

Grünenthal successfully completes Phase I trial with Nociceptin Receptor (NOP) Agonist

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- The investigational compound has a unique mechanism of action and the potential to become a first-in-class therapy option for the treatment of acute and chronic pain.
- In a Phase I trial, the investigational compound was demonstrated to be safe and well tolerated.
- A Phase II trial will commence later this year.

Grünenthal announced today that the company successfully concluded a Phase I trial evaluating the safety and tolerability of its proprietary NOP agonist. In the trial, which involved 113 healthy participants, the compound was demonstrated to be safe and well tolerated, with no dose-dependent adverse event pattern observed.[1] Grünenthal is now planning to progress its NOP agonist into a Phase II trial that aims to enrol 400 US-based patients undergoing bunionectomy – a well-established model for evaluating the efficacy and safety of a compound as a treatment for acute pain. The trial will commence later this year with results expected in the second half of 2027.

Through its specific selectivity for the nociceptin receptor, Grünenthal's NOP agonist features a unique mechanism of action for the treatment of acute and chronic pain and may present a first-in-class therapy option. The compound has the potential to deliver robust pain relief in a broad range of conditions without the side effects commonly associated with opioids. During the Phase I trial, no such adverse events, including somnolence, constipation or respiratory depression, or events suggesting any abuse liability potential were observed.

"We are excited about the successful completion of our Phase I clinical trial and double down on our efforts to bring the compound to patients", says Uli Brödl, MD, Chief Scientific Officer at Grünenthal. "With selective nociceptin receptor activation, Grünenthal hopes to introduce a new mechanism of action into the pain treatment landscape and provide patients with a much-needed alternative therapy option."

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

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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 μ -OP (MOP), κ -OP (KOP), and δ -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. More information: www.grunenthal.com and follow us on LinkedIn & Instagram For further information, please contact: Christopher Jansen, Global Communications at Grünenthal, christopher.jansen@grunenthal.com

[1] Grünenthal Data on File

[2] my.clevelandclinic.org (accessed 23 June 2026)

[3] Singla et al. Bunionectomy as an Acute Postoperative Pain Model: Overview of Common Experimental Methods, and Insights from Past Clinical Trials. *Journal of Pain Research* 2024; 17: 4399-4420.

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[6] Butour et al. Recognition and activation of the opioid receptor-like ORL 1 receptor by nociceptin, nociceptin analogs and opioids. *European Journal of Pharmacology* 1997; 321(1): 97–103.

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