



## Press Release

### **Grünenthal Initiates Pivotal Phase III Trials in Complex Regional Pain Syndrome**

**Aachen, Germany, June 12, 2018** – Grünenthal announced today that first patients have been enrolled in two trials of the company's pivotal phase III program investigating neridronate for the treatment of Complex Regional Pain Syndrome (CRPS). These two trials, KF7013-02 and KF7013-04, are investigating the efficacy and safety of neridronate in 360 patients with CRPS. Neridronate, a bisphosphonate, is an innovative investigational medicine discovered and developed by Abiogen Pharma and now being further developed by Grünenthal for the US territory.

CRPS is a rare disease and one of the most debilitating chronic pain conditions. Currently, with no FDA or EMA approved drugs available, there is a clear need for effective treatment options to address this significant unmet medical need. As a leading specialist in pain therapy and pain management, Grünenthal is highly committed to providing an innovative treatment for patients affected by CRPS.

"There is a huge unmet medical need in CRPS as this condition may result in loss of the physical function and may lead to significant and sometimes permanent disability. Neridronate has been granted Breakthrough Therapy and Fast Track designation by the FDA and our pivotal phase III development program is the next step to investigate neridronate's potential to make a difference in the lives of patients affected by this debilitating disease.", said Gabriel Baertschi, CEO Grünenthal.

"I'm excited to be part of a pivotal phase III efficacy trial in CRPS. Currently, there is no approved treatment available and affected patients face a permanently high pain level and immense restrictions in their daily life", said Prof. Claudia Sommer, International Coordinating Investigator for one of the trials. "If the efficacy of neridronate is confirmed, quality of life of the patients could be significantly improved."

#### **About KF7013-02 and KF7013-04**

KF7013-02 and KF7013-04 are confirmatory phase III efficacy and safety trials to investigate neridronate's effect on pain and other CRPS symptoms like swelling/edema and allodynia. The primary endpoint assesses the pain reduction after twelve weeks in comparison to placebo. The trials are conducted in the US, EU and certain countries in the Asia Pacific region.

Further information is available on [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

#### **About Neridronate**

Neridronate, an aminobisphosphonate, was discovered and developed for the Italian market by Abiogen Pharma, Pisa, Italy. Abiogen had licensed the development and commercial rights for North, South, Central America and the Caribbean to the U.S.-based company NovaPharm Therapeutics and Grünenthal obtained these rights in 2013.

#### **About CRPS**

Complex Regional Pain Syndrome (CRPS; formerly known as RSD or Reflex Sympathetic Dystrophy) is a debilitating condition characterized by severe, continuous, burning or throbbing pain often occurring in an extremity after injury or



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surgery. The excessive pain is accompanied by changes in skin color, temperature and/or swelling/edema. It is frequently persistent and is ranked as the most painful form of chronic pain that exists today by the McGill Pain Index. CRPS results in loss of physical function, and can lead to significant and sometimes permanent disability. There are currently no FDA or EMA approved treatments for patients with CRPS.

### **About Grünenthal**

Grünenthal is an entrepreneurial, science-based pharmaceutical company specialized in pain, gout and inflammation. Our ambition is to deliver four to five new products to patients in diseases with high unmet medical need by 2022 and become a €2 bn company. We are a fully integrated research & development company with a long track record of bringing innovative pain treatments and state-of-the-art technologies to patients. By sustainably investing in our R&D above the industrial average, we are strongly committed to innovation.

Grünenthal is an independent, family-owned company headquartered in Aachen, Germany. We are present in 32 countries with affiliates in Europe, Latin America and the US. Our products are sold in more than 100 countries and approx. 5,200 employees are working for Grünenthal worldwide. In 2017, Grünenthal achieved revenues of approx. €1.3 bn.

More information: [www.grunenthal.com](http://www.grunenthal.com)

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### **About Abiogen Pharma**

Abiogen Pharma is a privately owned specialist pharmaceutical company focused on bone metabolism and some rare diseases. The Company was founded in 1997 as a spin-off of Istituto Gentili. Abiogen employs about 385 people with its head quarter in Pisa, Italy. The team of R&D of Abiogen Pharma had developed and continues to develop several bisphosphonates, including alendronate, clodronate and neridronic acid. For more information, please visit [www.abiogen.it](http://www.abiogen.it).

### **For further information, please contact:**

Štěpán Kráčala, Head Global Communications

Tel.: +49 241 569-1335, [Stepan.Kracala@grunenthal.com](mailto:Stepan.Kracala@grunenthal.com)

Grünenthal GmbH, 52099 Aachen, Germany

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