

Press Release

Grünenthal starts Phase III trials for resiniferatoxin in osteoarthritis-related pain

- Global Phase III programme to enable marketing authorisation in the EU, the US and Japan for an innovative non-opioid investigational medicine.
- The programme will be conducted across approx. 200 study sites and include more than 1800 patients suffering from pain associated with osteoarthritis.
- Globally, more than 300 million patients suffer from osteoarthritis¹. The global osteoarthritis market is expected to grow to approximately \$11.0 billion in 2025².

Aachen, Germany – 18 August 2022 – Grünenthal announced today that the company has enrolled the first patient in its global clinical Phase III programme for resiniferatoxin (RTX).

RTX is a highly potent Transient Receptor Potential Vanilloid 1 (TRPV1) agonist, with a well-validated mechanism of action. The discovery of TRPV1 was awarded the Nobel Prize of Physiology or Medicine in 2021. If approved, resiniferatoxin may provide patients with long-lasting pain relief with a favourable safety profile. Grünenthal's Phase III programme will include more than 1800 patients with knee osteoarthritis who have exhausted available treatment options and still suffer from moderate to severe pain. Grünenthal will conduct three trials across approximately 200 sites across Europe, the US, Latin America, South Africa and Japan to investigate the efficacy and safety of intra-articular injections of RTX in adults. The efficacy endpoints observed in the trials mainly focus on an improvement in the pain and physical function score in the Western Ontario and McMaster Universities (WOMAC) osteoarthritis index from baseline up to 52 weeks. Upon completion, the Phase III programme is intended to enable marketing approval for RTX in the EU, the US, and Japan. Grünenthal aims to submit a new drug application in 2024, leading to a potential market entry of RTX in 2025.

“More than 300 million patients suffer from osteoarthritis¹, a progressive disease that currently cannot be cured. They often experience debilitating pain as a result of their condition”, says Jan Adams, Chief Scientific Officer Grünenthal. “We strive to provide these patients with a non-opioid treatment option that combines long-lasting pain relief with a functional improvement of the affected joints.”

“The global osteoarthritis market is expected to grow to approximately \$ 11.0 billion in 2025²”, says Gabriel Baertschi, Chief Executive Officer, Grünenthal. “Patients are in need for innovative treatment options with better efficacy than current treatments, and without the side-effects of opioids.”

¹ Cieza, A., Causey, K., Kamenov, K., Hanson, S. W., Chatterji, S., & Vos, T. (2020). Global estimates of the need for rehabilitation based on the Global Burden of Disease study 2019: a systematic analysis for the Global Burden of Disease Study 2019. *The Lancet*, 396(10267), 2006-2017.

² MarketsAndMarkets Report; Osteoarthritis Therapeutics Market by Anatomy (Knee, Hand), Drug Type (NSAIDs, Analgesics, Corticosteroids), Route of Administration (Parenteral), Distribution Channel (Hospital Pharmacies), Purchasing Pattern (Prescription Drugs) - Global Forecast to 2025; 2020.

<https://www.marketsandmarkets.com/Market-Reports/osteoarthritis-therapeutics-market-209565994.html>

Press Release

Grünenthal holds the global rights for RTX since the acquisition of the Swiss biotech company Mestex AG in 2021. If the outcome of the Phase III programme is positive, the company intends to explore the potential of RTX for the treatment of osteoarthritis-related pain in additional joints beyond the knee.

About RTX

RTX is an intra-articular injection of resiniferatoxin developed for the treatment of pain in patients with moderate to severe pain associated with knee osteoarthritis. Resiniferatoxin is a highly potent Transient Receptor Potential Vanilloid 1 (TRPV1) agonist. Its administration can reversibly defunctionalise TRPV1-expressing nociceptors. This may result in long-lasting pain relief. Initial data shows a long-lasting and significant analgesic effect and functional improvements compared to placebo, as well as a favourable safety profile.

About Osteoarthritis

Osteoarthritis (OA) can be defined as a group of distinct but overlapping diseases. They may have different etiologies but similar biological, morphological, and clinical outcomes that affect the articular cartilage, subchondral bone, ligaments, joint capsule, synovial membrane, and periarticular muscles. OA is the most common joint disease in people aged 65 and over. Its etiology is not fully understood, although several related factors include female gender, genetics, metabolism, and excessive mechanical stress. The diagnosis of OA is primarily based on the clinical history and physical examination. The cardinal radiographic features of OA are focal/non-uniform narrowing of the joint space in the areas subjected to the most pressure, subchondral cysts, subchondral sclerosis, and osteophytes.³

Osteoarthritis is a joint disease in which the tissues in the joint break down over time. Common symptoms of osteoarthritis include joint pain, stiffness and swelling, as well as changes in how the joint moves and feeling like the joint is loose or unstable. The most commonly affected joints include the knees, hips, hands, neck and lower back. Treatment of osteoarthritis usually includes exercises, maintaining a healthy weight, wearing braces to help with stability, and taking medication, if prescribed.⁴ Many patients will ultimately require joint replacement surgery.

About Grünenthal

Grünenthal is a global leader in pain management and related diseases. As a science-based, fully-integrated pharmaceutical company, we have a long track record of bringing innovative treatments and state-of-the-art technologies to patients worldwide. Our purpose is to change lives for the better – and innovation is our passion. We are focusing all of our activities and efforts on working towards our vision of a world free of pain.

Grünenthal is headquartered in Aachen, Germany, and has affiliates in 28 countries across Europe, Latin America and the US. Our products are available in more than 100 countries. In 2021, Grünenthal employed around 4,500 people and achieved sales of € 1.5 bn.

More information: www.grunenthal.com

Click here for our [Grünenthal Report 2021/2022](#)

Follow us on:

LinkedIn: [Grünenthal Group](#)

Instagram: [grunenthal](#)

³ ICD-11 <https://icd.who.int/browse11/l-m/en#/http%3a%2f%2fid.who.int%2f%2ficd%2fentity%2f558562409>

⁴ National Institute of Arthritis and Musculoskeletal and Skin Diseases; What Causes Osteoarthritis, Symptoms & More | NIAMS (nih.gov)



Press Release

For further information please contact

Christopher Jansen
Communication Business Partner
Grünenthal GmbH
52099 Aachen
Phone: +49 241 569-1428
E-mail: Christopher.Jansen@grunenthal.com

Florian Dieckmann
Head Global Communication
Grünenthal GmbH
52099 Aachen
Phone: +49 241 569-2555
E-mail: Florian.Dieckmann@grunenthal.com

###