

## **Press Release**

# Grünenthal to license osteoarthritis pain treatment to Shionogi in Japan in deal of up to > \$ 500 million

**Aachen, Germany – 4 August 2022 –** Grünenthal and Shionogi announced today that they have entered into a licensing agreement for Grünenthal's investigational medicine Resiniferatoxin ("RTX"). Shionogi obtained the exclusive rights to commercialise Grünenthal's asset in Japan for pain associated with osteoarthritis of the knee.

RTX is currently in Phase III of clinical development for the treatment of patients with moderate to severe pain associated with knee osteoarthritis. Osteoarthritis, a progressive and often painful joint disease, is an indication with high unmet medical need. If approved, RTX could become a well-tolerated, non-opioid therapy option for patients, providing long-lasting pain relief and functional improvement of the affected knee joints.

Under the terms of the agreement, Shionogi will obtain the exclusive commercialisation rights for RTX in Japan for a total consideration of up to \$ 525 million plus additional sales based payments. Thereof, Shionogi will pay \$ 75 million upon signature, and further milestone payments of \$ 70 million prior to regulatory approval. The agreement includes competitive investment commitments for launch and commercialisation. Manufacturing and supply of RTX to Shionogi will be carried out exclusively by Grünenthal.

"RTX is a promising asset for more than 300 million patients worldwide who suffer from osteoarthritis<sup>1</sup> and seek a meaningful non-opioid therapy option", says Gabriel Baertschi, Chief Executive Officer, Grünenthal. "With their established presence, strong commercial capabilities and wealth of experience in the pain market, Shionogi is our partner of choice to successfully bring RTX to patients in Japan."

RTX is a highly potent Transient Receptor Potential Vanilloid 1 (TRPV1) agonist with a well-validated mechanism of action. An ongoing clinical Phase III programme across sites in Europe, the US, Latin America, South Africa and Japan aims to enable marketing approval for the investigational medicine. New drug applications, including Japan, are targeted for 2024, leading to a potential market entry of RTX in 2025. If the outcome of the Phase III programme is positive, Grünenthal intends to explore the potential of RTX for the treatment of osteoarthritis-related pain in other joints beyond the knee. The global osteoarthritis market is expected to grow to approximately \$ 11.0 billion in 2025<sup>2</sup>. Japan represents one of the most important markets in Asia, with significant revenue potential for RTX.

#### **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

<sup>&</sup>lt;sup>1</sup> 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.

<sup>&</sup>lt;sup>2</sup> 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



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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.<sup>3</sup>

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. Many patients will ultimately require joint replacement surgery.

#### **About Shionogi**

Shionogi & Co., Ltd. is a leading global research-driven pharmaceutical company based in Japan, dedicated to bringing benefits to patients based on its corporate philosophy of "supplying the best possible medicine to protect the health and wellbeing of the patients we serve." We have declared that it will focus on psychoneurological diseases and pain as priority diseases as well as infectious diseases and contributed to improving the activities of daily living and quality of life and productivity of people suffering from pain. For more information, please visit <a href="https://www.shionogi.com/global/en/contact.html">https://www.shionogi.com/global/en/contact.html</a>

#### **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

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### For further information please contact

Florian Dieckmann Head Global Communication Grünenthal GmbH 52099 Aachen Christopher Jansen Communication Business Partner Grünenthal GmbH 52099 Aachen

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

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



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Phone: +49 241 569-2555 Phone: +49 241 569-1428

E-mail: Florian.Dieckmann@grunenthal.com E-mail: Christopher.Jansen@grunenthal.com

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