Grünenthal advances proprietary Nociceptin Receptor (NOP) Agonist into Phase II trial in acute pain

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- Potential first-in-class, selective nociceptin receptor (NOP) agonist that aims to provide safe, effective treatment for moderate to severe acute pain.
- Following successful Phase I results earlier this year demonstrating an excellent safety profile, the program has now progressed to Phase II.
- The randomized, double-blind, double-dummy, placebo- and active controlled, 2-part Phase II trial will evaluate the safety, tolerability and efficacy of this novel NOP agonist in patients post bunionectomy surgery. Grünenthal anticipates reporting results in early 2028.

Aachen, Germany, 20 October 2026 –
Grünenthal announced today that the first patient has been enrolled in KF7040-21, a Phase II trial to investigate the efficacy, safety and tolerability of its proprietary nociceptin receptor (NOP) agonist in adults with moderate-to-severe acute pain following bunionectomy. The trial is being conducted at sites in the US, with results expected to be available in early 2028.

The investigational compound has a unique mechanism of action that selectively engages with the NOP receptor and may represent a first-in-class therapy option for acute moderate to severe pain. Earlier this year, the investigational compound was shown to be safe and well-tolerated in a Phase I trial, supporting progression to Phase II.[1]

KF7040-21 is a randomised, double-blind, placebo- and active-controlled Phase II trial comprising a Proof of Concept (PoC) phase and a dose-ranging phase. Overall, up to 400 participants are expected to be enrolled. Initially, 96 participants will be included in the PoC phase. Following completion of this phase, an interim analysis will inform the decision to proceed to the dose-ranging phase, in which up to 304 additional participants may be enrolled to compare three dose levels of the investigational compound with placebo and an active comparator. Further information can be found on clinicaltrials.gov.

“The start of this Phase II trial is an important step in our efforts to provide patients living with pain with novel treatment options,” says Uli Brödl, Chief Scientific Officer at Grünenthal. “By selectively activating the nociceptin receptor, our investigational compound may offer a differentiated approach to deliver safe and effective pain relief.”

About Bunionectomy

Bunionectomy is the surgical procedure for removing a bunion, an enlargement of bone and soft tissue that develops on the side of the foot, which most commonly occurs in the joint at the base of the big toe: the big toe progressively angles outwards towards the smaller toes, creating a bony bump (hallux valgus deformity). Bunions may be caused by hereditary factors, inflammatory arthritic conditions, or through wearing poorly fitting or pointed shoes that constrict the toes.[2]

Bunionectomy is accepted by regulatory authorities as a postoperative hard (bony) tissue pain model in which the analgesic effect of an investigational compound may be evaluated as a treatment for acute pain.[3]

About the NOP Receptor

The Nociceptin/Orphanin Receptor (NOP) is a G protein-coupled receptor whose natural ligand is the 17-amino-acid neuropeptide nociceptin (N/OFQ).[4] NOP agonists have been shown to act as potent analgesics without the potential for abuse liability in pre-clinical models.[5]

Although the NOP receptor shares some sequence identity (~60%) with the opioid receptors ?-OP (MOP), ?-OP (KOP), and ?-OP (DOP), it possesses little or no affinity for opioid peptides or morphine-like compounds. Likewise, opioid receptors possess little affinity towards NOP's endogenous ligand nociceptin.[6]

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 focus 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 2025, Grünenthal employed around 4,100 people and achieved revenues of €1.8 billion.

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[1] Grünenthal Data on File

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