NeuroBo Pharmaceuticals Receives First Site IRB Approval for its Phase 2a Clinical Trial Evaluating DA-1241 for the Treatment of NASH

August 3, 2023

BOSTON, Aug. 3, 2023 /PRNewswire/ -- **NeuroBo Pharmaceuticals, Inc.** (Nasdaq: NRBO), a clinical-stage biotechnology company on a quest to transform cardiometabolic diseases, today announced that it has received the first site Institutional Review Board (IRB) approval for Zeid Kayali, M.D., Medical Director at Inland Empire Liver Foundation, in Rialto, CA, to proceed with the Phase 2a clinical trial of DA-1241, a novel G-Protein-Coupled Receptor 119 (GPR119) agonist, for the treatment of nonalcoholic steatohepatitis (NASH). The dosing of the first patient in part one of the two-part, Phase 2a clinical trial of DA-1241 is expected to occur in September of 2023.

"With this first IRB approval, we have achieved another significant milestone in the clinical development of DA-1241," stated Joe Hooker, Interim President and Chief Executive Officer of NeuroBo. "This promising cardiometabolic asset has been shown to be well tolerated in both healthy volunteers and in patients with type 2 diabetes mellitus (T2DM) in Phase 1a/1b clinical studies. Additionally, the therapeutic potential of DA-1241 has been demonstrated in multiple pre-clinical animal models of NASH and T2DM where DA-1241 reduced hepatic steatosis, inflammation, fibrosis, and improved glucose control. As a result, we believe that the mechanism of action of DA-1241 will translate into a safe and effective treatment for NASH. We look forward to working closely with our contract research organization (CRO) partner and our investigators, such as Dr. Kayali, to start screening this month and expect to dose the first patient in September of this year. The two-part design provides optionality for an interim analysis in the first half of 2024 and an anticipated full data readout in the second half of 2024."

The two-part, Phase 2a trial of DA-1241 is designed to be a 16-week, multicenter, randomized, double-blind, placebo-controlled, parallel clinical study to evaluate the efficacy and safety of DA-1241 in subjects with presumed NASH and confirmed pre-diabetes or T2DM.

- **Part 1**: will explore the efficacy of DA-1241 versus placebo, and is expected to enroll 49 subjects, with a planned maximum of 55 subjects to account for early discontinuations. Subjects will be randomized in a 1:2:1 ratio into 3 treatment groups: DA-1241 50 mg, DA-1241 100 mg, or placebo.
- **Part 2:** will explore the efficacy of DA-1241 in combination with sitagliptin versus placebo and will begin after completion of a confirmatory preclinical safety study of DA-1241 in combination with sitagliptin. It is expected to enroll 37 subjects, with a planned maximum of 43 subjects to account for early discontinuations, and subjects will be randomized in a 2:1 ratio into 2 treatment groups: DA-1241 100 mg/sitagliptin 100 mg or placebo.

For both Parts 1 and 2, the primary endpoint is the change from baseline in alanine transaminase (ALT) levels at Week 16. Key, secondary efficacy endpoints include the proportion of subjects with normalization of ALT, absolute change in aspartate transaminase (AST), gamma glutamyl transpeptidase (GGT), and alkaline phosphatase (ALP) from baseline, and absolute change in total cholesterol, low- and high-density lipoprotein cholesterol, triglyceride, and free fatty acids from baseline, among others.

Safety will be evaluated by monitoring adverse events (AEs), serious adverse events (SAEs) and AEs leading to discontinuation and laboratory abnormalities.

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 T2DM. In preclinical studies, DA-1241 demonstrated that GPR-119 agonism promotes the release of the key gut peptides GLP-1, GIP, and PYY, which have a beneficial effect on liver inflammation, lipid metabolism, weight loss, and glucose metabolism. The therapeutic potential of DA-1241 has been demonstrated in multiple pre-clinical animal models of NASH and T2DM whereby DA-1241 reduced hepatic steatosis, hepatic inflammation, and liver fibrosis, while also improving glucose control. Furthermore, in Phase 1a and 1b trials, DA-1241 was well tolerated in both healthy volunteers and those with T2DM.

About NeuroBo Pharmaceuticals
NeuroBo Pharmaceuticals, Inc. is a clinical-stage biotechnology company on a quest to transform cardiometabolic diseases. The company is currently developing DA-1241 for the treatment of Non-Alcoholic Steatohepatitis (NASH) and Type 2 Diabetes Mellitus (T2DM), and is developing DA-1726 for the treatment of obesity. 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. In preclinical studies, DA-1241 demonstrated positive effect on liver inflammation, lipid metabolism, weight loss, and glucose metabolism, reducing hepatic steatosis, hepatic inflammation, and liver fibrosis, while also improving glucose control. DA-1726 is a novel oxyntomodulin (OXM) analogue that acts as a glucagon-like peptide-1 receptor (GLP1R) and glucagon receptor (GCGR) dual agonist. OXM is a naturally-occurring gut hormone that activates GLP1R and GCGR, thereby decreasing food intake while increasing energy expenditure, thus potentially resulting in superior body weight loss compared to selective GLP1R 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 initiate and complete clinical trials on a timely basis; 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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