# 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 ASP0819 in Patients 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 also have fatigue, trouble sleeping, irritable bowel and problems with mood and memory. There are medicines that can be used to treat fibromyalgia, but they may not work well for most patients. Some of these medicines may have unwanted effects. Therefore, there is a need to study new medicines for this condition. ASP0819 is an oral (taken by mouth) experimental medicine for fibromyalgia.

This study was conducted in patients with fibromyalgia. Patients took either ASP0819 or placebo. The section below describes what placebo tablets are. The main questions this study asked are how well ASP0819 worked to reduce the patients' average daily pain, compared to placebo. It was also important to find out what unwanted effects these patients had from ASP0819.

The study started in March 2017 and ended in February 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. This helps make study results fair and unbiased. One of the study medicines was placebo. A "placebo" is a dummy treatment that looks like a medicine, but does not have any medicine in it.

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, prior to the beginning of the study. And their pain was located in at least 11 out of 18 tender points on their body.

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. In the scale, 0 is no pain at all and 10 is the worst pain imaginable. The

electronic diary was reviewed on visit 3 to see if the patients could remain in the study. To remain in the study, the patients' average daily pain had to be at least 4 and up to 9.

Patients who remained in the study were picked for treatment, by chance alone. Patients took 3 capsules of ASP0819 (total of 15 mg) or they took 3 capsules of placebo.

Patients took their assigned study medicine once a day for 8 weeks. In addition to the study medicines, patients could take acetaminophen (Tylenol®, an over-the-counter pain medicine similar to aspirin) if their pain became too great during the study. They could not take more than 3,000 mg of acetaminophen per day.

This study took place at 24 clinics in the US. 186 patients were in the study. Out of these patients, 184 patients took at least 1 dose of study medicine.

| | **Number of Patients (out of 184 patients)** |
|---|---|
| **Age Group** | |
| Aged 18 to 64 years | 170 |
| Aged 65 to 84 years | 14 |
| **Sex** | |
| Men | 7 |
| Women | 177 |

**What Were the Study Results?**

Patients with fibromyalgia took either ASP0819 or placebo for 8 weeks. They recorded a number value for their average pain every day (from 0 to 10). This study looked at how well ASP0819 worked to reduce the patients' average daily pain, compared to placebo.

Patients who took ASP0819 and patients who took placebo both had less pain over 8 weeks. The change in the mean daily average pain score was -1.60 for the patients taking ASP0819. The change was -1.26 for the patients taking placebo. A reduction in the pain score indicates the patient had less pain than they had at the beginning of the study. The difference between the 2 groups was -0.34. Statistical testing showed that this difference may 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 | Placebo (out of 94 patients) | ASP0819 15 mg (out of 90 patients) |
|---|---|---|
| Any adverse reaction | 29 (30.9%) | 22 (24.4%) |
| Headache or head pain | 8 (8.5%) | 5 (5.6%) |

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

No patient had a serious adverse reaction in this 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 May 2019. 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.

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