NeuroBo Pharmaceuticals Announces Submission of IND Application to the FDA for a Phase 2a Clinical Trial of DA-1241 for the Treatment of NASH

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BOSTON, April 3, 2023 /PRNewswire/ -- **NeuroBo Pharmaceuticals, Inc.** (Nasdaq: NRBO), a clinical-stage biotechnology company primarily focused on cardiometabolic diseases, today announced that it has submitted an Investigational New Drug (IND) application to the U.S. Food and Drug Administration (FDA). The IND application supports a Phase 2a clinical trial of DA-1241, a novel G-Protein-Coupled Receptor 119 (GPR119) agonist, in development for the treatment of nonalcoholic steatohepatitis (NASH).

"Filing of the IND for DA-1241 marks the first significant milestone for NeuroBo since acquiring the rights to this very promising cardiometabolic asset which is targeted to address the underserved NASH market," stated Joe Hooker, Interim President and Chief Executive Officer of NeuroBo. "I would like to thank our entire team, who worked tirelessly to move this asset into the IND process, ahead of schedule, bringing us one step closer in the development of this potential therapy, for which there are currently no approved treatments.

"Based on preclinical evidence generated, to date, administration of DA-1241 has shown reduced hepatic steatosis, inflammation, and fibrosis, as well as improved lipid metabolism and glucose control regardless of body weight reduction. Additionally, in Phase 1a/1b clinical studies, DA-1241 was well tolerated in both healthy volunteers and in patients with type 2 diabetes (T2D). It is our belief, based on this evidence, that the mechanism of DA-1241 will translate into a safe and effective treatment for NASH. We look forward to initiating the clinical development for DA-1241 and, if regulatory review of our IND is completed, key upcoming milestones for this program include enrollment of our first patient, expected in the third quarter of this year, with data targeted for the second half of 2024. We also intend to advance our second cardiometabolic asset, DA-1726, through the IND process this year, with the goal of initiating a Phase 1a safety study in the first half of next year, for which data would also be expected in the second half of the year. We are excited about the new direction of the company as well as the potential of these assets and look forward to executing on these new pipeline programs."

The Phase 2a trial of DA-1241 is expected to be a 16-week, multicenter, randomized, double-blind, placebo-controlled, parallel arm study to evaluate the efficacy and safety of DA-1241 in subjects with presumed NASH. The trial is expected to enroll a total of 87 subjects, with a planned maximum of 98 subjects to account for early discontinuations, who will be randomized into 4 treatment groups and will be dosed with: DA-1241 50 mg, DA-1241 100 mg, DA-1241 100 mg/Sitagliptin 100 mg, or Placebo in a 1:2:2:2 ratio. Randomization will be stratified by Type 2 Diabetes Mellitus (T2DM) status at baseline. The primary endpoint is the change from baseline in alanine transaminase (ALT) levels at Week 16/Day 112. Secondary efficacy endpoints include the proportion of subjects with normalization of ALT, relative percent change in liver fat fraction from baseline, absolute change in liver fat from baseline, and proportion of subjects with a 30% or more reduction in liver fat from baseline, among others. Safety will be evaluated by monitoring adverse events (AEs) including determination of serious adverse events (SAEs) and AEs leading to discontinuation and laboratory abnormalities as characterized by type, frequency, timing, severity (mild, moderate, severe), seriousness and relationship to DA-1241, vital signs measurements, clinical laboratory tests and electrocardiogram (ECG) assessments.

About DA-1241
DA-1241 is a novel G-Protein-Coupled Receptor 119 (GPR119) agonist with development optionality as a standalone and/or combination therapy for both NASH and T2D. Agonism of GPR119 in the gut promotes the release of key gut peptides GLP-1, GIP, and PYY. These peptides play a further role in glucose metabolism, lipid metabolism and weight loss. DA-1241 has beneficial effects on glucose, lipid profile and liver inflammation, supported by potential efficacy demonstrated during in vivo preclinical studies. The therapeutic potential of DA-1241 has been demonstrated in multiple pre-clinical animal models of NASH and T2D where DA-1241 reduced hepatic steatosis, inflammation, fibrosis, and improved glucose control. Furthermore, in Phase 1a and 1b human trials DA-1241 was well tolerated in both healthy volunteers and those with T2D.

About NeuroBo Pharmaceuticals
NeuroBo Pharmaceuticals, Inc., is a clinical-stage biotechnology company focused primarily on therapies for cardiometabolic diseases. Its primary therapeutics programs include DA-1241 and DA-1726. DA-1241 is a novel G-Protein-Coupled Receptor 119 (GPR119) agonist, which promotes the release of key gut peptides GLP-1, GIP and PYY, which, in turn, play an important role in glucose metabolism, lipid metabolism and weight loss. DA-1726 is a novel oxyntomodulin (OXM) analogue functioning as a glucagon-like peptide-1 receptor (GLP1R) and glucagon receptor (GCGR) dual agonist. OXM is a naturally-occurring, 37-amino acid peptide hormone that is released from the gut after ingestion of a meal, activating both the GLP-1 and glucagon receptors, prompting reduced food intake as well as an increase in energy expenditure, potentially resulting in superior body weight loss compared to selective GLP-1 receptor agonists. For more information, please visit www.neurobopharma.com.

Forward Looking Statements
Certain statements in this release may be considered forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including without limitation, statements about the closing of the offering of securities. Forward-looking statements are predictions, projections and other statements about future events that are based on current expectations and assumptions and, as a result, are subject to risks and uncertainties. Many factors could cause actual future events to differ materially from the forward-looking statements in this release, including, without limitation, those risks associated with our ability to execute on our commercial strategy, the timeline for regulatory submissions, regulatory steps and potential regulatory approval of our current and future product candidates, the ability to realize the benefits of the license agreement with Dong-A ST Co. Ltd., including the impact on future financial and operating results of NeuroBo; the ability to integrate the new product candidates into NeuroBo's business in a timely and cost-efficient manner; the cooperation of our contract manufacturers, clinical study partners and others involved in the development of our current and future product candidates; our ability to recruit subjects for our clinical trials; costs related to the license agreement, known and unknown, including costs of any litigation or regulatory actions relating to the license agreement; changes in applicable laws or regulations;

effects of changes to NeuroBo's stock price on the terms of the license agreement and any future fundraising; and other risks and uncertainties described in our filings with the SEC. Forward-looking statements speak only as of the date when made. NeuroBo does not assume any obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

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