

Press release

Catalent and Grünenthal Announce Successful Collaboration to Facilitate Expedited Clinical Development Timelines

- Catalent and Grünenthal have reached a milestone in a joint Chemistry, Manufacturing and Controls development project for the reformulation of an investigational medicine to improve its bioavailability
- Catalent provides its integrated development platforms to facilitate trials and accelerate early development to help Grünenthal progress its R&D portfolio.

SOMERSET, N.J., and AACHEN, Germany – March 15, 2023 — Catalent, the leader in enabling the development and supply of better treatments for patients worldwide, and Grünenthal, an international science-driven pharmaceutical company and a global leader in pain research and management, today announced their successful formulation design and clinical-phase manufacturing collaboration for an orally dosed small molecule in Grünenthal's pipeline.

Positive preclinical results from the molecule have allowed Grünenthal to progress its development program to first-in-human studies. In this phase, Catalent supported Grünenthal with the development of a bioavailability enhanced formulation, which, moving forward, enables expedited clinical development timelines.

The two companies have been working together on this program since 2021. Catalent has assisted Grünenthal in reformulating the molecule using a lipid-based drug delivery system formulated in softgel technology to improve its bioavailability. Scientific experts at Catalent's facilities in Beinheim, France, and Nottingham, U.K., carried out this development work using its OptiForm Solution Suite® platform, which allowed the rapid characterization and screening of dose forms and formulation technologies to optimize dose design.

Phase 1 studies of the molecule will be supported by scientists from Beinheim using the Catalent Xpress Pharmaceuticals™ platform, which provides rapid development of clinical formulations and on-demand manufacturing of dose forms at the clinical research organization undertaking the trials. Trials will be run for both single ascending dose (SAD) and multiple ascending dose (MAD) studies based on the real-time results of the adaptive study protocol.

"The OptiForm Solution Suite provides an efficient approach to expedite innovative candidates into first-in-human studies. It does this through assessing a broad range of technical solutions to



identify the most suitable formulation for the specific candidate," said Stephan Bulat, Head of Chemistry, Manufacturing and Controls at Grünenthal. "The Catalent Xpress Pharmaceuticals platform provides the flexibility to efficiently manage our candidates through early clinical development studies, supporting our ambition to achieve best-in-class development timelines."

"With innovators demanding shortened drug development timeframes, Catalent offers a number of integrated solutions to ensure programs can be accelerated to, and through, clinical phases as quickly and safely as possible, while providing design and delivery technology support to give molecules the greatest chance of success," said Ricky Hopson, President, Division Head for Clinical Development and Supply, Catalent. "Working with Grünenthal, we have been able to leverage multiple services that have not only reduced Phase 1 development timelines substantially, but have done so using a formulation and delivery technology that is scalable for future clinical and commercial needs as the program progresses."

Grünenthal is dedicated to creating innovative non-opioid pain treatments that address unmet medical needs. For R&D, Grünenthal executes a distinctive therapeutic area strategy and focuses on four key pain indications: peripheral neuropathic pain, chronic post-surgical pain, chronic low back pain, and osteoarthritis. Grünenthal seeks collaborations in these areas to develop life-changing treatments for patients, independent of the modality and their stage of development. To date, the company has launched six treatment options for patients suffering from pain.

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Notes for Editors

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 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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About Catalent

Catalent is the global leader in enabling pharma, biotech, and consumer health partners to optimize product development, launch, and full life-cycle supply for patients around the world. With broad and deep scale and expertise in development sciences, delivery technologies, and multi-modality manufacturing, Catalent is a preferred industry partner for personalized medicines, consumer health brand extensions, and blockbuster drugs.

Catalent helps accelerate over 1,000 partner programs and launch over 150 new products every year. Its flexible manufacturing platforms at over 50 global sites supply around 80 billion doses of nearly 8,000 products annually. Catalent’s expert workforce of approximately 18,000 includes more than 3,000 scientists and technicians.

Headquartered in Somerset, New Jersey, the company generated nearly \$5 billion in revenue in its 2022 fiscal year. For more information, visit www.catalent.com.

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