NeuroBo Pharmaceuticals Receives Safety Review Committee Approval to Continue With Its Phase 2a Clinical Trial Evaluating DA-1241 for the Treatment of MASH

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Blinded Safety Review Completed for the First 6 Months of the Phase 2a Clinical Trial Conduct; Recommending Trial Continue Without Modification

Full Data Readout Expected in the Second Half of 2024

CAMBRIDGE, Mass., March 13, 2024 /PRNewswire/ -- **NeuroBo Pharmaceuticals, Inc.** (Nasdaq: NRBO), a clinical-stage biotechnology company focused on transforming cardiometabolic diseases, today announced receipt of Safety Review Committee (SRC) approval, recommending that the two-part Phase 2a trial of DA-1241, a novel G-Protein-Coupled Receptor 119 (GPR119) agonist for the treatment of metabolic dysfunction-associated steatohepatitis (MASH), continue without modification following a blinded safety review of the first six months of study conduct. The Phase 2a clinical trial is designed to evaluate the efficacy and safety of DA-1241, for the treatment of MASH. The company anticipates a full data readout from the trial in the second half of 2024.

"The SRC's recommendation that the trial continue without modification based on no findings of significant adverse safety trends during the first six months of study conduct, is an early indication of the safety of our most advanced cardiometabolic asset, DA-1241, for patients with presumed MASH, a disease with no currently approved treatment options," stated Hyung Heon Kim, President and Chief Executive Officer of NeuroBo. "Based on the pre-clinical and clinical evidence generated to date, DA-1241 has demonstrated reduced hepatic steatosis, hepatic inflammation and liver fibrosis, while also improving glucose control, and was shown to be well tolerated in both healthy volunteers and in patients with type 2 diabetes mellitus (T2DM). We continue to believe that the mechanism of action of DA-1241 will translate into a safe and effective treatment for MASH and look forward to another blinded SRC analysis once the first 50% of patients have been randomized and dosed."

Each of the two-parts of the Phase 2a trial of DA-1241 are designed to be 16-week, multicenter, randomized, double-blind, placebo-controlled, parallel clinical studies to evaluate the efficacy and safety of DA-1241 in subjects with presumed MASH. Part 1 is exploring 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, which will explore the efficacy of DA-1241 in combination with sitagliptin versus placebo, is expected to enroll approximately 37 subjects who will be randomized in a 2:1 ratio into 2 treatment groups: DA-1241 100 mg/sitagliptin 100 mg or placebo.

For both Part 1 and Part 2, the primary endpoint is the change from baseline in alanine transaminase (ALT) levels at Week 16. Secondary efficacy endpoints include the proportion of subjects with normalization of ALT, absolute change in total cholesterol, low and high-density lipoprotein cholesterol, triglycerides, 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.

For more information on this clinical trial, please visit: www.clinicaltrials.gov NCT06054815.

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 MASH 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 MASH 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 focused on transforming cardiometabolic diseases. The company is currently developing DA-1241 for the treatment of Metabolic Dysfunction-Associated Steatohepatitis (MASH) 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 that promotes the release of key gut peptides GLP-1, GIP, and PYY. In preclinical studies, DA-1241 demonstrated a 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 functions 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. Words such as "believes", "expects", "anticipates", "may", "will", "should", "seeks", "approximately", "intends", "projects," "plans", "estimates" or the negative of these words or other comparable terminology (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements. 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 NeuroBo's ability to execute on its commercial strategy; the timeline for regulatory submissions; ability to obtain regulatory approval through the development steps of NeuroBo's 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 cooperation of our contract manufacturers, clinical study partners and others involved in the development of NeuroBo's current and future product candidates; potential negative interactions between our product candidates and any other products with which they are combined for treatment; NeuroBo's ability to initiate and complete clinical trials on a timely basis; our ability to recruit subjects for its clinical trials; whether NeuroBo receives results from NeuroBo's clinical trials that are consistent with the results of pre-clinical and previous clinical trials; impact of costs related to the license agreement, known and unknown, including costs of any litigation or regulatory actions relating to the license agreement; effects of 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, except as required by law.

Contacts:

NeuroBo Pharmaceuticals
Marshall H. Woodworth
Chief Financial Officer
+1-857-299-1033
marshall.woodworth@neurobopharma.com

Rx Communications Group
Michael Miller
+1-917-633-6086
mmiller@rxir.com

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