



## 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

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<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>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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