

## Clinical Trial Results

### A trial to learn how LIK066 works and how safe it is in Japanese patients with obesity and related medical problems

Protocol Number: **CLIK066B1201**

#### *Thank You!*

Novartis would like to thank you for taking part in this trial for the drug LIK066. You helped researchers learn more about how LIK066 works in patients with obesity who have medical problems related to their weight.

As a clinical trial participant, you belong to a large community of participants around the world. Your invaluable contribution to medicine and healthcare is greatly appreciated.

Important note: This summary only shows the results of a single clinical trial. Other clinical trials may have different findings. Researchers and health authorities look at the results of many clinical trials to understand which drugs work and if they are safe. It takes many participants in multiple clinical trials around the world to advance medical science and health care.

If you have any questions about these trial results, please talk to the doctor or staff at your trial site.

### What has happened since the trial ended?

The trial started in December 2017 and ended in July 2018. Participants like you were in the trial for up to 18 weeks. The whole trial took just over 7 months to complete.

When the trial ended the sponsor reviewed the data and created a report of the results. This is a summary of that report.

## Why was the research needed?

Obesity can cause medical problems like diabetes, high blood pressure, and heart disease. Patients who are obese and have related medical problems are often encouraged to lose weight by changing what they eat and how much they exercise. But some patients are unable to reach their weight loss goals with diet and exercise alone.

Researchers are looking for new ways to help these patients lose weight.

LIK066 is a medication that keeps some of the sugar in the food we eat from being absorbed by the body and stored as fat. Researchers in this trial wanted to find out if patients who took higher doses of LIK066 lost more weight than patients who took lower doses. They also looked at how much weight patients lost who took a placebo. A placebo looks like a treatment but does not have any medicine in it.

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

- Did the patients who took higher doses of LIK066 lose more weight?
- What medical problems did the patients have?

## What kind of trial was this?

This was a Phase 2 trial. In Phase 2 trials, a treatment is tested in a small number of participants.

This was also a “double-blind” trial. This means that none of the patients, doctors, or other staff knew during the trial which treatment each patient was taking. Some trials are done this way because knowing what treatment each patient is taking can affect the results. The researchers used a computer program to randomly choose the treatment each patient would take. This helped make sure the treatments were chosen fairly.

When the trial ended, the sponsor found out which treatment each patient took so they could report the trial’s results.

## What happened during the trial?

**Once patients agreed to join the trial**, the doctors gave each patient a full check-up to make sure they could take part. It took about 2 weeks after this check-up before patients found out if they could continue to the next part of the trial.

**After joining the trial**, all of the patients took a placebo for the first 4 weeks. During these 4 weeks, the trial doctors gave the patients advice about diet and exercise plans that would help them lose weight. They also asked them to take their study pill every morning.

After 4 weeks, the trial doctors gave the patients a full check-up again to make sure they could continue into the treatment phase of the trial. Patients who did not gain weight during these 4 weeks and who took their study pill for at least 23 of the 28 days could continue in the next part of the trial.

The patients were then assigned to different treatments. Some of the patients took 1 of 4 different doses of LIK066. Others kept taking a placebo. The patients took their assigned treatment every morning for the next 12 weeks.

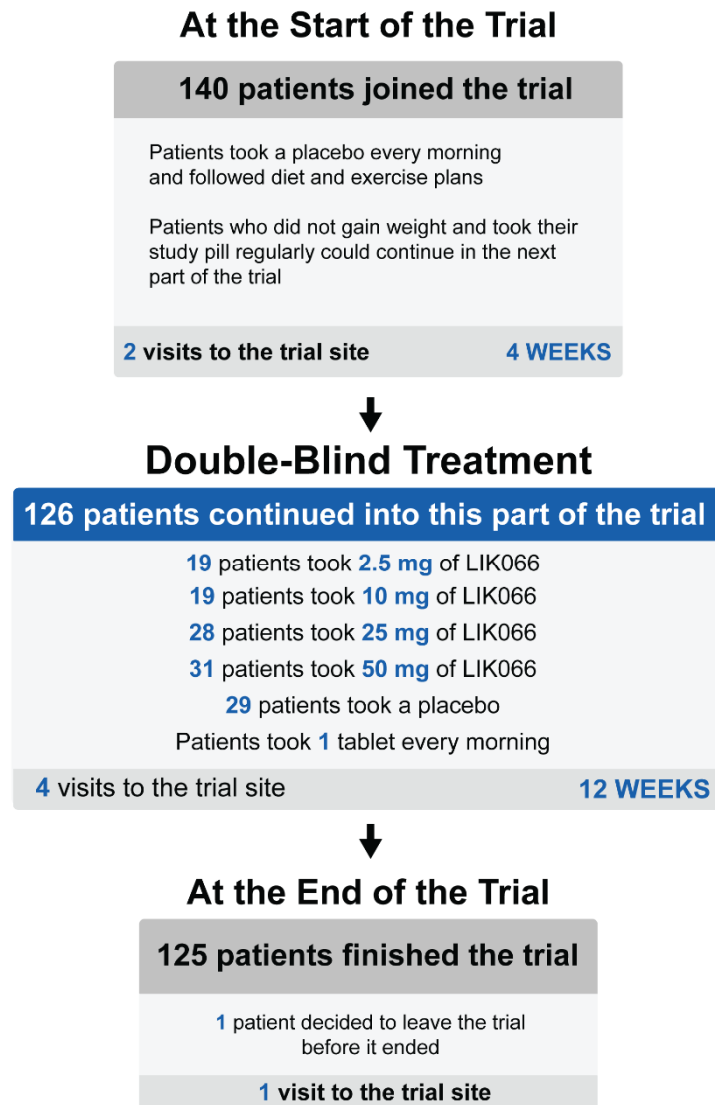
**Throughout the trial**, the patients visited the trial site. During these visits, the patients:

