

Press Release

Astellas Announces Transfer of Qutenza™ to Grünenthal

TOKYO and CHERTSEY – 12 December, 2016: Astellas Pharma Inc. (President and CEO: Yoshihiko Hatanaka, “Astellas”), today announced that Astellas Pharma Europe Ltd. (“Astellas Pharma Europe”) has entered into a definitive agreement with Grünenthal under which Astellas Pharma Europe will transfer the exclusive rights for Qutenza™ (capsaicin 8% patch) in Europe, Middle East and Africa to Grünenthal.

Qutenza is approved by the European Medicines Agency (EMA) for the treatment of peripheral neuropathic pain (PNP) in adults, and given Grünenthal’s heritage in the therapy area, Astellas believes that patients will benefit from the continued access and support this agreement ensures.

This agreement marks the start of a process that will see Astellas Pharma Europe transfer all of its commercialisation rights for Qutenza to Grünenthal in all 28 European Union member states, Switzerland, Iceland, Norway and Lichtenstein, and other East European, Middle East and African countries. It is anticipated to conclude in 2018.

Until the transfer is complete, Astellas will continue to fully support the transition to ensure that patients who rely on Qutenza for the management of their pain are unaffected by this change.

Yukio Matsui, President of Operations, Astellas Pharma Europe commented: “This agreement is a part of our work toward higher quality and efficiency of operations through optimisation of resources and will ultimately provide hope for more patients around the world. Grünenthal has a long track record in pain and will be well placed to provide Qutenza to more patients who stand to benefit. We are looking forward to working closely with Grünenthal to ensure smooth continuation of product supply.”

Gabriel Baertschi, CEO Grünenthal said: “We can look back on many successful partnerships. This agreement is a perfect strategic fit for us, because it will complement our existing business in the field of pain.”

Dott. Alberto Grua, member of the Corporate Executive Board, CCO Europe, North America and Global Operations at Grünenthal added: “This product will give us the opportunity to extend our portfolio in the neuropathic pain area. With our other pain products, Grünenthal has built up a high level of expertise in this area, which will allow us to market Qutenza successfully.”

Astellas reflected the impact from the transfer of Qutenza to Grünenthal in its current fiscal year (from April 1, 2016 to March 31, 2017) financial forecast.

Notes to editors

About Qutenza (capsaicin 8% patch)

The capsaicin 8% patch which was developed by NeurogesX and licensed to Astellas Pharma Europe in 2009 is approved by the European Medicines Agency for the treatment of peripheral neuropathic pain in adults either alone or in combination with other medicinal products for pain.¹ The capsaicin 8% patch is currently approved for use in 27 countries across Europe.

The capsaicin 8% patch delivers a high-dose of capsaicin directly to the damaged nerves in the skin that are the source of neuropathic pain. Applied to the area of pain, the capsaicin reduces their spontaneous activity and consequently reduces the neuropathic pain intensity.

Important information for the capsaicin 8% patch, including safety information, is included in the full Summary of Product Characteristics at: <https://www.medicines.org.uk/emc/medicine/23156>.

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About Astellas

Astellas Pharma Inc., based in Tokyo, Japan, is a company dedicated to improving the health of people around the world through the provision of innovative and reliable pharmaceutical products. We focus on Urology, Oncology, Immunology, Nephrology and Neuroscience as prioritized therapeutic areas while advancing new therapeutic areas and discovery research leveraging new technologies/modalities. We are also creating new value by combining internal capabilities and external expertise in the medical/healthcare business. Astellas is on the forefront of healthcare change to turn innovative science into value for patients. For more information, please visit our website at www.astellas.com/en.

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Cautionary Notes

In this press release, statements made with respect to current plans, estimates, strategies and beliefs and other statements that are not historical facts are forward-looking statements about the future performance of Astellas. These statements are based on management's current assumptions and beliefs in light of the information currently available to it and involve known and unknown risks and uncertainties. A number of factors could cause actual results to differ materially from those discussed in the forward-looking statements. Such factors include, but are not limited to: (i) changes in general economic conditions and in laws and regulations, relating to pharmaceutical markets, (ii) currency exchange rate fluctuations, (iii) delays in new product launches, (iv) the inability of Astellas to market existing and new products effectively, (v) the inability of Astellas to continue to effectively research and develop products accepted by customers in highly competitive markets, and (vi) infringements of Astellas' intellectual property rights by third parties. Information about pharmaceutical products (including products currently in development) which is included in this press release is not intended to constitute an advertisement or medical advice.

Astellas Pharma Inc.

References:

1. European Medicines Agency (2015). European Public Assessment Report for Qutenza (capsaicin). Available at: http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000909/human_med_001008.jsp&mid=WC0b01ac058001d124. Accessed 8 November 2016.

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