NeuroBo Pharmaceuticals Acquires ANA Therapeutics for Late-Stage Oral Antiviral Development Program

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Transformative Acquisition Deepens Pipeline with In-Process Phase 2/3 Clinical Study of Proprietary Oral Formulation of Niclosamide for the Treatment of COVID-19

Development Timeline Supports Multiple Value Drivers Over Next 12-18 Months

BOSTON, Jan. 6, 2021 /PRNewswire/ -- **NeuroBo Pharmaceuticals, Inc.** (Nasdaq: NRBO), a clinical-stage biotechnology company, today announced that on December 31, 2020 it acquired ANA Therapeutics, a privately held biotechnology company developing ANA-001, a proprietary capsule formulation of niclosamide for coronavirus indications, currently in Phase 2/3 clinical trials as a treatment for COVID-19. The transaction was unanimously approved by both the NeuroBo Pharmaceuticals' and ANA Therapeutics' Boards of Directors.

"This is an exciting and transformative acquisition for NeuroBo that expands our pipeline with a late-stage clinical development program that addresses the urgent need for new treatments to address COVID-19, a highly-infectious and often deadly virus," stated Richard J. Kang, Ph.D., President and Chief Executive Officer of NeuroBo. "ANA-001 is advancing through the 505(b)(2) clinical pathway, which allows us to leverage earlier data on niclosamide and streamlines and accelerates the timelines to bring this potentially life-saving therapy to patients suffering with COVID-19. As a result, the development timeline supports a number of value-creating milestones over the coming 12 to 18 months, including the data readout of the Phase 2 portion of the trial, expected in the third quarter of 2021."

"While the introduction of vaccines is expected to play a significant role in stemming the tide of the COVID-19 pandemic, the ongoing complexities and mutation of the disease will require therapies to treat the infected population for the foreseeable future," commented Irene Kim, Chair of the Board of NeuroBo. "Similar to influenza, taking a COVID-19 vaccine and therapy could become an annual routine. Preclinical data has demonstrated niclosamide's ability to inhibit viral replication of SARS-CoV-2 and underscores ANA-001's potential to effectively address the ongoing need for safe and effective COVID-19 treatments on a global scale."

"We are delighted to join with the NeuroBo team in order to bring ANA-001 to the millions of patients infected with COVID-19. NeuroBo has the leadership and platform to support the accelerated development of this important compound as a potential treatment for this viral pandemic," said Akash Bakshi, Chief Executive Officer of ANA Therapeutics.

About Niclosamide and ANA-001

ANA-001 is a proprietary oral niclosamide formulation in development as a treatment for patients with moderate to severe COVID-19 (patients not requiring ventilators). Niclosamide is a potential oral antiviral and anti-inflammatory agent with a long history of use and a well-understood safety profile in humans. ANA-001 is currently being studied in a 60-subject 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. 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.

Specifically, 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 to a broad homology 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 cardiovascular and/or pulmonary conditions.

As a result, the company believes ANA-001 has the potential to reduce the viral load and inflammation associated with cytokine dysregulation, acute respiratory distress syndrome (ARDS), and coagulation abnormalities and thus improve time to clinical improvement as defined as hospital discharge recorded using the WHO Ordinal Scale for Clinical Improvement.

The company believes ANA-001 has distinct competitive advantages in this market, including (1) offering an effective treatment for moderate to severe COVID-19 (patients not requiring ventilators); (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).

Clinical Development Plans for ANA-001

In October 2020, a Phase 2/3 clinical trial evaluating ANA-001 as a treatment for COVID-19 was initiated. The two-part Phase 2/3 multi-center, double blind, placebo-controlled study to assess the safety, tolerability, and efficacy of ANA-001 is being conducted at up to 20 clinical sites in the U.S. In both phases of the study, hospitalized patients with moderate to severe COVID-19 (patients not requiring ventilators) will be administered a seven-day course of ANA-001 (niclosamide capsules) in addition to standard-of-care treatment. The first phase of the trial will enroll 60 patients. The primary objective of the first phase of the trial is to assess safety and tolerability; secondary objectives include measurements of efficacy (median time to hospital discharge) and pharmacokinetics. The company expects to complete enrollment of the first phase of the study and to have topline data from this segment of the trial in the third quarter of 2021.

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

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

Acquisition Details

Under the terms of the acquisition agreement, ANA became a wholly-owned subsidiary of NeuroBo and ANA equity holders were issued an aggregate of approximately 3.24 million shares of Neurobo common stock, representing 19.7% of NeuroBo's outstanding shares. ANA shareholders will receive additional payments (in cash or NeuroBo common shares) upon the achievement of various development and net sales milestones for ANA-001 and will also receive royalties based on net sales of ANA-001.

Three key executives from ANA Therapeutics have joined the NeuroBo management team including, Akash Bakshi, as Senior Vice President and Chief Operating Officer, Nadja Mannowetz, Ph.D., as Senior Vice President, and Andrew Bartynski, Ph.D., as Senior Vice President. In addition, Mr. Bakshi has joined NeuroBo's board of directors.

About NeuroBo Pharmaceuticals

NeuroBo Pharmaceuticals, Inc., a clinical-stage biotechnology company focused on developing and commercializing multimodal, disease-modifying therapies for neurodegenerative and cardiometabolic diseases, has a current portfolio of four drug candidates. The company's recently acquired ANA-001 candidate is a proprietary oral niclosamide formulation in development as a treatment for patients with moderate to severe COVID-19 (patients not requiring ventilators). Niclosamide is a potential oral antiviral and anti-inflammatory agent with a long history of use and a well-understood safety profile in humans. ANA-001 is currently being studied in a 60-subject 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 global COVID-19 crisis, a planned Phase 3 study 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 third program, Gemcabene, was developed for the treatment of dyslipidemia, a serious medical condition that increases the risk of life-threatening cardiovascular disease.

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 timeline for niclosamide for the treatment of COVID-19, the market size for COVID-19-related therapeutics and the competitive advantages of ANA-001, the potential benefits of ANA-001 as a treatment for patients with moderate to severe COVID-19 (patients not requiring ventilators), and potential milestone payments and royalties that may become due to the former equity holders of ANA under the acquisition agreement. 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 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 ANA-001; the timing of the availability of data from NeuroBo's clinical trials, including with respect to ANA-001; the clinical utility, potential benefits and market acceptance of NeuroBo's product candidates, including ANA-001; ; 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 and in our other filings with the Securities and Exchange Commission. 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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