- Had their body weight and waist size measured
- Gave blood and urine samples
- Completed questionnaires
- Got CT scans of the area around their waist so doctors could measure body fat
- Told the doctors about how they were feeling, any medications they were taking, and any medical problems they were having
- Got advice from the doctors about diet and exercise plans that would help them lose weight

The doctors kept track of the patients' health and weight loss throughout the trial.

**At the end of treatment**, the patients visited the trial site one last time.

## How was this trial done?



## Who took part in the trial?

In this trial, 140 patients from 24 centers in Japan took a placebo at the start of the trial.

Of these patients, 126 patients were assigned to different doses of LIK066 or placebo – 78 of these patients were men and 48 of these patients were women. These patients were between 33 and 75 years old when they joined.

All the patients in the trial were obese and had at least 1 health problem linked to their obesity including high blood sugar or diabetes.

## What were the results of the trial?

### Did the patients who took higher doses of LIK066 lose more weight?

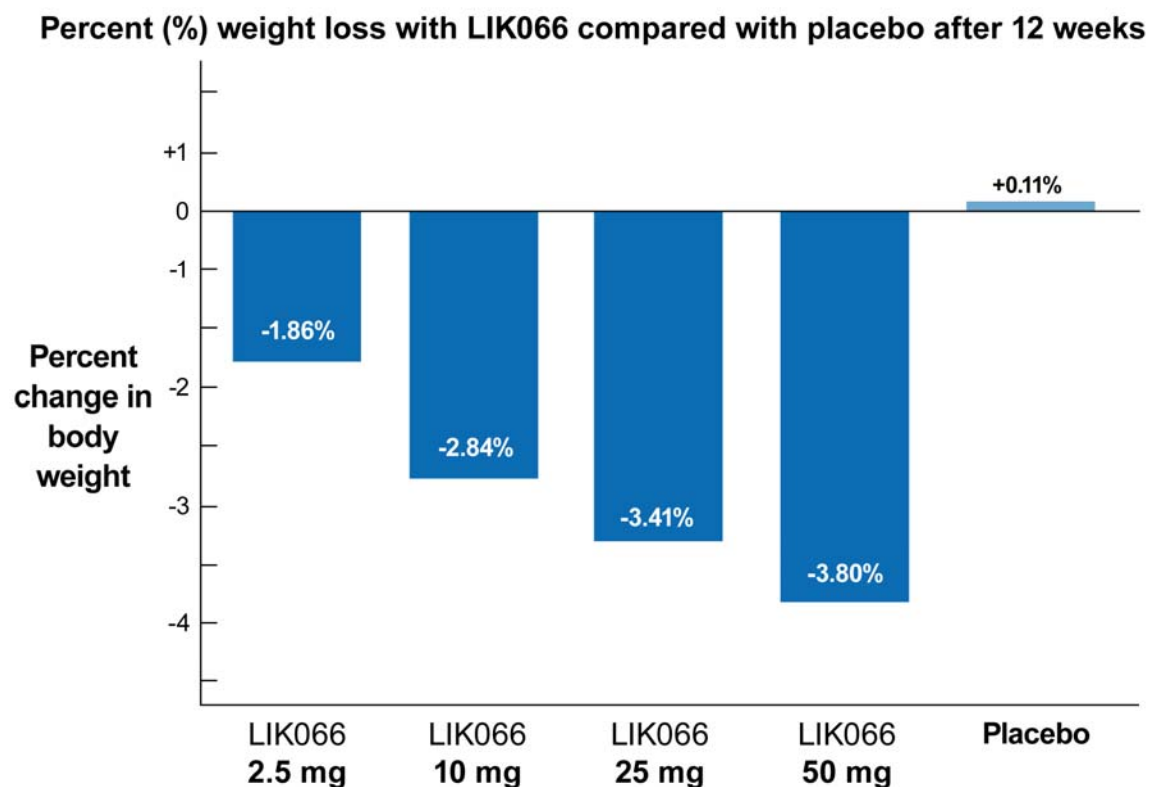
Yes. The patients who took higher doses of LIK066 lost more weight than the patients who took lower doses.

