



NeuroBo Pharmaceuticals Completes Last Patient Last Visit in Its Phase 2a Clinical Trial Evaluating DA-1241 for the Treatment of MASH

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Topline Data Readout From Part 1 and Part 2 Expected in December 2024

CAMBRIDGE, Mass., Nov. 4, 2024 /PRNewswire/ -- [NeuroBo Pharmaceuticals, Inc.](#) (Nasdaq: NRBO), a clinical-stage biotechnology company focused on transforming cardiometabolic diseases, today announced the completion of the last patient last visit in 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).

"Completion of patient dosing in the Phase 2a clinical trial of DA-1241, in patients with presumed MASH, marks an important milestone for this promising cardiometabolic asset, bringing us one step closer to the topline data readout from both Part 1 and Part 2 of the Phase 2a clinical trial expected in December of this year," stated Hyung Heon Kim, President and Chief Executive Officer of NeuroBo. "As a reminder, Part 1 of this Phase 2a trial is exploring DA-1241 compared to placebo, while Part 2 is investigating the efficacy of DA-1241 in combination with sitagliptin, a DPP-4 inhibitor, which we believe will show synergistic effects compared to DA-1241, alone. In a previously reported Phase 1 study, DA-1241 was well tolerated in both healthy volunteers and individuals diagnosed with type 2 diabetes mellitus (T2DM). Based on the pre-clinical and clinical evidence, we maintain our belief that the distinctive mechanism of action DA-1241, which addresses the inflammation linked to MASH, will result in a safe and effective therapeutic option for this disease."

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. A total of 109 patients were randomized, while 95 patients completed the dosing. These patients were enrolled in either Part 1, which is exploring the efficacy of DA-1241 versus placebo, and randomized in a 1:2:1 ratio into 3 treatment groups: DA-1241 50 mg, DA-1241 100 mg or placebo, or into Part 2, which is exploring the efficacy of DA-1241 in combination with sitagliptin versus placebo, 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-1726 for the treatment of obesity, and is developing DA-1241 for the treatment of Metabolic Dysfunction-Associated Steatohepatitis (MASH). 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. 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 pre-clinical 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.

For more information, please visit www.neurobopharma.com.

Forward Looking Statements

Certain statements in this press 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", "potential", "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 press release, including, without limitation, those risks associated with NeuroBo's ability to execute on its commercial strategy; the timeline for regulatory submissions; the 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 NeuroBo's contract manufacturers, clinical study partners and others involved in the development of NeuroBo's current and future product candidates; potential negative interactions between NeuroBo's 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; NeuroBo's 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; the effects of changes in applicable laws or regulations; the 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 NeuroBo's filings with the Securities and Exchange Commission, including NeuroBo's most recent Annual Report on Form 10-K. 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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