



NeuroBo Pharmaceuticals Doses First Patient in the MAD Part 2 of Its Phase 1 Clinical Trial Evaluating DA-1726 for the Treatment of Obesity

June 26, 2024

Top-Line Data Readout From the Single Ascending Dose Part 1 Expected in the Third Quarter of 2024, and From the Multiple Ascending Dose Part 2 in the First Quarter of 2025

Planned Part 3 Will Assess Total Weight Loss at 24 Weeks, Exploring Maximum Titratable Dose and Dietary Changes; Interim Data Readout Expected Mid-2026 with Top-Line Data in the Second Half of 2026

Recent Financing of up to \$70 million Will Fund the Ongoing Clinical Development of DA-1726

CAMBRIDGE, Mass., June 26, 2024 /PRNewswire/ -- [NeuroBo Pharmaceuticals, Inc.](#) (Nasdaq: NRBO), a clinical-stage biotechnology company focused on transforming cardiometabolic diseases, today announced dosing of the first patient in the multiple ascending dose (MAD) Part 2 of its Phase 1 clinical trial of DA-1726, a novel, dual oxyntomodulin (OXM) analog agonist that functions as a glucagon-like peptide-1 receptor (GLP1R) and glucagon receptor (GCGR), for the treatment of obesity.

"Dosing of the first patient in Part 2 of this trial, late in the second quarter, ahead of schedule, is a further reflection of our strong commitment to swiftly advancing the clinical development of DA-1726, which holds promise as a highly differentiated therapy for the treatment of obesity," stated Hyung Heon Kim, President and Chief Executive Officer of NeuroBo. "As we have noted previously, in pre-clinical mouse models, DA-1726 showed superior weight loss versus semaglutide (Wegovy®) and resulted in similar weight reduction while consuming more food compared to tirzepatide (Zepbound®). Additionally, as we presented at the American Diabetes Association 84th Scientific Sessions, DA-1726 also demonstrated superior weight loss, compared to survodutide, a drug with the same mechanism of action, while also demonstrating retention of relative lean body mass preservation compared to survodutide and exhibiting superior glucose lowering. Based on this evidence, we believe that DA-1726 may potentially distinguish itself as a best-in-class obesity drug with a better tolerability profile than currently marketed GLP-1 agonists, as well as those in late-stage clinical trials, given its balanced activation of GLP1R and glucagon receptors, while increasing energy expenditure. Both Part 1 and Part 2 of the Phase 1 trial are proceeding well, and we anticipate reporting top-line data from the SAD Part 1 during the third quarter of this year, and from the MAD Part 2 in the first quarter of 2025.

"We are now well capitalized to execute on our upcoming DA-1726 milestones following our recent, successful financing of up to \$70 million in aggregate gross proceeds, with \$20 million upfront and \$50 million of clinical milestone-based warrants, which we expect will enable us to fully fund a planned multicenter, randomized, double-blind, placebo-controlled Part 3 of this Phase 1 trial, which would begin upon completion of Part 2. Part 3 will explore changes in baseline, at 24 weeks, for total weight loss, dietary changes, weight loss through fat or lean muscle mass reduction, maximum-tolerated individualized dose and other exploratory endpoints. We believe this planned Part 3 will help position the novel DA-1726 drug candidate as a potentially best-in-class GLP1R/GCGR dual agonist for the treatment of obesity. Upon clearance of an updated Investigational New Drug (IND) application with the U.S. Food and Drug Administration, we expect to dose the first patient in the third quarter of 2025, provide an interim data readout in or around mid-2026 and issue top-line results in the second half of 2026."

The Phase 1 trial is currently designed to be a randomized, placebo-controlled, double-blind, two-part study to investigate the safety, tolerability, pharmacokinetics (PK), and pharmacodynamics (PD) of single and multiple ascending doses of DA-1726 in obese, otherwise healthy subjects. The Part 1 SAD study is expected to enroll approximately 45 participants, randomized into one of 5 planned cohorts. Each cohort will be randomized in a 6:3 ratio of DA-1726 or placebo. Part 2 is designed as a MAD study, expected to enroll approximately 36 participants, who will be randomized at the same 6:3 ratio into 4 planned cohorts, each to receive 4 weekly administrations of DA-1726 or placebo.

The primary endpoint will assess the safety and tolerability of DA-1726 by monitoring adverse events (AEs), serious adverse events (SAEs), treatment emergent adverse events (TEAEs) and AEs leading to treatment discontinuation. Secondary endpoints include the PK of DA-1726, assessed via serum concentrations over time and metabolite profiling at the highest doses of DA-1726. Exploratory endpoints will include the effect of DA-1726 on metabolic parameters, cardiac parameters, fasting lipid levels, body weight, waist circumference and body mass index (BMI), among others.

For more information on this clinical trial, please visit: www.clinicaltrials.gov NCT06252220.

About DA-1726

DA-1726 is a novel oxyntomodulin (OXM) analogue functioning as a GLP1R/GCGR dual agonist for the treatment of obesity and Metabolic Dysfunction-Associated Steatohepatitis (MASH) that is to be administered once weekly subcutaneously. DA-1726 acts as a dual agonist of GLP-1 receptors (GLP1R) and glucagon receptors (GCGR), leading to weight loss through reduced appetite and increased energy expenditure. DA-1726 has a well understood mechanism and, in pre-clinical mice models, resulted in improved weight loss compared to semaglutide and cotadutide (another OXM analogue). Additionally, in pre-clinical mouse models, DA-1726 elicited similar weight reduction, while consuming more food, compared to tirzepatide and survodutide, while also preserving lean body mass and demonstrating improved lipid-lowering effects compared to survodutide.

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 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 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. 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 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", "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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