The researchers looked at how much weight patients lost during the 12 weeks of treatment after some patients switched to LIK066 and some kept taking a placebo. They measured weight loss as a percentage of a patient's total body weight.

- The patients who took 2.5 mg of LIK066 lost about 1.9% of their body weight
- The patients who took 10 mg of LIK066 lost about 2.8% of their body weight
- The patients who took 25 mg of LIK066 lost about 3.4% of their body weight
- The patients who took 50 mg of LIK066 lost about 3.8% of their body weight
- The patients who took a placebo gained about 0.1% of their body weight

These results were estimates for each group overall. Individual patients in each group might have had different results. The results for each patient are not in this summary.

The figure below shows the results for each dose of LIK066 compared with placebo.



## What medical problems did the patients have?

Medical problems that happen in clinical trials are called “adverse events”. An adverse event is any unwanted sign or symptom that participants have during a trial. An adverse event is considered “serious” when it is life-threatening, causes lasting problems, or leads to hospitalization.

During a trial, researchers keep a record of all medical problems that participants have whether or not they are caused by a trial drug.

This is a summary of medical problems that happened in this trial. A lot of research is needed to know whether a drug causes a medical problem and how safe it is for patients.

### **What were the serious adverse events?**

There was 1 serious adverse event in this trial. A patient who took LIK066 50 mg had a problem with inflammation of the gallbladder, causing it to become swollen and irritated.

None of the patients died in this trial.

### **What were the most common adverse events?**

The most common adverse event was diarrhea. More patients who took the highest dose of LIK066 had diarrhea than any other group.

The table below shows the most common adverse events that happened in at least 6% of patients in any treatment group in the trial.

### Most common adverse events in this trial

	<b>LIK066 2.5 mg</b> Out of 19 patients	<b>LIK066 10 mg</b> Out of 19 patients	<b>LIK066 25 mg</b> Out of 28 patients	<b>LIK066 50 mg</b> Out of 31 patients	<b>Placebo</b> Out of 29 patients
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The numbers below show the number of patients in each group (and the percentage of the group) who had each adverse event.

<b>Diarrhea</b>	0 (0.0%)	0 (0.0%)	4 (14.3%)	12 (38.7%)	2 (6.9%)
<b>Common cold</b>	2 (10.5%)	3 (15.8%)	5 (17.9%)	4 (12.9%)	1 (3.5%)
<b>Low blood sugar</b>	0 (0.0%)	1 (5.3%)	2 (7.1%)	2 (6.5%)	2 (6.9%)
<b>Higher levels of albumin (a type of protein) in urine</b>	0 (0.0%)	2 (10.5%)	0 (0.0%)	2 (6.5%)	2 (6.9%)
<b>Protein in urine</b>	1 (5.3%)	0 (0.0%)	2 (7.1%)	0 (0.0%)	1 (3.5%)
<b>Acid reflux</b>	1 (5.3%)	0 (0.0%)	2 (7.1%)	0 (0.0%)	1 (3.5%)
<b>Having gas</b>	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (6.5%)	0 (0.0%)
<b>Headache</b>	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (6.9%)

## How has this trial helped patients and researchers?

This trial helped researchers learn how different doses of LIK066 work in a small number of Japanese patients with obesity who have at least 1 medical problem related to their weight.

The results presented here are for a single trial. Other trials may have different results. Researchers look at the results of many trials to learn how well drugs work and how safe they are. If you have questions about these trial results, please speak with the trial doctor or staff at your trial site.

## Where can I learn more about this trial?

More information about the results and adverse events that happened in this trial can be found on the Novartis Clinical Trial Results website: [www.novctrd.com](http://www.novctrd.com). Once on the site, click “Explore” under “Clinical trial results.” After agreeing to enter the site, select “Search by study number”, type **CLIK066B1201** into the search box, and click “**Search**”.

You can also find more results of this trial at this website:

<https://www.clinicaltrials.gov/ct2/show/NCT03320941>

**Full Trial Title:** A randomized, double-blind, dose-finding study to evaluate the change in weight after 12 weeks treatment with 4 doses of LIK066 compared to placebo in Japanese patients with obesity disease

## *Thank you*

It is said that the greatest gift is one which is given anonymously, giving when you do not know whether you will get direct personal benefit. This is the gift that you have given by taking part in a clinical trial. It is a brave and selfless act, one that advances medical knowledge and benefits public health. Thank you for the gift of your participation in clinical research.



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