NeuroBo Pharmaceuticals Completes Enrollment of Part 1 of Its Phase 2a Clinical Trial Evaluating DA-1241 for the Treatment of MASH

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Full Data Readout Expected in the Second Half of 2024

CAMBRIDGE, Mass., April 1, 2024 /PRNewswire/ -- **NeuroBo Pharmaceuticals, Inc.** (Nasdaq: NRBO), a clinical-stage biotechnology company focused on transforming cardiometabolic diseases, today announced the completion of enrollment of Part 1 of its two-part, Phase 2a clinical trial evaluating the efficacy and safety, of DA-1241, a novel G-Protein-Coupled Receptor 119 (GPR119) agonist for the treatment of metabolic dysfunction-associated steatohepatitis (MASH). Approximately 49 patients with presumed MASH have been randomized into Part 1 with a 1:2:1 ratio into 3 treatment groups: DA-1241 50 mg, DA-1241 100 mg, or placebo.

"Enrollment of the final patient in Part 1 our Phase 2a clinical trial of DA-1241, in patients with presumed MASH, is another important event in the clinical development of our cardiometabolic assets," stated Hyung Heon Kim, President and Chief Executive Officer of NeuroBo. "Part 2 of this Phase 2a trial, exploring the efficacy of DA-1241 in combination with sitagliptin, a DPP-4 inhibitor, continues to enroll patients, which we believe will show synergistic effects compared to DA-1241 alone. As previously reported, DA-1241 was well tolerated in healthy volunteers and in patients with type 2 diabetes mellitus (T2DM). Based on the pre-clinical and clinical evidence to date, we believe that the unique mechanism of action of this promising cardiometabolic asset, targeting the inflammation associated with MASH, will translate into a safe and effective treatment for this disease. We look forward to reporting the full trial data expected in the second half of this year."

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 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) and serious adverse events (SAEs) 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 type 2 diabetes (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 MASH and T2D where DA-1241 reduced hepatic steatosis, inflammation, fibrosis, and improved 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.

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