Summary of Results for Laypersons

Astellas is grateful to the patients who took part in this clinical study. Thank you.

What was the Study Called?

A Phase 2a, Randomized, Double-blind Placebo-controlled, Parallel-group Study to Assess the Analgesic Efficacy and Safety of ASP8062 in Subjects with Fibromyalgia

Why was this Study Needed?

Fibromyalgia is a pain disorder in muscles and bone that can last a long time. People with this condition have tender points on the body (places on the neck, shoulders, back, hips, arms, legs). Tender points hurt when someone presses on them. And people can have fatigue, trouble sleeping, and problems with mood and memory. There are medicines that can be used to treat fibromyalgia but they may not work well for some patients. Or they may have unwanted effects. Therefore, there is a need to study new medicines for this condition. ASP8062 is an oral (taken by mouth) experimental medicine for fibromyalgia.

This study was conducted in patients with fibromyalgia. Patients took either ASP8062 or placebo. The section below describes what placebo tablets are. The questions this study asked are whether ASP8062 is safe and how well patients with fibromyalgia tolerate it. And it looked at the effect ASP8062 has on fibromyalgia pain compared to placebo. It was also important to find out what unwanted effects these patients had from ASP8062.

The study started in May 2017 and ended in March 2018. When the study ended, the sponsor of this study (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 (ASP8062 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 aged 18 to 80 years. These patients were diagnosed with fibromyalgia. They had widespread pain for 3 months or more. And their pain was located in 11 or more tender points on their body. They scored their pain 4 or higher in a questionnaire with a scale from 0 to 10.

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 and were taking prescription medicine for their fibromyalgia stopped taking it for several days. This allowed that medicine to leave their body. At visit 2, they began completing a 7-day electronic diary. They recorded their average daily pain with scores on a 0-10 scale. This showed what level their average pain was without any medicine. At visit 3,

patients were picked for treatment with 30 mg ASP8062 or placebo by chance alone (randomization). Patients took their assigned study medicine once a day for 8 weeks. In addition to the study medicines, patients could take acetaminophen (similar to aspirin) if their pain became too great during the study. They could not take more than 3,000 mg per day.

This study took place at 24 clinics in the US. 183 patients were in the study and took at least 1 dose of study medicine.

	Number of Patients
Age Group	
Aged less than 65 years	154
Aged 65 years or older	29
Sex	
Men	7
Women	176

What Were the Study Results?

This study was conducted in patients with fibromyalgia. Patients took either ASP8062 or placebo for 8 weeks. This study looked at the effect ASP8062 has on fibromyalgia pain compared to placebo. To do this, patients recorded in an electronic diary a number value for their average pain (from 0 to 10) every day for 8 weeks. The patient's average pain at week 8 was compared to their average pain before they took the study medicine.

Patients who took ASP8062 and patients who took placebo both had an improvement in pain over 8 weeks. The change in the mean daily average pain score was -1.36 for the patients taking ASP8062 (95 patients). And it was -1.42 for the patients taking placebo (88 patients). A reduction in the pain score indicates an improvement in pain. The difference between the 2 groups was 0.06. Statistical testing showed that this difference was likely to be due to chance.

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 researchers 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	ASP8062 30 mg (out of 95 patients)	Placebo (out of 88 patients)
Any adverse reaction	45 (47.4%)	19 (21.6%)
Dizziness (or sensation of lightheadedness, unsteadiness, or giddiness)	27 (28.4%)	2 (2.3%)
Headache	10 (10.5%)	6 (6.8%)
Nausea or the urge to vomit	5 (5.3%)	3 (3.4%)

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

No patient experienced a serious adverse reaction.

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 August 2018. You can find this summary and more information about this study online at http://www.astellasclinicalstudyresults.com.

Please remember that researchers 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. Your doctor may help you understand more about the results of this study.

Sponsor contact details:

Astellas Pharma Global Development US
1 Astellas Way
Northbrook, IL 60062
USA