

## Summary of Results for Laypersons

### What was the Study Called?

A Multicentre, Single-Arm, Open-Label Study of the Repeated Administration of QUTENZA™ for the Treatment of Peripheral Neuropathic Pain. This is also known as the STRIDE study.

### Why was this Study Needed?

The peripheral nerves are the nerves outside of the spinal cord and brain. Peripheral neuropathic pain is caused by damage to these nerves (called “peripheral nerve damage”). This pain usually occurs in the hands and feet but can also occur in other body locations. The causes of common types of peripheral nerve damage are as follows:

- The chickenpox (herpes zoster) virus can cause a painful rash with blisters that break open and crust over (“shingles”). Shingles can result in pain even after the rash is gone.
- The cause of painful diabetic peripheral neuropathy, or diabetic nerve pain, is chronic high blood sugar and diabetes.
- The cause of human immunodeficiency virus (HIV)-associated neuropathy is an infection with that virus.
- The cause of post-traumatic nerve injury is surgery or trauma.

There are already medicines for the treatment of peripheral neuropathic pain. Those medicines may cause unwanted effects or may not work in all patients. The capsaicin 8% patch (“capsaicin patch”) delivers capsaicin into the skin to the nerves that cause pain. The high doses of capsaicin in the patch overstimulate these nerves. The nerves then become less sensitive and can no longer produce pain signals.

The patients in this study had pain caused by different types of peripheral nerve damage. The patients received capsaicin patches on the same painful skin spot several times in a row. This is called repeated applications of the patch. This study looked at sensory function at the painful spots where capsaicin patches were applied. On a scale from 0 (“did not feel”) to 5 (“painful”), patients rated 6 touch tests (light brush, warm, cold, pinprick, reflex and vibration sensations). This study helped answer if repeated applications of the patch made the painful spots less sensitive to the touch tests. Or if this sensitivity stayed the same or got worse after repeated applications of the patch. It was also important to find out what unwanted effects these patients had after repeated applications of the patch.

This study for the capsaicin patch (also known as Qutenza®) took place at 63 clinics in Austria, Belgium, Czech Republic, Finland, France, Greece, Hungary, Ireland, Italy, the Netherlands, Poland, Romania, Slovakia, Slovenia, Spain and the UK. The study took place from October 2010 to September 2013. 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 an “open-label” study. All patients knew that they received capsaicin patches.

Men and women took part in the study. They could be in the study if:

- They were between 18 and 90 years old and in good health according to the study doctor.
- They had peripheral nerve damage. This could be postherpetic neuralgia, HIV-associated neuropathy, post-traumatic nerve injury or other peripheral neuropathy.
- Between study visits 1 and 2, their pain was at least 4 on a scale of zero (“no pain”) to 10 (“pain as bad as you can imagine”). This pain was the average pain.
- The skin of the painful spots was dry and was not damaged or irritated.

Patients could not take part in the study if:

- They had used Qutenza patches in the past.
- They had used opioids within 7 days before the study start. The dose of opioids taken by mouth or as a patch was greater than the dose allowed by the study protocol.
- They did not want to use opioid analgesics. Or they were used to taking high doses of opioids.
- They had drug addiction or alcoholism within 1 year before the study start.
- They had put pain medication on the painful spots within 7 days before the study start.

At visit 1, patients were checked to see if they could be in the study. If patients could be in the study, they kept a daily record of their pain for 4 to 10 days. At visit 2, patients who could stay in the study received capsaicin patches on up to 4 painful spots. The capsaicin patches were put on the feet for 30 minutes. The patches were put on other body locations for 60 minutes. If the pain came back, the patients could receive up to 5 more patch applications at intervals of 12 weeks. Patients whose pain came back early could receive patch applications every 9 weeks. Patients could receive up to 6 patch applications over the study period, which was 1 year.

A total of 306 patients were in this study and received a capsaicin patch.

	<b>Number of Patients (out of 306 patients)</b>
<b>Age Group</b>	
Aged between 18 and 64 years	197
Aged between 65 and 74 years	58
Aged 75 years and older	51
<b>Sex</b>	
Men	174
Women	132
<b>Clinic Location</b>	
EU Countries	306
Austria	15
Belgium	22
Czech Republic	16
Finland	13
France	40
Greece	9
Hungary	5
Ireland	7
Italy	34
The Netherlands	11
Poland	8
Romania	12
Slovakia	5
Slovenia	3
Spain	33
The UK	73
Outside EU	0

### **What Were the Study Results?**

The patients in this study had pain caused by different types of peripheral nerve damage. The patients received repeated applications of the capsaicin patch on their painful spots. This study looked at sensory function at these spots. On a scale from 0 (“did not feel”) to 5 (“painful”), patients rated 6 touch tests (light brush, warm, cold, pinprick, reflex and vibration sensations). The study found that, in general, the painful spots got smaller after 5 patch applications. Most patients rated the sensitivity of their painful spot to the touch tests as the same or worse during the study.

### **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 received at least 1 capsaicin patch. Pain where the study patch was applied was most common in the groups of postherpetic neuralgia and post-traumatic nerve injury. Superficial reddening of the skin was least common in the group of HIV-associated neuropathy. This could be superficial reddening of the skin at a location that was not specified or where the study patch was applied.

Adverse Reaction	Number of Patients				
	Postherpetic Neuralgia (out of 107 patients)	HIV-associated Neuropathy (out of 80 patients)	Post-traumatic Nerve Injury (out of 99 patients)	Other Peripheral Neuropathic Pain (out of 20 patients)	Total (out of 306 patients)
Pain where the study patch was applied	46 (43.0%)	21 (26.3%)	40 (40.4%)	5 (25.0%)	112 (36.6%)
Superficial reddening of the skin (location not specified)	29 (27.1%)	1 (1.3%)	29 (29.3%)	3 (15.0%)	62 (20.3%)
Superficial reddening of the skin where the study patch was applied	24 (22.4%)	2 (2.5%)	19 (19.2%)	6 (30.0%)	51 (16.7%)
Burning sensation	11 (10.3%)	8 (10.0%)	19 (19.2%)	6 (30.0%)	44 (14.4%)
Pain	7 (6.5%)	4 (5.0%)	11 (11.1%)	7 (35.0%)	29 (9.5%)
Leg and/or arm pain	0	9 (11.3%)	0	1 (5.0%)	10 (3.3%)

An adverse reaction is considered “serious” when it is life-threatening, causes lasting problems or needs hospital care. None of the patients experienced a serious adverse reaction. Three patients died during the study. The patients did not die because of capsaicin patches.

### Where Can I Learn More About This Study?

Astellas may perform additional studies to better understand capsaicin patches.

This summary of the clinical study results is available 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. If you have questions about capsaicin patches, please discuss these with your doctor.

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