Press Release

Pharnext announces successful manufacturing of registration batches of PXT3003 in the United States

PARIS, France, November 20, 2023, 08:30 am CET – Pharnext SCA (FR001400JXB0 - ALPHA) (the "Company"), an advanced late-clinical stage biopharmaceutical company developing novel therapeutics for neurodegenerative diseases with high unmet medical need, announces the successful manufacturing of the three registration batches of PXT3003 oral solution sachets in the United States (U.S.), utilizing an innovative and state-of-the-art "form-fill-seal liquid sachets technology" and initiated the new drug application (NDA) registration stability at Unither Manufacturing LLC in Rochester, NY (USA).

This will serve as an important step in preparing the NDA submission to the U.S. FDA ("Food and Drug Administration") in 2024 and potential commercialization of PXT3003 for patients with Charcot-Marie-Tooth disease type 1A (CMT1A) in the U.S. if the pivotal Phase III clinical study of PXT3003 (the PREMIER trial) is positive (topline data to be announced in December 2023).

Contingent upon FDA approval, this product will be commercialized as 5-mL unit dose oral solution sachet.
As a reminder, manufacturing transfer and scale-up of PXT3003 were successfully completed in the U.S. in January 2023[1].

Raj Thota, Chief Manufacturing Officer, and Head of CMC of Pharnext, said*: "It gives me immense pleasure to share update on the major milestones: completion of PXT3003 Oral solution registration batches' manufacturing and initiation of the stability for NDA registration. These activities will bring us further closer to our goal of filing NDA in 2024 and a potential launch upon NDA approval in 2025."*

Hugo Brugière, Managing Director, concluded: "*We have taken another major step towards commercializing PXT3003. We are now eagerly awaiting the preliminary data from our pivotal Phase III clinical trial, which are now expected before mid-December. We will specify the timetable in the coming days.*"

Disclaimer
Pharnext arranged convertible bonds financing (OCEAN-BSA) with Global Tech Opportunities 13 which, after receiving the shares resulting from the conversion or exercise of these instruments, will not remain shareholder of the Company.
The shares resulting from the conversion or exercise of the above-mentioned securities will generally be sold on the market at very short notice, which may create strong downward pressure on the share price.
Shareholders may suffer a loss of their invested capital due to a significant fall in the Company's share price, as well as significant dilution due to the large number of securities issued to Global Tech Opportunities 13.
Investors are advised to exercise extreme caution before deciding to invest in the securities of a listed company that carries out such dilutive financing transactions, particularly when they are carried out in succession. The Company wishes to point out that this is not the first dilutive financing transaction it has undertaken.
Investors are invited to familiarize themselves with the risks associated with these transactions, as mentioned in the press release above.

About Pharnext
Pharnext is an advanced clinical-stage biopharmaceutical company developing novel therapies for neurodegenerative diseases currently without satisfactory therapeutic solutions. Pharnext has a first-in-class drug candidate, PXT3003, in development for Charcot-Marie-Tooth disease type 1A (CMT1A), a rare, debilitating, inherited peripheral neuropathy. PXT3003 benefits from orphan drug status in Europe and the United States. In 2018, PXT3003 completed a Phase III clinical trial, the PLEO-CMT trial, with encouraging topline results. This trial was followed by an open-label extension study,

[1] Pharnext announces successful completion of manufacturing transfer and scale-up of PXT3003 in the United States in January 2023.

the PLEO-CMT-FU trial, with 120 patients continuing treatment with PXT3003. Long-term data suggest a sustained benefit, safety, and efficacy, after 6 years of total trial time. An international pivotal Phase III study of PXT3003, the PREMIER trial, enrolling 387 CMT1A patients was completed in August 2023. PREMIER topline results are expected in Q4 2023. PXT3003 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: FR001400JXB0).

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