Summary of Results for Laypersons

What was the Study Called?

A Phase 2a, Randomized, Double-blind, Placebo- and Naproxen-controlled, Parallel-group Study to Assess the Analgesic Efficacy of ASP7962 in Patients With Pain Due to Osteoarthritis of the Knee

Why was this Study Needed?

Osteoarthritis (OA) can be caused by aging joints and obesity and occurs when the protective cartilage on the ends of the bones wears down over time. Cartilage is a firm, slippery tissue that permits the joints to move smoothly. Patients with OA can have joint pain (caused by bone rubbing on bone) and stiffness. Although OA can damage any joint in the body, it most commonly affects joints in the hands, knees, hips and spine. Treatments for OA focus on reducing pain and stiffness and improving function and the patient's quality of life. Such treatments may include weight loss, exercise, heat and ice, braces, antiinflammatory medicines (such as ibuprofen, aspirin and naproxen), opioids (narcotic pain medicines that are used to treat moderate to severe pain) and pain relieving injections into the joint. However, these medications may not work well for all patients. Therefore, there was a need to study new treatments that reduce pain in patients with OA. ASP7962 is an experimental medicine that works by blocking proteins that help the nerves send pain signals to the brain. Blocking these proteins may reduce OA pain in patients.

This study was conducted in patients with pain due to OA of the knee. Patients took ASP7962, naproxen or placebo. The section below describes what placebo tablets are. The main question the study helped answer was if ASP7962 helped reduce the knee pain of patients with OA of the knee compared to placebo or naproxen. During the study, it was also important to find out what unwanted effects the patients had from the study medicines.

The study started in February 2016 and ended in September 2017. When the study ended, the sponsor (Astellas) reviewed all the study information and created a report of the results. This is a summary of that report.

What Kind of Study was This and Who Took Part in it?

This was a "double-blinded" study. That means that the patients and the study doctors did not know who took which of the study medicines (ASP7962, naproxen or placebo). A "placebo" is a dummy treatment such as a tablet or capsule that looks like a medicine, but does not have any medicine in it. Using a placebo helps make study results fair and unbiased, because study doctors and patients cannot tell who is taking a placebo, and who is taking the test medicine.

This study included adult women and men who were diagnosed with OA of the knee at least 6 months before the start of the study. The study doctor determined that they had OA of the knee and X-rays also showed that they had OA in their knee. They had moderate or severe

pain in the knee due to OA at least 5 days a week for at least 3 months before the start of the study. They were able to walk and their knee did not contain any artificial body parts.

During the study, the study doctor did a check-up of the patients at several study visits. At the first visit, patients were checked to see if they could be in the study. Patients who could be in the study were picked for a treatment (ASP7962, placebo or naproxen) by chance alone. Twice as many patients were picked for ASP7962 and placebo than for naproxen. All patients also took an additional dose of placebo twice a day.

- ASP7962: patients took 100 mg ASP7962 tablets twice a day and a dose of the placebo tablets twice a day
- Placebo: patients took the placebo tablets twice a day and a second dose of the placebo tablets twice a day
- Naproxen: patients took 500 mg naproxen tablets twice a day and a dose of the placebo tablets twice a day

The patients could take study medicine until their OA got worse, they had unwanted effects they could not tolerate or they asked to stop treatment.

This study took place at 31 clinics in several countries. 215 patients were in the study. Out of these patients, 212 patients took at least 1 dose of study medicine.

	Number of Patients (out of 212 patients)
Age Group	
Aged 64 years or younger	107
Aged 65 to 74 years	79
Aged 75 years or older	26
Sex	
Men	72
Women	140
Clinic Location	
European Union Countries (*at the time of the study*)	212
Belgium	6
Spain	49
Hungary	65
Czech Republic	20
United Kingdom	8
Germany	64

What Were the Study Results?

This study in patients with OA of the knee looked at whether ASP7962 helped reduce the knee pain of patients compared to placebo or naproxen.

The mean (or average) pain score for patients in this study was 4.21 in the ASP7962 group, 4.13 in the placebo group and 3.38 in the naproxen group. The average pain reduction after 4 weeks of treatment for patients in the ASP7962 group and in the placebo group was similar.

This meant that ASP7962 did not reduce the knee pain in patients with OA. Naproxen did reduce the knee pain in patients with OA.

What Adverse Reactions did Patients Have?

A lot of research is needed to know whether a medicine causes a medical problem. So when new medicines are being studied study doctors keep track of all medical problems that patients have while they are in the study. These medical problems are called "adverse events" and are recorded whether or not they might be caused by the treatment taken. An "adverse reaction" is any medical problem or "adverse event" that is judged by the study doctor to be possibly caused by a medicine or treatment used in the study.

The table below shows the most common adverse reactions experienced by patients who took at least 1 dose of study medicine in this study.

Adverse Reaction	ASP7962 (out of 85 patients)	Placebo (out of 85 patients)	Naproxen (out of 42 patients)
Any adverse reaction	8 (9.4%)	10 (11.8%)	7 (16.7%)
Diarrhea	2 (2.4%)	0	1 (2.4%)
Headache or head pain	0	2 (2.4%)	1 (2.4%)
Heartburn	0	2 (2.4%)	0
Nausea or the urge to vomit	1 (1.2%)	2 (2.4%)	0
Upper belly pain	1 (1.2%)	0	2 (4.8%)

An adverse reaction is considered "serious" when it is life-threatening, causes lasting problems or needs hospital care.

None of the patients experienced serious adverse reactions in the study.

Where Can I Learn More About This Study?

This document is a short summary of the main results from this study and reflects the information available as of March 2018. You can find this summary and more information about this study online at http://www.astellasclinicalstudyresults.com.

Please remember that study doctors look at the results of many studies to find out how well medicines work and which adverse reactions they might cause. This summary only shows the results of this 1 study.

Sponsor contact details:

Astellas Pharma Europe B.V. (APEB)
Sylviusweg 62
2333 BE Leiden
The Netherlands