Novus Therapeutics Provides Update on OP0201

January 13, 2020

– Phase 2a study C-006 enrollment to be completed in 1Q 2020; data expected in 2Q 2020 –

IRVINE, Calif.--(BUSINESS WIRE)--Jan. 13, 2020-- Novus Therapeutics, Inc. (NASDAQ: NVUS), a specialty pharmaceutical company focused on developing products for patients with disorders of the ear, nose, and throat, today provided an update on the ongoing phase 2a study C-006 in acute otitis media patients. To date, 77 patients have been enrolled into the study. The company plans to close enrollment in the first calendar quarter of 2020 once approximately 100 patients have been enrolled. Results of study C-006 are expected in the second calendar quarter of 2020.

"We look forward to completing the first OP0201 clinical trial in pediatric patients with acute otitis media," said Gregory J. Flesher, Chief Executive Officer. "We recently amended the protocol to include a second primary efficacy endpoint and to revise the statistical methods for analysis, which has allowed us to reduce the sample size from approximately 140 to 100 patients without sacrificing statistical power. We are planning to close enrollment by the end of the current calendar quarter and expect to share the results in the second calendar quarter of 2020," concluded Mr. Flesher.

The amended C-006 study is designed to detect a 25% difference between treatment groups in at least 1 of the 2 primary efficacy endpoints, assuming 40% of placebo-treated patients have no bulging tympanic membrane at the visit that occurs between days 4-6 (visit 2), and 30% of placebo-treated patients have no middle ear effusion at the visit that occurs between days 12-14 (visit 3).

The company's current cash, including expected proceeds from the exercise of warrants, is enough to support operations into 4Q 2020.

About Study C-006

Study C-006 is a phase 2a, single center, double-blind, randomized, placebo-controlled, parallel group study to assess the safety, tolerability, and efficacy of 20 mg per day intranasal OP0201 as an adjunct therapy to oral antibiotic treatment of acute otitis media in infants and children aged 6 to 24 months. Patients are treated for 10 days and followed for up to 20 additional days after treatment is completed (clinicaltrials.gov identifier NCT03818815).

About Novus Therapeutics

Novus Therapeutics, Inc. (Novus) is a specialty pharmaceutical company focused on developing products for patients with disorders of the ear, nose, and throat. The Company has two platform technologies, each with the potential to be developed for multiple indications. Novus' lead program (OP0201) is a surfactant-based nasal aerosol drug-device combination product candidate being developed as a potential first-in-class treatment option for patients at risk for, or with, otitis media (OM), which is middle ear inflammation and effusion with or without infection. Globally, OM affects more than 700 million adults and children every year, with over half of the cases occurring in children under five years of age. OM is one of the most common disorders seen in pediatric practice, and in the U.S. is a leading cause of health care visits and the most frequent reason children are prescribed antibiotics or undergo surgery. Novus also has a foam-based drug delivery technology platform (OP01xx), which may be developed in the future to deliver drugs into the ear, nasal, and sinus cavities. For more information, please visit novustherapeutics.com.

Forward-Looking Statements

This press release contains forward-looking statements that involves substantial risks and uncertainties. Any statements about the company's future expectations, plans and prospects, including statements about its strategy, future operations, development of its product candidates, and other statements containing the words "believes," "anticipates," "plans," "expects," "estimates," "intends," "predicts," "projects," "targets," "looks forward," "could," "may," and similar expressions, constitute forward -looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, although not all forward-looking statements include such identifying words. Forward-looking statements include, but are not limited to statements regarding: risks related to market conditions, the completion of the common stock and warrant financing, including the satisfaction of the closing conditions, and the use of anticipated proceeds; expectations regarding the timing for the commencement and completion of product development or clinical trials, including the ongoing OP0201 clinical trial; expectations regarding the success of clinical trials; the rate and degree of market acceptance and clinical utility of the company's products; the company's commercialization, marketing and manufacturing capabilities and strategy; the company's intellectual property position and strategy; the company's ability to identify additional products or product candidates with significant commercial potential; the company's estimates regarding expenses, future revenue, capital requirements and needs for additional financing; developments relating to the company's competitors and industry; and the impact of government laws and regulations. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the ability to develop commercially viable product formulations; the sufficiency of the company's cash resources; the ability to obtain necessary regulatory and ethics approvals to commence additional clinical trials; whether data from early clinical trials will be indicative of the data that will be obtained from future clinical trials; whether the results of clinical trials will warrant submission for regulatory approval of any investigational product; whether any such submission will receive approval from the United States Food and Drug Administration or equivalent foreign regulatory agencies and, if we are able to obtain such approval for an investigational product, whether it will be successfully distributed and marketed. These risks and uncertainties, as well as other risks and uncertainties that could cause the company's actual results to differ significantly from the forward -looking statements contained herein, are discussed in our quarterly 10-Q, annual 10-K, and other filings with the SEC, which can be found at www.sec.gov. Any forward-looking statements contained in this press release speak only as of the date hereof and not of any future date, and the company expressly disclaims any intent to update any forward-looking statements, whether as a result of new information, future events or otherwise.

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