Novus Therapeutics Receives FDA Guidance on OP0201 Phase 2a Study in Patients with Chronic Otitis Media with Effusion

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IRVINE, Calif.--(BUSINESS WIRE)--Oct. 29, 2019-- Novus Therapeutics, Inc. (NASDAQ: NVUS), a specialty pharmaceutical company focused on developing products for patients with disorders of the ear, nose, and throat (ENT), today announced that the U.S. Food and Drug Administration (FDA) has agreed with the Company's proposed patient population, endpoints, and statistical analysis plan for a phase 2a study of OP0201 in patients with chronic otitis media with effusion (COME) (study C-009). The FDA's feedback on the study C-009 was detailed in the minutes from a Type C meeting held with the Company's management team on September 20, 2019.

Study C-009 is designed to explore the effect of daily administration of OP0201 in patients with COME, a non-infectious form of otitis media. The study will enroll infants and children with three months or longer of bilateral middle ear effusion and hearing loss. The primary endpoints of study C-009 will be the resolution of middle ear effusion and/or restoration of hearing.

"We are pleased to have alignment with the FDA on our planned Phase 2a chronic otitis media with effusion study," said Dr. Catherine C. Turkel, President of Novus Therapeutics, Inc. "Persistent middle ear effusion and associated hearing loss is problematic, particularly for young patients in their developmental years. To date, no drug product has been approved for the treatment of this condition and surgery to insert tympanostomy tubes to clear the middle ear effusion is the only option for these patients. We look forward to studying OP0201 in this population."

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 (ENT). 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 four ongoing OP0201 clinical trials; 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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