



NeuroBo Pharmaceuticals Announces Continuation of Partial Clinical Hold of Gemcabene

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BOSTON, May 26, 2020 /PRNewswire/ -- **NeuroBo Pharmaceuticals, Inc.** (Nasdaq: NRBO), a clinical-stage biotechnology company focused on developing and commercializing multimodal, disease-modifying therapies for neurodegenerative and cardiometabolic diseases, today announced that it received written communication from the U.S. Food and Drug Administration (FDA) that the clinical development program for Gemcabene, a peroxisome proliferation-activated receptor (PPAR α) agonist, under development as a once-daily, oral therapy for the treatment of dyslipidemia, remains on partial clinical hold. In January 2016, the Gemcabene Phase 2 clinical study was placed on partial clinical hold as the FDA requested 2-year rat and mouse carcinogenicity studies to be completed and submitted.

In May 2018, the company submitted the requested data to the FDA, which the Agency determined was insufficient to lift the partial clinical hold at that time. On April 20, 2020, the company filed an amendment to the FDA's partial clinical hold letter received in June 2018.

"While we are disappointed that the partial clinical hold was not lifted at this time, we plan to request additional clarification regarding the resolution options the FDA suggest in their response letter, in order to better evaluate a path forward for Gemcabene as a treatment for dyslipidemia," said Richard J. Kang, Ph.D., President and Chief Executive Officer of NeuroBo.

About NeuroBo Pharmaceuticals

NeuroBo Pharmaceuticals, Inc. is focused on novel treatments for neurodegenerative and cardiometabolic diseases affecting millions of patients worldwide. The company's multimodal approach has the potential to address multiple underlying mechanisms of neurodegenerative diseases, alleviate symptoms and slow disease progression. The company's drug candidate, NB-01, for the treatment of painful diabetic neuropathy (PDN), has been shown in a Phase 2 study to significantly reduce pain symptoms associated with PDN with a superior safety profile when compared to currently available treatments. Due to the global COVID-19 crisis, a planned Phase 3 study is currently postponed. In the interim, NeuroBo is exploring a potential orphan drug indication and/or a nutraceutical pathway targeting chronic pain for NB-01. NeuroBo's drug candidate, NB-02, is focused on the treatment of Alzheimer's disease and neurodegenerative diseases associated with the pathological dysfunction of tau proteins in the brain. The company is also exploring an orphan drug pathway for NB-02. The company's third program, Gemcabene, is focused on developing and commercializing therapies for the treatment of dyslipidemia, a serious medical condition that increases the risk of life-threatening cardiovascular disease.

NeuroBo Pharmaceuticals was jointly founded by Dr. Roy Freeman, professor of neurology at Harvard Medical School and renowned expert in neuropathic pain, and JK BioPharma Solutions, a biotechnology consulting company, to commercialize natural product-based research into ethical medicines. In December 2019, NeuroBo merged with Gemphire Therapeutics and through such merger, became listed on the Nasdaq Stock Market and added the Gemcabene family of related assets to its portfolio. For more information visit: <https://www.neurobopharma.com>.


Forward Looking Statements

Any statements in this press release that are not statements of historical fact constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These statements include, but are not limited to, statements regarding the development of NeuroBo's product candidates and the therapeutic potential, timing and nature of clinical trials and potential regulatory approval of NeuroBo's clinical programs and pipeline. Forward-looking statements are usually identified by the use of words, such as "believes," "anticipates," "expects," "intends," "plans," "may," "potential," "will," "could" and similar expressions. Actual results may differ materially from those indicated by forward-looking statements as a result of various important factors and risks. These factors, risks and uncertainties include, but are not limited to the factors discussed in the "Risk Factors" section of NeuroBo's Annual Report on Form 10-K and in our other filings with the Securities and Exchange Commission. In addition, the forward-looking statements included in this press release represent NeuroBo's views as of the date hereof. NeuroBo anticipates that subsequent events and developments will cause its views to change. However, while NeuroBo may elect to update these forward-looking statements at some point in the future, NeuroBo specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing NeuroBo's views as of any date subsequent to the date hereof.

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