



Grünenthal to acquire commercialization rights of *Qutenza*[®] in Europe from Astellas Pharma Europe

- *Grünenthal adds Qutenza[®] to its portfolio to bring benefit to patients by widening treatment options in neuropathic pain*

Aachen, December 12, 2016. Grünenthal Group today announced that it has entered into a definitive agreement with Astellas Pharma Europe Ltd., (“Astellas Pharma Europe”), the European subsidiary of Tokyo-based Astellas Pharma Inc. (“Astellas”), for the exclusive rights to the dermal patch *Qutenza*[®] (capsaicin 8%) in Europe, Middle East and Africa. *Qutenza*[®] is approved by the European Medicines Agency (EMA) for the treatment of peripheral neuropathic pain (PNP).

Grünenthal will hold exclusive rights for *Qutenza*[®] in all 28 European Union member states, Switzerland, Iceland, Norway and Lichtenstein, and other East European, Middle East and African countries.

The high-dose capsaicin (8%) containing dermal patch *Qutenza*[®] (Rx) was developed by NeurogesX and licensed to Astellas Pharma Europe in 2009. The original EMA approval for *Qutenza*[®] was obtained in 2009 for the treatment of peripheral neuropathic pain excluding diabetic polyneuropathy (DPN). Following a label extension in 2015, DPN is now included, thus broadening the *Qutenza*[®] label to all peripheral neuropathic pain subgroups.

Grünenthal, a privately owned mid-cap pharmaceutical company is a recognized specialist in pain and offers a wide range of products and support for physicians and patients. Gabriel Baertschi, CEO Grünenthal said: “We have a clear strategy to further build our pain portfolio through in-house innovation and external acquisition. Adding *Qutenza*[®] is a perfect strategic fit and will broaden the options available to physicians, especially in localized neuropathic pain – an area of remaining high unmet need for patients.”

Dott. Alberto Grua, member of the Corporate Executive Board, CCO Europe, North America and Global Operations at Grünenthal added: “Grünenthal is one of the leading companies in the field of pain in Europe. With our products we have built up a high level of expertise in neuropathic pain which will allow us to market *Qutenza*[®] successfully”.

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.”

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 pain¹. 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>

About Grünenthal

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GRÜNENTHAL GROUP

Press Release



The Grünenthal Group is an independent, family-owned, international research-based pharmaceutical company headquartered in Aachen, Germany. We are an entrepreneurial specialist delivering true benefits to patients. By sustainably investing in research and development above the industrial average, we are committing to innovation in order to treat unmet medical needs and bring value adding products to markets. Grünenthal is a fully integrated research & development company with a long track record of bringing innovative pain treatments and state-of-the-art technologies to patients. Altogether, the Grünenthal Group is present in 32 countries with affiliates in Europe, Latin America and the US. Grünenthal products are sold in more than 155 countries and approx. 5,300 employees work for the Grünenthal Group worldwide. In 2015, Grünenthal achieved revenues of €1.2 bn. More information: www.grunenthal.com .

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 .

About Astellas Pharma Europe Ltd.

Astellas Pharma Europe Ltd. operates in 40 countries across Europe, the Middle East and Africa, and is the EMEA regional business of Tokyo-based Astellas Pharma Inc (Astellas). 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' presence in Europe also includes an R&D site and three manufacturing plants. The company employs over 4,700 people across the EMEA region.

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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