# Clinical trial SUMMARY

## Short study title

Efficacy of S201086/GLPG1972 in patients with knee osteoarthritis.

### Full scientific title:

Efficacy and safety of 3 doses of S201086/GLPG1972 administered orally once daily in patients with knee osteoarthritis. A 52-week international, multi-regional, multi-centre, randomised, double-blind, placebo-controlled, dose-ranging study. ROCCELLA Study

## In this summary:



Therapeutic area:
Rheumatology

Indication:
Osteoarthritis

Study phase:
2


30 April 2021
Final version

# CLINICAL TRIAL SUMMARY

Efficacy of S201086/GLPG1972 in patients with knee osteoarthritis.

We would like to thank all the patients who participated in the study. As clinical study participants, they help researchers discover new medicines for the benefit of all patients.

This document is a summary of the study. It is written for a general audience.

Researchers need many studies to decide which medicines work the best and are the safest for the patients. For medical science to progress, a lot of people are involved in many studies all around the world. This summary only shows the results from this one study. Other studies, evaluating the same drug, may find different results.

You should not change your current treatment based on the results of this single study. If you have any questions on this study, please speak to your doctor.

## 1 Why was this study done?

Osteoarthritis (OA) is a disease of the joints, in which the natural cushioning between joints, called cartilage, gets thinner over time. OA causes pain and sometimes stiffness in the affected joints. Knee OA is one of the most common forms of OA.

This study was done to test a new drug called S201086/GLPG1972 (study drug), in patients who had knee OA. The study drug acts on the cartilage.

The main objective of the study was to test if the study drug works better than a placebo in reducing cartilage loss in the knee.
A placebo looks like a medicine but does not have any real medicine in it.

This study is called a Phase 2 study. The aim of a Phase 2 study is to find out if a new treatment could help patients with their disease.

## 2 When and where did this study take place?

### When was it carried out?

This study started in August 2018 and continued until July 2020.

### Where did the study take place?

The study took place in the following countries:

| Country | Number of patients |
|---|---|
| Argentina | 67 |
| Brazil | 139 |
| Canada | 64 |
| Denmark | 74 |
| Hungary | 32 |
| Japan | 67 |
| Poland | 52 |
| Russia | 38 |
| South Korea | 31 |
| Spain | 26 |
| Taiwan | 16 |
| USA | 326 |

## 3 Who participated in the study?

### Which patients were included in the study?

To take part in the study, patients had to:

- Be 40 to 75 years of age.
- Have osteoarthritis in the knee.
- Have a history of knee pain for at least 6 months.
- Need treatment for knee pain.

### How many patients participated in the study?

932 patients joined the study: 646 women and 286 men. 173 patients did not complete the study: Most left because of unwanted events (61 patients out of 173) or due to a patient's decision (50 patients out of 173). Unwanted events thought to be related to the treatments are described below.

### How old were the patients?

The average age of the patients was 63 years. The youngest patient was 40 years old. The oldest patient was 75 years old and few months, rounded up to 76.

## 4 Which treatments did patients receive?

The study drug was called S201086/GLPG1972. It was a tablet of 75 mg of medicine. It was compared to placebo.

Patients took the treatment (study drug or placebo) by mouth preferably in the morning.

Patients received one of the following:
- 75 mg of the study drug once a day.
- 150 mg of the study drug once a day.
- 300 mg of the study drug once a day.
- Placebo once a day.

## 5 How was the study done?

The study is called a "randomised" study. It means that patients were put by chance into one of the 4 groups of treatment.

Among the 932 included patients:
- 234 patients took 75 mg of the study drug.
- 231 patients took 150 mg of the study drug.
- 232 patients took 300 mg of the study drug.
- 234 patients took placebo.
- 1 patient stopped the study before receiving the treatment.

The study was also a "double-blind" study. This means that neither patients nor doctors knew who was given which treatment. Therefore, there was no influence of patients or doctors on study results.

Patients took the treatment for an average of 1 year.

## 6 What were the side effects?

### What about side effects?

Like all medicines, the study drug can cause side effects although not everybody gets them.
Side effects are unwanted events thought to be related to the treatments in the study.

