Grünenthal’s resiniferatoxin receives Breakthrough Therapy Designation from U.S. FDA for pain associated with osteoarthritis of the knee

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- Knee osteoarthritis is a progressive condition affecting over 360 million people worldwide and may have severe symptoms, including pain.
- Grünenthal is running a global Phase III programme to investigate the efficacy and safety of intra-articular injections of resiniferatoxin, a non-opioid therapy, in adults with pain associated with knee osteoarthritis.
- The U.S. Food and Drug Administration’s Breakthrough Therapy Designation process aims to expedite the development of investigational medicines intended to treat severe conditions and where preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy on clinically significant endpoints.

Aachen, Germany, 22 May 2023 – Grünenthal today announced that its investigational non-opioid medicine resiniferatoxin (RTX), currently undergoing clinical Phase III development, received Breakthrough Therapy Designation from the U.S. Food and Drug Administration (FDA) for pain associated with osteoarthritis (OA) of the knee. The decision is based on clinical phase I and II data indicating significant pain relief and a favourable safety profile.

“Millions of patients suffering from knee osteoarthritis are waiting for additional treatment options. Resiniferatoxin targets one of the most common and severe symptoms of this currently incurable disease: pain,” says Jan Adams, M.D., Chief Scientific Officer Grünenthal. “The decision shows that the FDA considers osteoarthritis a serious disease and shares our assessment of resiniferatoxin’s potential to make a positive impact. We are hopeful that the Breakthrough Therapy Designation will help us to bring this non-opioid therapy option more quickly to patients.”

Resiniferatoxin is a highly potent Transient Receptor Potential Vanilloid 1 (TRPV1) agonist with a well-validated mechanism of action. The discovery of a number of receptors, including TRPV1, and their role in the perception of temperature and touch was awarded the 2021 Nobel Prize in Physiology or Medicine. If approved, resiniferatoxin has the potential to become a meaningful non-opioid treatment option providing long-lasting pain relief and functional improvement of the affected joint, combined with a favourable safety profile.

Grünenthal is running a Phase III programme studying resiniferatoxin that will include more than 1800 patients with knee osteoarthritis who have insufficient pain relief with available nonsurgical treatment options. The programme comprises three trials across Europe, the United States, Latin America, South Africa and Japan to enable marketing approval for resiniferatoxin in the European Union, the United States, Japan, and other countries worldwide. Grünenthal aims to submit the first Marketing Authorization Application in 2025, leading to a potential market entry of resiniferatoxin in 2025/2026. Globally, over 360 million people are estimated to be affected by OA of the knee.[1] The global osteoarthritis market is expected to grow to approximately $11.0 billion in 2025.[2]

Grünenthal holds the global rights for resiniferatoxin since the acquisition of the Swiss biotech company Mestex AG in 2021 and has since been holistically developing the asset to maximise its positive impact on patients worldwide. Since then, Grünenthal started a global Phase III programme, entered into a development cooperation with NovaQuest Capital Management and a licensing agreement with Shionogi for the Japanese market. If the outcome of the current Phase III programme is positive, Grünenthal intends to explore the potential of resiniferatoxin for the treatment of OA-related pain in other joints beyond the knee.

About Breakthrough Therapy Designation

The Breakthrough Therapy Designation is a process designed by the U.S. Food and Drug Administration (FDA) to expedite the development and review of investigational medicines intended to treat a serious condition.

An investigational medicine must demonstrate preliminary clinical evidence that it may offer a substantial improvement over existing therapies. The FDA evaluates the data and determines whether the investigational medicine meets the criteria for breakthrough therapy status. If so, the company developing the asset is given enhanced guidance and support throughout the development and review process.

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About Osteoarthritis

Osteoarthritis 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 there are several related factors, including female gender, genetics, metabolism, and excessive mechanical stress. The diagnosis of OA is primarily based on 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 OA 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 hands, knees, hips, 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 require joint replacement surgery.

About resiniferatoxin (RTX)

Resiniferatoxin is developed as an intra-articular injection for the treatment of pain in patients 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 Grünenthal

Grünenthal is a global leader in pain management and related diseases. As a science-based, privately-owned 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 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 U.S. Our products are available in approx. 100 countries. In 2022, Grünenthal employed around 4,400 people and achieved revenues of €1.7 bn.

More information: www.grunenthal.com

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1 Long et al., (2022). Publication Prevalence Trends of Site-Specific Osteoarthritis From 1990 to 2019: Findings From the Global Burden of Disease Study 2019. Arthritis & Rheumatology. 74(7); 1172–1183.

[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.

3 ICD-11 https://icd.who.int/browse11/l-m/en#/http://id.who.int/icd/entity/558562409

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

Florian Dieckmann
Head Global Communication Grünenthal
52099 Aachen
Florian.Dieckmann@grunenthal.com

+49 241 569 2555

Christopher Jansen
Communication Business Partner Grünenthal
52099 Aachen
Christopher.Jansen@grunenthal.com
+49 241 569 1428

Company Contact:

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