Novus Therapeutics Announces Topline Results of Phase 2a Clinical Trial of OP0201 in Acute Otitis Media

June 1, 2020

Resolution of middle ear effusion in 56% of OP0201 vs. 38% of placebo patients (p=0.07)

Company engages financial advisors to explore strategic options

IRVINE, Calif.--(BUSINESS WIRE)--Jun. 1, 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 announced topline results from the company's exploratory phase 2a clinical trial of OP0201 in acute otitis media (study C-006).

Study C-006 was a phase 2a, single center, double-blind, randomized, placebo-controlled, parallel group clinical trial to assess the safety, tolerability, and efficacy of 20 mg per day intranasal OP0201 as an adjunct therapy to oral antibiotic in the treatment of acute otitis media in infants and children 6 to 24 months of age. Subjects were treated twice-daily for 10 days and followed up to one month. Post-randomization visits occurred between days 4-6 (visit 2), days 12-14 (visit 3), and days 28-30 (visit 4). The primary efficacy endpoints included resolution of bulging tympanic membrane at visit 2 and resolution of middle ear effusion at visit 3.

"Although we did not achieve statistical significance for the primary efficacy endpoints, we are encouraged with the statistical trend that favored the OP0201 treatment group with regard to resolution of middle ear effusion," said Dr. Catherine Turkel, President and Head of Global R&D for Novus Therapeutics. "Middle ear effusion is a key diagnostic criterion for otitis media disorders, including acute otitis media. When middle ear effusion persists after an episode of acute otitis media, it may make children susceptible to more serious otitis media disorders, such as recurrent acute otitis media and/or chronic otitis media with effusion. These topline results, including evidence supporting the safety and tolerability in infants and children, support continued development of our surfactant-based nasal aerosol. We are grateful to the young patients, their parents/caregivers, and the investigators who supported this clinical trial," concluded Dr. Turkel.

Primary Efficacy Endpoints (Modified Intent-to-Treat Population)

	Placebo (N=46)	OP0201 (N=54)
Bulging tympanic membrane at visit 2		
No bulging tympanic membrane (standard error)	47.3% (8.66)	51.0% (7.69)
p-value		p=0.62
Middle ear effusion at visit 3		
No middle ear effusion (standard error)	37.9% (8.44)	55.9% (8.29)
p-value		p=0.07

Summary of Treatment-Emergent Adverse Events (TEAE) (Safety Population)

	Placebo (N=48)	OP0201 (N=55)	All Subjects (N=103)
Subjects with any TEAE	36 (75.0%)	48 (87.3%)	84 (81.6%)
Subjects with 1 or more TEAE related to treatment	11 (22.9%)	17 (30.9%)	28 (27.2%)
TEAE resulting in interruption or discontinuation of treatment	1 (2.1%)	0 (0.0%)	1 (1.0%)
Serious TEAE	1 (2.1%)	0 (0.0%)	1 (1.0%)

The company also today announced that the Board of Directors has initiated a process to explore strategic options intended to maximize shareholder value. The company has engaged financial advisors, including Ladenburg Thalmann & Co. Inc., to assist in the review and evaluation of strategic options. Such options may result in a financing to continue development of the surfactant-based nasal aerosol, a company sale, merger, asset sale, in-license, out-license, or other business transaction.

"We recognize that continued development of our surfactant-based nasal aerosol will require significant time and capital," said Gregory J. Flesher, CEO of Novus Therapeutics, Inc. "We must fund the company for several years in order to complete additional formulation and device development, initiate the next otitis media clinical trial, and ultimately deliver clinical data. Given our current valuation relative to our capital needs, and given the operational challenges with the ongoing COVID-19 pandemic, we believe that exploration of all options is the appropriate course of action," concluded Mr. Flesher.

There can be no assurance that the exploration of strategic options will result in the company entering or completing any transaction. Novus does not intend to make any further disclosures regarding this process unless and until a specific course of action is approved by the Board of Directors.

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, which is middle ear inflammation and effusion with or without infection. Globally, otitis media affects

more than 700 million adults and children every year, with over half of the cases occurring in children under five years of age. Otitis media 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, including the Company's ability to raise capital or successfully pursue a strategic transaction; expectations regarding the timing for the commencement and completion of product development and formulation, as well as future 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 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; the impact of government laws and regulations; and the impact of the ongoing coronavirus pandemic. 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 a formulation suitable for future clinical trials; 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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