

What treatments did the participants receive?

Researchers studied the following treatments:

DRB436: 150 milligrams (mg), provided as capsules, taken by mouth, 2 times a day.

TMT212: 2 mg, provided as tablets, taken by mouth, once a day.

The participants, researchers, and trial staff knew that all participants were receiving **DRB436** and **TMT212**.

What happened during this trial?

Before treatment

Up to 4 weeks

Trial doctors checked the participants' health to make sure they could be in this clinical trial.

During treatment

For as long as participants benefited from treatment

A total of 40 participants recieved treatment with **DRB436** and **TMT212** during this trial.

Participants continued treatment as long as it provided benefit. They stopped treatment if adverse events became unacceptable, their cancer got worse, or they died. They could also choose to leave the trial at any time.

After treatment

Up to the end of trial

Participants were checked:

- For adverse events, for up to 1 month after the last dose.
- For their cancer status, until they could not be followed up, until they died, or until the trial ended.

Trial staff checked the participants' general health throughout the trial.

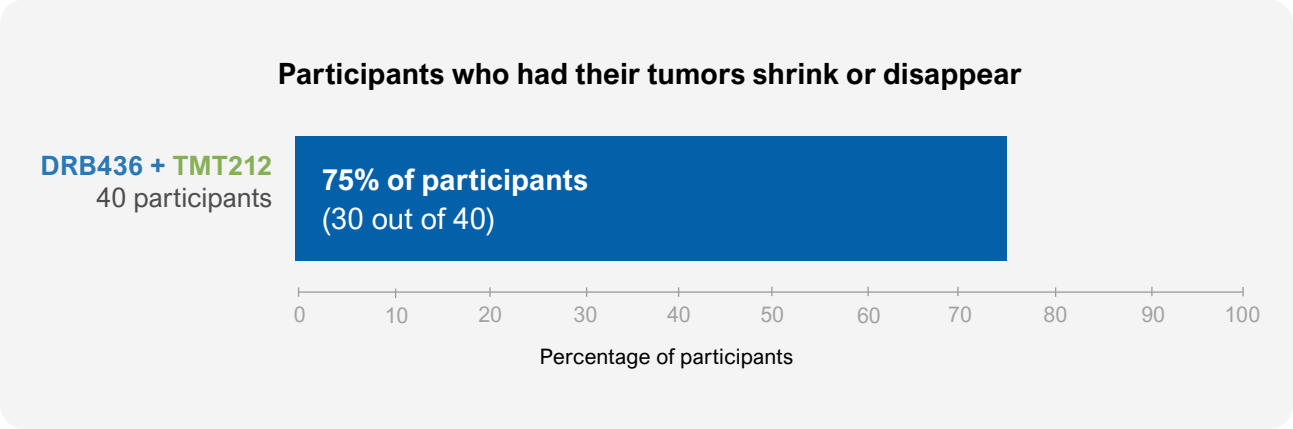
What were the main results of this trial?

How many participants had their tumors shrink or disappear after treatment?

Researchers found that **30 out of 40 participants (75%)** had their tumors shrink or disappear after treatment.

Doctors monitored how well the treatment worked by using imaging scans such as computed tomography (CT), magnetic resonance imaging (MRI), or whole-body bone scans. These scans helped track changes in participants' cancer over time.

The results below include 40 participants who received treatment during this trial.



What medical problems, also called adverse events, happened during this trial?

Trial doctors keep track of all medical problems, also called adverse events, that happen in trials. They track **adverse events** even if they think the adverse events are not related to the trial treatments.

Many trials are needed to know if a drug or treatment causes an adverse event.

This section is a summary of the adverse events that happened from the start of the treatment up to 1 month after the last dose.

An **adverse event** is:

- Any **sign or symptom** that the participants have during a trial
- Considered **serious** when it is life-threatening, causes lasting problems, the participant needs hospital care, or results in death

Adverse events **may** or **may not** be caused by treatments in the trial.

A total of **39 out of 40 participants (98%)** participants had adverse events.

- **20 out of 40 participants (50%)** had adverse events that were considered serious.
- **5 out of 40 participants (13%)** left the trial due to an adverse event.
- **6 out of 40 participants (15%)** died due to any cause, including their **NSCLC**.

There were no new, unexpected safety concerns with **DBR436** and **TMT212**.

How many participants had adverse events?

The table below shows how many participants had adverse events during the trial.

Participants who:	DRB436 + TMT212 (40 participants)
Had at least 1 **adverse event (including serious and other)**	39 of 40 **(98%)**
Had at least 1 **Serious adverse event**	20 of 40 **(50%)**
Left the trial **due to an adverse event**	5 of 40 **(13%)**
Died due to any cause	6 of 40 **(15%)**

What serious adverse events did the participants have?

The table below shows the most common serious adverse events that happened during the trial.

	DRB436 + TMT212 (40 participants)
Lung infection Pneumonia	5 of 40 **(13%)**
Fever Pyrexia	5 of 40 **(13%)**
Increased levels of creatinine in the blood (a waste product filtered by the kidneys) Blood creatinine increased	2 of 40 **(5%)**
Shortness of breath Dyspnea	2 of 40 **(5%)**

What other (not including serious) adverse events did the participants have?

The table below shows the most common other adverse events that happened during the trial.

	DRB436 + TMT212 (40 participants)
Low levels of red blood cells Anemia	21 of 40 **(53%)**
Low levels of a blood protein called albumin Hypoalbuminaemia	19 of 40 **(48%)**
Fever Pyrexia	18 of 40 **(45%)**
Increased liver protein Aspartate aminotransferase increased	17 of 40 **(43%)**
Excess protein in the urine Proteinuria	15 of 40 **(38%)**
Decreased levels of neutrophils, a type of white blood cell Neutrophil count decreased	15 of 40 **(38%)**

What was learned from this trial?

This trial helped researchers learn about the effects of **DRB436** given along with **TMT212** in participants with **non-small cell lung cancer (NSCLC)**.

The researchers concluded that:

- Most of the participants (75%) had their tumors shrink or disappear after treatment with **DRB436** and **TMT212**.
- There were no new or unexpected safety concerns with **DRB436** and **TMT212**. The safety results were similar to those seen in previous trials.

While this trial was ongoing, the combination of **DRB436** and **TMT212** received approval in China for **BRAF-mutated NSCLC**. When this summary was written, the sponsor had no plans for future trials of **DRB436** and **TMT212** in people with **NSCLC**.

Where can I learn more about this trial?

More information about the results and adverse events in this trial can be found in the scientific summary of the results available on the Novartis Clinical Trial Results website, www.novctrd.com.

Follow these steps to find the scientific summary:

Go to www.novctrd.com → Click **Clinical Trial Results** → Accept the terms ☑ **I accept** → Search for **CDRB436ECN01**

For more information about this trial go to this website:

clinicaltrials.gov – search using the number **NCT04452877**

Other trials with **DRB436** and **TMT212** appear on the public websites above. When there, search for **DRB436** or **dabrafenib** and **TMT212** or **trametinib**.

Full clinical trial title: An Open-Label, Single-arm Study to Evaluate the Safety and Efficacy of Dabrafenib in Combination with Trametinib in Chinese Patients with BRAF V600E Mutation-Positive Metastatic Non-Small Cell Lung Cancer

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1-888-669-6682 (US); +41-61-324 1111 (EU)

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