Press Release

Pharnext announces successful completion of manufacturing transfer and scale-up of PXT3003 in the United States

PARIS, France, January 26th, 2023, 08:30 am CET – Pharnext SA (FR001400BV89 - ALPHA) (the "Company"), an advanced late-clinical stage biopharmaceutical company developing novel therapeutics for neurodegenerative diseases with high unmet medical need, today announces the successful completion of the manufacturing transfer of PXT3003 from Unither's facility in Colomiers, France, to Unither's U.S.A. facility in Rochester, New York, and manufacturing scale-up of PXT3003 in the United States. Pharnext is now able to manufacture batches of up to 3,500 liters of PXT3003 oral solution, a volume potentially compatible with a commercial supply chain of PXT3003.

If the results of the pivotal Phase III clinical trial of PXT3003 in Charcot-Marie-Tooth disease type 1A (CMT1A), the PREMIER trial, are positive in Q4 2023 and allow a marketing authorization in Europe and the U.S., PXT3003 would be marketed as a 5-mL unit dose oral solution sachet to be stored in a cold chain. These unit dose sachets are designed to deliver the required doses precisely and safely. This change was driven by the willingness to provide a more convenient and flexible form for CMT1A patients to use, allowing for better compliance.

Manufacturing of PXT3003 unit dose sachets used in the PREMIER trial is manufactured at the Unither Colomiers facility in France for the time being. The Unither Rochester facility would be dedicated for commercial manufacturing. Pharnext pursues the development of PXT3003 unit dose oral solution sachets manufacturing process at the Unither Rochester facility and will communicate on this new step when it is completed.

Raj Thota, Chief Manufacturing Officer and Head of CMC, said: "*I am delighted that the PXT3003 manufacturing transfer and scale up from Unither's French and U.S. facilities have been successful. This is an important step in preparing for the potential commercialization of PXT3003, should our lead product obtain marketing authorization for CMT1A, a disease for which there is currently no specific therapeutic solution".*

About Pharnext

Pharnext is an advanced clinical-stage biopharmaceutical company developing novel therapeutics for neurodegenerative diseases that currently lack curative and/or disease-modifying treatments. Pharnext has two lead products in clinical development. PXT3003 completed an international Phase III trial with positive topline results for the treatment of Charcot-Marie-Tooth disease type 1A ('CMT1A') and benefits from orphan drug status in Europe and the United States. An international pivotal Phase III study of PXT3003 in CMT1A, the PREMIER trial, is currently ongoing. PXT864 has generated encouraging Phase II results in Alzheimer's disease and will be advanced through partnerships. Both of Pharnext's lead assets originated from the Pleotherapy™ R&D approach. Pharnext draws the attention of investors to the financial and other risk factors detailed in its financial reports. More information can be found at www.pharnext.com.
Pharnext is listed on the Euronext Growth Stock Exchange in Paris (ISIN code: FR001400BV89).

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