# Novus Therapeutics Receives FDA Guidance at Type C Meeting for OP-02 in the Treatment and Prevention of Otitis Media

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IRVINE, Calif.--(BUSINESS WIRE)--Jun. 19, 2018-- Novus Therapeutics, Inc. (NASDAQ: NVUS), a specialty pharmaceutical company focused on developing products for patients with disorders of the ear, nose, and throat (ENT), announced receipt of final meeting minutes from the U.S. Food and Drug Administration (FDA) following a Type C meeting held at the Company's request to discuss its OP-02 development program in otitis media.

"The FDA provided guidance on our planned 505(b)(2) development path for OP-02 and confirmed that no additional preclinical or clinical studies beyond our planned phase 1 safety study in healthy adults will be required before initiation of phase 2 studies in children 6-months of age or older with otitis media," said Dr. Catherine C. Turkel, President of Novus Therapeutics, Inc.

"In addition, the FDA confirmed that development of OP-02 for separate otitis media treatment and prevention indications is acceptable and provided us with initial guidance on study design for these indications. We look forward to working with the FDA as we continue to develop OP-02 as a potential first-in-class treatment option for the millions of patients burdened by otitis media," concluded Dr. Turkel.

**About OP-02**

OP-02 is a drug-device combination product comprised of a novel formulation of the surfactant dipalmitoylphosphatidylcholine (DPPC) and the spreading agent cholesteryl palmitate (CP) suspended in a propellant. The product is administered intranasally via a metered dose inhaler and is intended to be used to restore the normal physiologic activity of the Eustachian tube (ET). Together DPPC and CP effectively absorb to the air-liquid interface of the mucosa and reduce the interfacial surface tension of the ET, which reduces passive pressure required for the ET to open. In other words, OP-02 promotes "de-sticking" of the ET so that ventilation and drainage of the middle ear may occur.

**About Novus Therapeutics**

Novus Therapeutics is a specialty pharmaceutical company focused on developing products for disorders of the ear, nose, and throat (ENT). Novus has two technologies, each that has the potential to be developed for multiple ENT indications. The company's lead product (OP-02) is a surfactant-based, combination drug product being developed as a potential first-in-class treatment option for patients at risk for or with otitis media ("OM") (middle ear inflammation with or without infection). Globally, OM affects more than 700 million adults and children every year. OM is a common disorder seen in pediatric practice, and in the United States is the most frequent reason children are prescribed antibiotics and undergo surgery. Novus also has a foam-based drug delivery technology (OP-01), 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**

Any statements in this press release about the company's future expectations, plans and prospects, including statements about its strategy, future operations, development of its product candidates, the review of strategic alternatives and the outcome of such review and other statements containing the words "believes," "anticipates," "plans," "expects," "may," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Forward-looking statements include, but are not limited to, expectations regarding the timing for the commencement and completion of our clinical trials, manufacture drug product and our ability to accelerate the development of our drug candidates. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the sufficiency of the company's cash resources; the ability to timely develop and manufacture clinical batches of our study drugs; the ability to obtain necessary 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, 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, it will be successfully distributed and marketed. 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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