The table below shows the number of patients who had side effects.

| | Study drug 75 mg 234 patients | Study drug 150 mg 231 patients | Study drug 300 mg 232 patients | Placebo 234 patients |
|---|---|---|---|---|
| Patients who had side effect(s) | 36 patients (15%) | 30 patients (13%) | 47 patients (20%) | 37 patients (16%) |
| Patients who had serious* side effect(s) | 0 | 2 patients (1%) | 1 patient (0.4%) | 2 patients (1%) |
| Patients who withdrew because of side effect(s) | 5 patients (2%) | 8 patients (4%) | 12 patients (5%) | 4 patients (2%) |

**See definition of serious side effects below*

## How many patients had serious side effects?

A side effect is serious when:

- The patient needs to be hospitalised.
- The patient's life is in danger.
- It causes permanent damage or death.
- Or it may put the patient at risk and requires a medical intervention to prevent the situations listed above.

In this study, 5 patients out of 931 who received the treatment (0.5%) had serious side effects:

With 150 mg of the study drug:

- One patient had a stroke.
- One patient had a disease of the muscles that causes pain or weakness.

With 300 mg of the study drug:

- One patient had depression with suicidal thoughts.

With placebo:

- One patient had a heart attack.
- One patient had liver injury considered to be caused by drugs.

Among the 29 patients who stopped the treatment because of a side effect, 3 patients stopped because of a serious one: 1 patient in the 150 mg study drug group, 1 patient in the 300 mg study drug group, and 1 patient in the placebo group.

During the study, one patient died. The death was due to coronavirus disease (COVID-19) and was not related to the study drug. The patient had COVID-19 two months after the last intake of study drug.

## What were the other side effects?

The table below shows the other side effects (unwanted events thought to be related to the treatments) reported in the study. Only the most common (reported by at least 4 patients in any treatment group) are presented. The side effects in this summary may be presented differently to those in other documents related to study.

| | Study drug 75 mg 234 patients | Study drug 150 mg 231 patients | Study drug 300 mg 232 patients | Placebo 234 patients |
|---|---|---|---|---|
| Increase in liver enzyme called GGT | 1 patient (0.4%) | 1 patient (0.4%) | 10 patients (4.3%) | 3 patients (1.3%) |
| Increase in liver enzyme called ALT | 2 patients (0.9%) | 2 patients (0.9%) | 7 patients (3.0%) | 4 patients (1.7%) |
| Increase in liver enzyme called AST | 1 patient (0.4%) | 1 patient (0.4%) | 7 patients (3.0%) | 3 patients (1.3%) |
| Headache | 8 patients (3.4%) | 4 patients (1.7%) | 5 patients (2.2%) | 3 patients (1.3%) |
| Feeling sick | 0 | 2 patients (0.9%) | 4 patients (1.7%) | 1 patient (0.4%) |
| High blood pressure | 0 | 1 patient (0.4%) | 4 patients (1.7%) | 3 patients (1.3%) |
| Increase in CPK, an enzyme which is found mainly in muscles, heart and brain | 4 patients (1.7%) | 1 patient (0.4%) | 3 patients (1.3%) | 2 patients (0.9%) |

## 7 What were the study results?

The study was completed as planned.

To test the effectiveness of the study drug, the doctors measured the cartilage thickness of the knee. This measurement was done using a technique called "quantitative magnetic resonance imaging" which is an examination that consists of taking pictures of the knee. To test the effectiveness of the study drug, each patient had one measurement of their cartilage thickness before the first treatment intake (baseline), one measurement after six months of treatment and one measurement after one year of treatment.

Change in cartilage thickness was not different between patients treated with S201086/GLPG1972 and patients treated with placebo. It means that S201086/GLPG1972 was not better than placebo in reducing cartilage loss in patients with knee OA.

The study drug also had no effect on pain, mobility and stiffness.

## 8 How has this study helped patients and researchers?

This study helped researchers to better understand knee OA. Unfortunately, the study did not show that the study drug worked better than placebo in reducing cartilage loss on knee OA.

This study helped patients to have additional and valuable care for their disease.

## 9 Are there plans for further studies?

No other studies with the study drug are foreseen in knee OA in the coming year.

## 10 Further information

### What is the identification number of the clinical study?

- Protocol Number: CL2-201086-002/GLPG1972-CL-201
- EudraCT Number: 2017-004581-10
- Universal Trial Number: U1111-1205-0321
- Clinicaltrials.gov Number: NCT03595618

### Who did the study?

The companies that organised and funded the research, called “sponsors”, are the Institut de Recherches Internationales Servier, based in Suresnes, France, and Galapagos NV, based in Mechelen, Belgium.

### How can you contact the sponsor?

Contact us on the Servier website (servier.com).

### Where can you learn more about this study?

- The scientific study summary is also available on the Servier Clinical Trial Data website. (clinicaltrials.servier.com)
- In this document, we translated medical terms into lay terms. You can find the corresponding medical terms in the Servier glossary on the Servier Clinical Trial Data website.