

Grünenthal to enter into hospital segment in Europe with non-invasive drug device

- *Grünenthal receives EU Marketing Authorization for Zalviso® 15 micrograms sublingual tablets for treatment of acute moderate to severe post-operative pain in adult patients*
- *Zalviso® represents first step for Grünenthal to enter into hospital market, building on its leadership in pain therapy innovation*

Aachen, Germany, September 22, 2015. The Grünenthal Group, a family owned international research based pharmaceutical company with headquarters in Germany, today announced that it has received EU marketing authorization for Zalviso® 15 micrograms sublingual tablets for the management of acute moderate to severe post-operative pain in adult patients. With the approval of the Zalviso® 15 micrograms sublingual tablets delivered through the easy-to-use, pre-programmed, non-invasive administration device, Grünenthal will enter the European hospital market and further build its leading position in the area of pain therapy innovation. Grünenthal has in-licensed Zalviso® from AcelRx Pharmaceuticals Inc. (Redwood City, CA, USA) for Europe and Australia. The product will be available to patients in Western Europe in the first half of 2016.

Strong partner for pain and niche indications in Europe

“Grünenthal continuously strives to improve patients’ quality of life. We are delighted that with Zalviso®, we bring a new, innovative therapy to manage post-operative pain to patients in Europe,” says Prof. Dr. Eric-Paul Pâques, CEO Grünenthal and Chairman of the Corporate Executive Board. With its expertise in the area of pain and its track record of bringing value-adding therapies to patients especially in the European and Latin American markets, Grünenthal enriches its pipeline with further products. The company is looking for partnerships in pain projects that are close to market as well as R&D projects in niche areas with a high unmet medical need. The main geographical focus is on Europe and the Latin American region. “The recent marketing authorization clearly shows our ability to successfully manage the complex European regulatory framework to bring hospital products to market that have been developed by one of our partners,” concludes Prof. Dr. Eric-Paul Pâques.

Contact: Fabia Kehren, Corporate Communications
Tel.: +49 241 5691616, Fabia.kehren@grunenthal.com

Grünenthal GmbH, 52099 Aachen, Germany, www.grunenthal.com

GRÜNENTHAL GROUP

Press Release



In December 2013, Grünenthal in-licensed Zalviso® from AcelRx Pharmaceuticals Inc. (Redwood City, CA, USA) for Europe and Australia. Grünenthal submitted a Marketing Authorization Application (MAA) for the medicinal product (Zalviso® 15 micrograms sublingual tablets) to EMA in July 2014. In November 2014, AcelRx received the approval of the CE certificate for the Zalviso® administration device after successful completion of the conformity assessment by the Notified Body BSI (British Standards Institute).

About Zalviso®

Zalviso® is an innovative, pre-programmed, non-invasive, handheld system that allows hospital patients with acute moderate to severe post-operative pain to self-dose with sufentanil sublingual tablets to manage their pain. It allows a strong, sustained and reliable pain relief with a fast onset of action. The sublingual application of sufentanil with the Zalviso® system represents a convenient, comparatively safe and efficient route of administration that is easy to set-up and use. It is designed to optimize post-operative analgesia and to avoid some of the issues associated with the current systems for patient-controlled analgesia (PCA). Such issues include the invasive IV route of delivery of current PCA systems, the complexity of infusion pumps and the relatively high incidence of side effects of orally administered opioids and have been shown to potentially result in harm to patients. Grünenthal holds the rights for Zalviso® in Europe and Australia while AcelRx retains all rights in North America, Asia, Latin America and Middle East/Africa.

About Grünenthal

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, Australia, Latin America and the US. Grünenthal products are sold in more than 155 countries and approx. 5,200 employees are working for the Grünenthal Group worldwide. In 2014, Grünenthal achieved revenues of €1.154 bn. More information: www.grunenthal.com.

Contact: Fabia Kehren, Corporate Communications
Tel.: +49 241 5691616, Fabia.kehren@grunenthal.com

Grünenthal GmbH, 52099 Aachen, Germany, www.grunenthal.com