NeuroBo Pharmaceuticals Reports Positive Pre-Clinical Safety Data of DA-1241 in Combination with Sitagliptin and Opens Enrollment for Part 2 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., Jan. 18, 2024 /PRNewswire/ -- **NeuroBo Pharmaceuticals, Inc.** (Nasdaq: NRBO), a clinical-stage biotechnology company focused on transforming cardiometabolic diseases, today announced positive pre-clinical safety data of DA-1241, a novel G-Protein-Coupled Receptor 119 (GPR119) agonist, in combination with sitagliptin, a DPP4 inhibitor. Additionally, having satisfied its 45-day commitment with the U.S. Food and Drug Administration (FDA) related to its amended protocol, the company has opened enrollment for Part 2 of its Phase 2a clinical trial of DA-1241 when co-administered with sitagliptin for the treatment of metabolic dysfunction-associated steatohepatitis (MASH).

The pre-clinical results demonstrated that once daily oral administration in rats, of sitagliptin alone (180 mg/kg/day), DA-1241 alone (100 mg/kg/day), or sitagliptin in combination with DA-1241 (up to 180/100 mg/kg/day sitagliptin+DA-1241) for 13 weeks, was well tolerated with no adverse effects.

"Initiating Part 2 of our clinical study of DA-1241 in MASH patients paves the way to begin dosing in combination with sitagliptin, marking another significant clinical milestone for our most advanced asset," stated Hyung Heon Kim, President and Chief Executive Officer of NeuroBo. "Based on the pre-clinical evidence to date, DA-1241 has been shown to improve both hepatic and systemic inflammation effectively, and the combination with sitagliptin increased the anti-inflammatory effects compared to DA-1241 as a monotherapy. As previously reported, DA-1241 was also well tolerated in healthy volunteers and in patients with type 2 diabetes mellitus (T2DM). Given the totality of this data, we believe that the mechanism of action could allow DA-1241 to become a safe and effective treatment for MASH, and its anti-MASH and anti-diabetic effects could be potentiated when co-administered with a DPP4 inhibitor. We expect to report the full data from the Part 2 trial in the second half of 2024."

Each of the two-parts of the 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 MASH. Part 1, currently dosing subjects, is exploring the efficacy of DA-1241 versus placebo, and is expected to enroll approximately 49 subjects, who 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, 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, 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 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.

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