



Press Release

# Pharnext Announces PXT3003 was Granted Priority Review by the China Food and Drug Administration

PARIS, France, 7.30 am, June 14, 2018 (CEST) – Pharnext SA (FR0011191287 - ALPHA), a biopharmaceutical company pioneering a new approach to the development of innovative drug combinations based on big genomic data and artificial intelligence, today announced that PXT3003 was granted priority review for Charcot-Marie-Tooth Type 1A disease (CMT1A) by the China Food and Drug Administration (CFDA).

Pharnext's first-in-class PLEODRUG™ PXT3003 is currently in a Phase 3 clinical trial in Europe and the United States, with results expected before the end of 2018. PXT3003, developed using Pharnext's R&D platform PLEOTHERAPY™, is a novel oral fixed-low dose combination of baclofen, naltrexone and sorbitol, with EMA and U.S. FDA Orphan Drug Designation.

GeneNet Co, Ltd, a joint venture between Tasly and Pharnext, owns the commercialization rights for PXT3003 for CMT1A in Greater China (Mainland China, Hong Kong, Taiwan, and Macau), as well as exclusive license rights to all PXT3003 patents applied for and authorized in Greater China.

In December 2017, GeneNet applied for clinical approval for PXT3003 to be registered as an imported pharmaceutical in China. PXT3003's inclusion in the priority review process will greatly shorten the waiting time for clinical approval and also expedite registration as an imported pharmaceutical.

"We are pleased that PXT3003 has been identified as a priority by the CFDA, and that its fast-track status will decrease the waiting time for the drug's approval," said Prof. Daniel Cohen, M.D., Ph.D., Pharnext's Co-Founder and CEO.

## **About Pharnext**

Pharnext is an advanced clinical-stage biopharmaceutical company developing novel therapeutics for orphan and common neurodegenerative diseases that currently lack curative and/or disease-modifying treatments. Pharnext has two lead products in clinical development. PXT3003 is currently in an international Phase 3 trial for the treatment of Charcot-Marie-Tooth Type 1A disease and benefits from orphan drug status in Europe and the United States. The results of this trial are expected in the second half of 2018. PXT864 has generated positive Phase 2 results in Alzheimer's disease. Pharnext has developed a new drug discovery paradigm based on big data genomics and artificial intelligence: PLEOTHERAPY™. The Company identifies and develops synergic combinations of drugs called PLEODRUG™ offering several key advantages: efficacy, safety and robust intellectual property. The Company was founded by renowned scientists and entrepreneurs including Professor Daniel Cohen, a pioneer in modern genomics, and is supported by a world-class scientific team.

Pharnext is listed on Euronext Growth Stock Exchange in Paris (ISIN code: FR0011191287). For more information, visit <a href="https://www.pharnext.com">www.pharnext.com</a>.

## **About Tasly**

Tasly Pharmaceutical Group Co., Ltd. was listed on the Shanghai Stock Exchange in August 2002 (Stock Code 600535). The company concept is "To share the joy of health with all" and the company mission "To improve human life and quality of life". Tasly is committed to promoting the integration of Traditional Chinese Medicine (TCM) with modern medical and pharmaceutical technologies. It is also committed to building the first international brand of modernized TCM. "To become the global innovation leader of modern TCM and the scientific standard maker of modern TCM" is our target. To achieve this goal, Tasly will strive to bring modernized TCM to international pharmaceutical standards. To support its development strategy of "Comprehensive Internationalization", Tasly has set up a complete manufacturing chain which respects international guidelines and exploits intelligent manufacturing systems. Based on its "Two Wheels of Innovation and Capitalization" strategy, Tasly has developed several core competitive advantages, such as its R&D model, a multi-level product system, a multi-dimensional patent protection system and a commercial and marketing network.

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