

Press Release

GRÜNENTHAL & NOVAQUEST



Grünenthal and NovaQuest enter agreement to advance the resiniferatoxin global Phase III program in osteoarthritis

Aachen, Germany, and Raleigh, North Carolina - USA, 29 March 2022 – Grünenthal and NovaQuest announced today that they have entered into an agreement to advance the global clinical Phase III programme of Grünenthal's asset resiniferatoxin (RTX). The investigational medicine is being developed with the aim of providing patients suffering from pain associated with osteoarthritis with a well-tolerated, non-opioid therapy option that is intended to provide long-lasting pain relief and functional improvement of the affected joints.

RTX is a highly potent Transient Receptor Potential Vanilloid 1 (TRPV1) agonist with a well-validated mechanism of action. The Phase III trials will investigate the efficacy, safety and tolerability of RTX in patients with pain associated with osteoarthritis of the knee. The trials will start in 2022 and are designed to meet the requirements for marketing approval in the EU, the US, and Japan.

"Globally, more than 300 million patients suffer from osteoarthritis¹. For many of them, the available treatment options are not sufficient and they may at some point in time experience severe symptoms including pain", says Jan Adams, MD, Chief Scientific Officer Grünenthal. "We are delighted to partner with NovaQuest to invest into the development of this promising asset that may provide benefits to patients who suffer from pain associated with osteoarthritis. This agreement provides Grünenthal headroom for further investments in the execution of its growth strategy and the advancement of a promising pipeline into the clinic."

Under the terms of the agreement, NovaQuest will reimburse Grünenthal's investments into the clinical phase III programme of RTX and share the clinical development and approval risks with Grünenthal. In case of successful development and marketing approval, NovaQuest receives one-time payments or milestones and revenue-based payments over the course of the commercialization.

"NovaQuest is excited to partner with the leading company in the therapeutic area of pain to develop RTX, a promising asset that may enter the market as soon as 2025," says Ryan Wooten, Managing Director at NovaQuest. "We are confident that Grünenthal has the right capabilities in place to position RTX on the global osteoarthritis market and leverage the full potential of the asset for patients in need."

Grünenthal holds the global rights for RTX and is well-positioned to tap into the global osteoarthritis market that is expected to exhibit strong growth from \$7.3 billion in 2020 to approximately \$11.0

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.

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billion in 2025², constituting a large global commercial opportunity. For the indication of knee osteoarthritis only, Grünenthal estimates potential peak sales to be above €1 billion in Europe and the United States. In addition, Grünenthal intends to explore the potential of RTX for the treatment of osteoarthritis-related pain in additional joints beyond the knee.

Osteoarthritis is a progressive condition that currently cannot be cured. The inflamed, swollen, and painful joints limit the mobility of the affected patients and may impact their quality of life significantly.

About Novaquest

NovaQuest Capital Management, located in North Carolina's Research Triangle, is a life science investment firm with a specialization in biopharmaceuticals. Founded in 2010, and with more than \$2.5 billion raised across four funds, NovaQuest provides tailored capital solutions that fund innovation in biopharmaceutical development and invests in compelling healthcare companies with products and technologies aimed at helping humans and animals live healthier, longer, more productive lives.

Learn more at www.novaquest.com.

About RTX

RTX is an intra-articular injection of resiniferatoxin developed for the treatment of pain in patients with advanced 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 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 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 hands, knees, hips, neck and lower back. Treatment of osteoarthritis usually includes exercises, maintaining a healthy weight, wearing

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>

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

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braces to help with stability, and taking medication, if prescribed.⁴ Many patients will require joint replacement surgery.

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 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 29 countries across Europe, Latin America and the US. Our products are available in more than 100 countries. In 2020 Grünenthal employed around 4,500 people and achieved sales of € 1.3 bn.

More information: www.grunenthal.com

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