NeuroBo Pharmaceuticals Announces Positive Recommendation from Independent Data Safety Monitoring Committee of Phase 2/3 Clinical Trial of ANA001 in Hospitalized Patients with Moderate to Severe COVID-19

October 13, 2021

Committee Advises Continuation of Trial Without Modification

BOSTON, Oct. 13, 2021 /PRNewswire/ -- **NeuroBo Pharmaceuticals, Inc.** (Nasdaq: NRBO), a clinical-stage biotechnology company focused on developing and commercializing multimodal disease-modifying therapies for viral, neuropathic and neurodegenerative diseases, today announced that an independent Data Monitoring Committee (DMC) reviewed safety data from 36 patients treated in the Phase 2/3 clinical trial of NeuroBo's lead drug candidate, ANA001, a proprietary oral niclosamide formulation being developed as a potential treatment for COVID-19. Based on those findings, the DMC recommended the continuation of the trial without modification.

The two-part Phase 2/3 multi-center, double blind, placebo-controlled study to assess safety, tolerability, and efficacy of ANA001 is being conducted in the U.S. In both phases of the study, hospitalized patients with moderate to severe COVID-19 (patients not requiring ventilators) receive a seven-day course of ANA001 (niclosamide capsules) in addition to standard-of-care treatment. The Phase 2 part of the trial is expected to enroll 60 patients and the primary objective is to assess safety and tolerability. Secondary objectives include measurements of efficacy (median time to hospital discharge) and pharmacokinetics (PK).

The Phase 3 part of the trial is expected to enroll several hundred patients, with the primary endpoints being median time to hospital discharge, safety and tolerability. Secondary objectives will evaluate clinical improvement and the need and duration for rescue therapy.

"The DMC's recommendation to continue enrollment of the Phase 2/3 clinical trial, without modification, is an important milestone for our lead drug candidate, ANA001, as a potential treatment for COVID-19," stated Richard J. Kang, Ph.D., President and Chief Executive Officer of NeuroBo. "We look forward to continuing the development of this potentially life-saving therapy to address the ongoing need for safe and effective COVID-19 treatments, particularly as this pandemic is evolving into an endemic. We expect to complete the Phase 2 portion of the trial in the fourth quarter of this year and to achieve a number of value-creating milestones with this program in the coming months, including initiation of the Phase 3 of trial."

For more information on this clinical trial, please visit: www.clinicaltrials.gov, NCT04603924

About Niclosamide and ANA001

ANA001 is a proprietary oral niclosamide formulation in development as a treatment for patients with COVID-19. Niclosamide has antiviral and anti-inflammatory properties, and a well-understood safety profile in humans. ANA001 is currently being studied in a 60-subject Phase 2 clinical trial conducted in the U.S. Niclosamide has demonstrated both antiviral and immunomodulatory activity with possible downstream effects on coagulation abnormalities observed in COVID-19. In preclinical research by an independent academic group published in Antimicrobial Agents and Chemotherapy, niclosamide inhibited viral replication in vitro and was more potent than remdesivir in the same assay.

Additional in vitro studies have shown that niclosamide prevents replication of SARS-CoV-2 at very low concentrations and that the compound appears to exhibit three distinct mechanisms of action: 1) acting as a potent antiviral against a variety of other viruses including influenza; 2) reducing inflammation without suppressing the immune system; and 3) providing bronchodilation, which is a useful pulmonary mechanism for at-risk patients with underlying pulmonary and/or cardiovascular conditions.

As a result, the company believes ANA001 has the potential to reduce viral load and inflammation associated with cytokine dysregulation, acute respiratory distress syndrome (ARDS), and coagulation abnormalities and thus improve time to clinical improvement defined as hospital discharge recorded using the WHO Ordinal Scale for Clinical Improvement.

The company believes ANA001 has distinct competitive advantages in this market, including (1) offering an effective treatment for COVID-19; (2) having 3+ year marketing exclusivity in the U.S. upon U.S. Food and Drug Administration (FDA) approval; (3) providing ease of administration via a capsule formulation and potential to dramatically lower overall treatment cost; and (4) possessing a proven safety profile (generic niclosamide has been used safely for 50 years as a treatment for tapeworm infections).

