Novus Therapeutics Advances OP0201 Development Program Across Several Clinical Trials

January 30, 2019

Screening Initiated for Phase 1 Pharmacodynamic Effects Trial (Study C-001)

Screening Initiated for Second Cohort of Phase 1 Trial in Healthy Adults (Study C-002)

Enrollment Completed in Phase 1 Trial in Adults with Acute Otitis Media (Study C-004)

New Phase 2a Trial in Infants and Children with Acute Otitis Media Planned for 2019 (Study C-006)

IRVINE, Calif.--(BUSINESS WIRE)--Jan. 30, 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 provided updates on several ongoing and planned clinical trials with OP0201, the company's lead product candidate being developed for otitis media.

"We have made good progress with the OP0201 development program over the past few months and we are looking forward to reporting data from four clinical trials this year," said Gregory J. Flesher, CEO of Novus Therapeutics. "We initiated screening for study C-001, a single-dose phase 1 safety and pharmacodynamic effects study. We completed the first dose cohort of study C-002, the ongoing 14-day phase 1 adult safety and tolerability study, and have initiated screening for the second higher dose cohort. We expect data from these two clinical trials to be available in the second calendar quarter of 2019. In addition, we recently completed enrollment of study C-004, the single-dose phase 1 safety and exploration of efficacy study in adults with acute otitis media. Given the rapid enrollment of study C-004, we now expect to have data by the end of the first calendar quarter of 2019."

"Finally, we are pleased to announce the addition of study C-006, an exploratory phase 2a placebo-controlled study in infants and children with acute otitis media. This trial replaces the previously announced phase 1 open-label study in children with otitis media with effusion. This new phase 2a study is designed to explore multiple endpoints and help the company design larger phase 2 studies in patients. We expect enrollment of this trial to begin in the coming weeks, with data available in the second half of 2019," concluded Mr. Flesher.

Study OP0201-C-001 ("C-001")

Study C-001 is a phase 1 clinical trial designed to evaluate safety, tolerability, and Eustachian tube ("ET") function following a single intranasal dose of OP0201 in 16 healthy adults. The randomized, double-blind, placebo-controlled, cross-over trial will explore the effect of a 20 mg dose of OP0201 on ET function. Assessment of ET function will be captured using continuous tympanic impedance while subjects are exposed to changes in atmospheric pressure produced in a hyperbaric/hypobaric chamber. The single center study will be conducted in Germany.

Study OP0201-C-002 ("C-002")

Study C-002 is a phase 1 clinical trial designed to evaluate safety and tolerability of daily intranasal administration of OP0201 over 14 consecutive days in 30 healthy adults. The randomized, double-blind, placebo-controlled, parallel-group, dose-escalation trial includes a 30 mg per day dose (Cohort A) and 60 mg per day dose (Cohort B) of OP0201. The study is being conducted at a single phase 1 unit in the United States. Additional information about the study can be found at clinicaltrials.gov using the identifier NCT03748758.

Study OP0201-C-004 ("C-004")

Study C-004 is a phase 1 clinical trial designed to evaluate safety, tolerability, and relief of ear pain over a 60-minute observation period following a single intranasal dose of OP0201 in 24 adults with acute otitis media. The randomized, double-blind, placebo-controlled, parallel-group trial will explore the effects of a 20 mg intranasal dose of OP0201. Assessment of pain relief will be captured utilizing a Visual Analog Scale (VAS), Numeric Rating Scale (NRS-11), Patient Global Impression of Change (PGIC), and Clinical Global Impressions Scale: Global Improvement (CGI-I). The multicenter study was conducted in the United States. Additional information about the study can be found at clinicaltrials.gov using the identifier NCT03766373.

Study OP0201-C-006 ("C-006")

Study C-006 is an exploratory phase 2a clinical trial designed to evaluate safety, tolerability, and efficacy of daily intranasal administration of OP0201 over 10 consecutive days in 50 pediatric patients, 6 to 24 months of age, with acute otitis media. The randomized, double-blind, placebo-controlled, parallel-group trial will explore the effects of a 20 mg per day dose of OP0201 as an adjunct to oral antibiotics. Patients will receive 10 days of treatment and will be followed for up to 30 days, during which multiple endpoints will be explored. The single center study will be conducted in the United States. Additional information about the study can be found at clinicaltrials.gov using the identifier NCT03818815.

About OP0201

OP0201 is being developed as a potential first-in-class treatment option for otitis media ("OM"), which is often caused by Eustachian tube dysfunction ("ETD"). OP0201 is a drug-device combination product comprised of a proprietary formulation of a surfactant (dipalmitoylphosphatidylcholine or "DPPC") and a spreading agent (cholesteryl palmitate or "CP") suspended in propellant. The product is administered intranasally via a pressurized metered-dose inhaler ("pMDI") and is intended to be used to restore the normal physiologic activity of the Eustachian tube ("ET"), which is the small tube that connects the middle ear to the back of the nasopharynx. Together DPPC and CP are designed to effectively absorb to the air-liquid interface of the mucosa and reduce the interfacial surface tension of the ET, which reduces the passive pressure required for the ET to open. In other words, OP0201 is intended to promote 'de-sticking' of the ET so that ventilation of the middle ear may occur.

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”). Novus has two technologies, each that has the potential to be developed for multiple ENT indications. Novus’ lead product candidate (OP0201) is a surfactant-based, drug-device combination product being developed as a potential first-in-class treatment option for patients at risk for, or with, otitis media (“OM” or middle ear inflammation 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 United States 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 (OP0102), 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,” “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: expectations regarding the timing for the commencement and completion of product development or 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 report on Form 10-Q for the quarter ended September 30, 2018, as well as 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.

View source version on businesswire.com: https://www.businesswire.com/news/home/20190130005201/en/

Source: Novus Therapeutics, Inc.

Timothy McCarthy
LifeSci Advisors, LLC
tim@lifesciadvisors.com
Tel: (212) 915-2564