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European Commission Approves New Pre-treatment Options for QUTENZA(TM) (8% Capsaicin Patch) in Peripheral Neuropathic Pain

Press Release

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Approval allows for more flexible approach to 8% capsaicin patch treatment of peripheralneuropathic pain

CHERTSEY, England, March 14, 2013 /PRNewswire/ -- The European Commission (EC) has approved expanded options for pre-treatment prior to use of QUTENZA (8% capsaicin patch). Before application the patient may now take an oral analgesic, or the treatment area may be pre-treated with a topical anaesthetic.[1] The 8% capsaicin patch is the first and only licensed high concentration (8%) capsaicin cutaneous patch for the treatment of peripheral neuropathic pain in Europe.

The EC approval of the 8% capsaicin patch label amendment is valid in all of the 27 European Union Member States plus Iceland, Liechtenstein and Norway. The regulatory submission was supported by data from the LIFT study, which aimed to investigate the use of an oral analgesic as an alternative form of pre-treatment for the 8% capsaicin patch.

In the LIFT study patients were randomised to either application of lidocaine cream (a topical anaesthetic) or tramadol tablets (an oral analgesic), prior to application of the 8% capsaicin patch.[2],[3] All patients were then treated with the 8% capsaicin patch for 60 minutes and followed up for 7 days to monitor pain scores and tolerability. The primary endpoint of the LIFT study was the proportion of subjects who tolerated 8% capsaicin patch treatment which was defined as a patient using the patch for at least 90% of the intended patch duration. The LIFT study was completed in April 2012 and the results will be presented at The 4th International Congress on Neuropathic Pain (NeuPSIG) in May 2013.

Dr. Arun Bhaskar, Consultant in Pain Medicine, Anaesthesia & Critical Care at The Christie NHS Foundation Trust in Manchester says, "The 8% capsaicin patch has been a useful addition to the management of difficult-to-treat neuropathic pain conditions like post-herpetic neuralgia, HIV neuropathy and chemotherapy-induced neuropathy. This label change will provide greater flexibility to treating clinicians and should enable them to carry out treatment of more patients per session, thus reducing the cost of treatment per patient."

Anne Hodgkins, Senior Brand Director, Pain Management at Astellas Pharma Europe Ltd commented, "Managing peripheral neuropathic pain is challenging and the individual needs of the patient are paramount when treatment decisions are made. We are committed to ensuring the 8% capsaicin patch is an accessible and convenient treatment option for physicians and patients."

Conventional therapies for peripheral neuropathic pain can be restricted by factors such as systemic side effects, drug-drug interactions, slow onset of action, the need for titration and multiple daily dosing.[4],[5],[6] The 8% capsaicin patch is designed to act locally on the affected area and has not been associated with the systemic side effects such as sedation and dizziness.[4],[5],[7]

Notes to editors

About Peripheral Neuropathic Pain

Peripheral neuropathic pain is caused by lesion or disease to the peripheral somatosensory nervous system. Nerve damage that can lead to peripheral neuropathic pain can happen as a result of a range of different diseases, medications or traumatic injuries.

Exactly how many people suffer from neuropathic pain is not known but estimates of the prevalence of neuropathic pain range from 3% to as high as 8% according to a UK study.[8],[9] Estimates vary considerably because of differences in the way neuropathic pain is defined, the way in which the condition is assessed and the selection of patients.[10]

It is a complex and difficult to treat disorder that can have a detrimental effect on a patient's quality of life.[11],[12] Studies suggest that, at present, only around a third of patients receiving treatment for neuropathic pain achieve adequate pain relief.[13]

About the 8% capsaicin patch

8% capsaicin patch is approved by the European Commission for the treatment of peripheral neuropathic pain in non-diabetic adults either alone or in combination with other medicinal products for pain. The 8% capsaicin patch is available in over 21 countries across Europe.[7]

The efficacy and safety of the 8% capsaicin patch have been shown in a broad range of neuropathic pain conditions, including post-herpetic neuralgia and HIV-associated neuropathy.[7],[14],[15],[16],[17] Phase-III clinical studies in painful diabetic neuropathy and longterm safety studies are ongoing.[7],[8]

Pain relief following application of the 8% capsaicin patch can take up to two weeks to take full effect

and can last for up to 12 weeks following a single application.[7] Significant reductions in pain have been achieved with the 8% capsaicin patch when used alone or in combination with other treatments for pain.[7] In addition to providing pain relief, use of the 8% capsaicin patch has been shown to reduce the use of concomitant medications and lead to improvements in quality of life for patients.[20],[21],[22] The most commonly reported side effects with the 8% capsaicin patch are transient and self-limiting application site reactions such as pain and erythema that tend to be mild to moderate in intensity.[7]

The treatment area may be pre-treated with a topical anaesthetic or the patient might be administered an oral analgesic to reduce potential application related discomfort. The 8% capsaicin patch is applied to the area of pain and left in place for either 30 minutes (when used on the feet) or 60 minutes (when used elsewhere on the body).[7] Treatment can be repeated, if required, after 90 days. As a result of treatment-related discomfort, transient increases in blood pressure may occur during and shortly after treatment with the 8% capsaicin patch.[7]

The patch delivers a high-dose of a synthetic form of capsaicin, the substance found in chilli peppers, directly to the damaged pain sensing nerves in the skin.[23] Applied to the area of pain, the high concentration of capsaicin contained in the treatment is released into the skin where it overstimulates the pain sensing nerves. Overstimulating the pain sensing nerves makes them become "defunctionalised", effectively reducing their spontaneous activity and making them unresponsive to stimuli that normally cause pain for patients with peripheral neuropathic pain.[24]

About Astellas Pharma Europe Ltd.

Astellas Pharma Europe Ltd., located in the UK, is the European headquarters of Tokyo-based Astellas Pharma Inc. Astellas is a pharmaceutical company dedicated to improving the health of people around the world through the provision of innovative and reliable pharmaceuticals. The organisation's focus is to deliver outstanding R&D and marketing to continue growing in the world pharmaceutical market. Astellas Pharma Europe Ltd. is responsible for 21 affiliate offices located across Europe, the Middle East and Africa, an R&D site and three manufacturing plants. The company employs approximately 4,300 staff across these regions. For more information about Astellas Pharma Europe, please visit http://www.astellas.eu.

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Astellas Pharma Europe Ltd

CONTACT: Contacts for enquiry or additional information: Astellas Pharma Europe Ltd.: Mindy Dooa, Tel: +44-(0)203-379-8035 / +44-(0)7826-912-339, mindy.dooa@astellas.com; Pegasus: Sylva Michelli, Tel: +44-(0)1903-836745 / +44-(0)7507-598-427, smichelli@pegasuspr.co.uk

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