

Press Release GRÜNENTHAL

Grünenthal acquires Mestex AG and its Phase-III-ready investigational medicine MTX-071 for the treatment of pain associated with osteoarthritis of the knee

- With the acquisition of Mestex AG, Grünenthal secures global rights for an attractive late-stage asset that could offer an innovative therapy option for millions of patients affected by pain related to osteoarthritis of the knee.
- MTX-071 (resiniferatoxin) is a highly potent TRPV1 agonist. Its intra-articular application leads to a reversible desensitisation and defunctionalisation of the TRPV1 receptor, which can significantly reduce pain for several months.

Aachen, Germany, 12 April 2021 – Today, Grünenthal has announced the acquisition of Mestex AG through the takeover of all of its shares and options. Mestex AG is a Swiss biotech company that has developed the innovative investigational medicine MTX-071 (resiniferatoxin) for the intra-articular treatment of pain associated with osteoarthritis of the knee. The investigational medicine is currently concluding Phase II of clinical development and is about to enter Phase III. Initial data showed a long-lasting and significant analgesic effect and functional improvements compared to placebo (saline injection), as well as a favourable safety profile.

"Osteoarthritis is a progressive condition that currently cannot be cured. The inflamed, swollen and painful joints lead to limitation on mobility of the affected patients and may impact their quality of life significantly. Millions of patients currently receive intra-articular corticosteroids or need to undergo knee replacement surgery as last remaining treatment option," says Jan Adams, MD, Chief Scientific Officer Grünenthal. "With MTX-071, we aim to provide these patients with a well tolerable, non-opioid therapy option that provides long-lasting pain relief and functional improvement of the affected joints."

Grünenthal is currently preparing two pivotal Phase III studies to investigate the efficacy, safety and tolerability of MTX-071 in patients with pain associated with osteoarthritis of the knee. The studies will start in 2021 and they are part of a global development programme aimed at meeting the requirements for approval in the EU, the US, Japan and China. The mechanism of action is well validated by clinical studies with other TRPV1 agonists.

"Through the acquisition of Mestex, Grünenthal is well positioned to tap into the global osteoarthritis market. Over 50 million people are affected by osteoarthritis of the knee across the US and the EU." says Gabriel Baertschi, Chief Executive Officer Grünenthal. "We are confident in the mechanism of action of MTX-071 and will explore its potential for the treatment of osteoarthritis related pain in additional joints."

This acquisition will further strengthen Grünenthal's pain-focused late-stage pipeline. The company recently announced a Phase III trial that studies the efficacy, safety and tolerability of QUTENZA® (capsaicin) 8% topical system in post-surgical neuropathic pain (PSNP) with the goal of expanding the current US label.



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About MTX-071

MTX-071 is an intra-articular injection of resiniferatoxin 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 desensitise and defunctionalise the TRPV1 receptor, which plays a critical role in pain signalling. This can significantly reduce pain for several months. The investigational medicine is currently concluding Phase II and about to enter Phase III. Data shows a long-lasting and significant analgesic effect and functional improvements compared to placebo (saline injection), 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.¹

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 braces to help with stability, and taking medication, if prescribed.² 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

¹ ICD-11 https://icd.who.int/browse11/l-m/en#/http%3a%2f%2fid.who.int%2ficd%2fentity%2f558562409

² National Institute of Arthritis and Musculoskeletal and Skin Diseases; What Causes Osteoarthritis, Symptoms & More | NIAMS (nih.gov)



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