About NeuroBo Pharmaceuticals

NeuroBo Pharmaceuticals, Inc., a clinical-stage biotechnology company focused on developing and commercializing multi-modal disease-modifying therapies for viral, neuropathic, and neurodegenerative diseases, has a current portfolio of four drug candidates. The company's recently acquired ANA001 candidate is a proprietary oral niclosamide formulation in development as a treatment for patients with COVID-19. Niclosamide has antiviral and anti-inflammatory properties, and a well-understood safety profile in humans. ANA001 is currently being studied in a Phase 2/3 clinical trial conducted at up to 20 clinical sites in the U.S. Niclosamide has demonstrated both antiviral and immunomodulatory activity with possible downstream effects on coagulation abnormalities observed in COVID-19. The company's NB-01 candidate has been shown in a Phase 2 study to significantly reduce pain symptoms associated with painful diabetic neuropathy (PDN), with a superior safety profile when compared to currently available treatments. Due to the global COVID-19 crisis, a planned Phase 3 study of NB-01 was postponed. In the interim, NeuroBo is exploring a potential orphan drug indication targeting chronic pain for NB-01. NeuroBo's NB-02 drug candidate is focused on the treatment of Alzheimer's disease and neurodegenerative diseases associated with the pathological dysfunction of tau proteins in the brain. The company's fourth program, Gemcabene, was previously being developed for the treatment of dyslipidemia, a serious medical condition that increases the risk of life-threatening cardiovascular

disease. Gemcabene is currently being assessed as an acute treatment for COVID-19.

For more information visit: https://www.neurobopharma.com.

Forward Looking Statements

Any statements in this press release that are not statements of historical fact constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These statements include, but are not limited to, statements regarding the development of NeuroBo's product candidates and the therapeutic potential, timing and nature of clinical trials and potential regulatory approval of NeuroBo's clinical programs and pipeline. Forward-looking statements are usually identified by the use of words, such as "believes," "anticipates," "expects," "intends," "plans," "may," "potential," "will," "could" and similar expressions. Actual results may differ materially from those indicated by forward-looking statements as a result of various important factors and risks. These factors, risks and uncertainties include, but are not limited to: the failure to obtain all of the benefits or recognize all of the synergies anticipated from the ANA acquisition; the integration of ANA potentially diverting management resources from operational matters and other strategic opportunities; the effect of future milestone payments and royalties specified in the ANA acquisition agreement on the results of operations and financial position of NeuroBo; the occurrence of health epidemics or contagious diseases, such as COVID-19, and potential effects on NeuroBo's business, clinical trial sites, supply chain and manufacturing facilities; NeuroBo's ability to continue as a going concern; the timing of completion of NeuroBo's planned clinical trials, including with respect to ANA001 and Gemcabene; the timing of the availability of data from NeuroBo's clinical trials, including with respect to ANA001 and Gemcabene; NeuroBo's plans to research, develop and commercialize its current and future product candidates, including the potential alternative pathways for NB-01; NeuroBo's ability to successfully collaborate with existing collaborators or enter into new collaborations and to fulfill its obligations under any such collaboration agreements; the clinical utility, potential benefits and market acceptance of NeuroBo's product candidates, including ANA001 and Gemcabene; the impact of government laws and regulations; NeuroBo's ability to protect its intellectual property position; and NeuroBo's need for additional financing to fulfill its stated goals; and other factors discussed in the "Risk Factors" section of NeuroBo's Annual Report on Form 10-K filed with the Securities and Exchange Commission on or about the date hereof. In addition, the forward-looking statements included in this press release represent NeuroBo's views as of the date hereof. NeuroBo anticipates that subsequent events and developments will cause its views to change. However, while NeuroBo may elect to update these forward-looking statements at some point in the future, NeuroBo specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing NeuroBo's views as of any date subsequent to the date hereof.

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