NeuroBo Pharmaceuticals Receives Approval for Amendment of Contingent Value Rights for Gemcabene

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Gemcabene to be Studied as a Stand-alone Treatment for COVID-19 and in Combination with Lead Asset, ANA001

BOSTON, March 24, 2021 /PRNewswire/ -- **NeuroBo Pharmaceuticals, Inc.** (Nasdaq: NRBO), a clinical-stage biotechnology company, today announced that it has received approval of an amendment to its Contingent Value Rights (CVR) agreement from a majority of the holders of a majority of the outstanding CVRs, incentivizing the evaluation of Gemcabene as a treatment for COVID-19.

The CVRs were distributed to the holders of Gemphire Therapeutics, Inc. common stock on December 30, 2019, immediately prior to its merger with NeuroBo Pharmaceuticals, Inc. The CVR amendment will allow NeuroBo to pursue Gemcabene as a therapy for COVID-19, with its own resources. In exchange, CVR holders will receive 10% of certain gross proceeds received by the company for any indication outside of treating cardiometabolic diseases. CVR holders will retain the original CVR for 80% of any proceeds of Gemcabene for cardiovascular conditions.

"The amendment to the CVR agreement represents another important milestone for NeuroBo and underscores investors' enthusiasm to explore additional therapeutic indications for Gemcabene that may strengthen our pipeline of assets to treat viral diseases including COVID-19," stated Richard J. Kang, Ph.D., President and Chief Executive Officer of NeuroBo. "We intend to evaluate Gemcabene both as a stand-alone treatment for COVID-19, and in a treatment combination with ANA001, our proprietary oral niclosamide formulation, which is currently in a 60-patient phase 2/3 trial as a treatment for moderate to severe COVID-19. We expect data from the Phase 2 segment of the ANA001 study in the third quarter of 2021 and are currently pursuing an abbreviated 505(b)(2) regulatory pathway.

Dr. Kang continued, "Even with the development of COVID-19 vaccines, current and future variants of the virus will likely necessitate a toolbox of effective therapies to treat various patient populations suffering from COVID-19. We look forward to achieving multiple value-creating milestones in the coming year, including the data monitoring committee results, the pharmacokinetic (PK) data for the phase 2 trial of ANA001, the top-line data readout from the phase 2 trial of ANA001 to treat COVID-19 and preclinical *in vitro* data for Gemcabene against COVID-19 variants alone and in treatment combination with ANA001. We are excited to continue the development of these potentially life-saving therapies to address the ongoing need for safe and effective COVID-19 treatments on a global scale."

About Gemcabene

Gemcabene, a peroxisome proliferation-activated receptor (PPARα) agonist, is a novel, once daily, oral therapy, for patients who are unable to achieve normal levels of LDL C or triglycerides with currently approved therapies, primarily statin therapy. Gemcabene's mechanism of action is designed to enhance the clearance of very low-density lipoproteins (VLDLs) in the plasma and inhibit the production of fatty acids and cholesterol in the liver.

Gemcabene was being evaluated in a Phase 2 randomized, double-blind, placebo-controlled study to assess its efficacy safety and tolerability in patients with severe hypertriglyceridemia. In January 2016, the Gemcabene Phase 2 clinical study was placed on partial clinical hold as the U.S. Food and Drug Administration requested 2-year rat and mouse carcinogenicity studies to be completed and submitted. The study currently remains on partial clinical hold for the treatment of dyslipidemia. Gemcabene is currently being assessed as an acute treatment for COVID-19.

About Niclosamide and ANA001

ANA001 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. ANA001 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 ANA001 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 ANA001 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).

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 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. ANA001 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 fourth program, Gemcabene, was 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 SAR-CoV-2.

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 ANA001, the potential benefits of ANA001 as a treatment for patients with moderate to severe COVID-19 (patients not requiring ventilators), the potential distribution of proceeds to CVR holders, and the timing or receipt of regulatory approvals. 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 ANA001 and Gemcabene; the timing of the availability of data from NeuroBo's clinical trials, including with respect to ANA001 and Gemcabene; the clinical utility, potential benefits and market acceptance of NeuroBo's product candidates, including ANA001 and Gemcabene; 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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