

# Novus Therapeutics Announces Formation of Scientific Advisory Board

## December 4, 2018

IRVINE, Calif.--(BUSINESS WIRE)--Dec. 4, 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), today announced the formation of a new Scientific Advisory Board (SAB), which is comprised of international experts in otolaryngology, pediatrics, and infectious diseases. The SAB will work closely with the Novus management team to advance OP0201, the company's lead product candidate being developed for otitis media.

"We are honored to have such a highly distinguished team of experts join our newly formed scientific advisory board," said Dr. Catherine Turkel, President of Novus Therapeutics. "This group of seasoned clinicians and researchers have extensive backgrounds in otitis media and will be instrumental as we advance OP0201 through clinical development. We look forward to working with them over the coming years."

Members of the Novus SAB include:

### • Hamid Djalilian, M.D.

Director of Otology, Neurotology, and Skull Base Surgery and a Professor of Otolaryngology and Biomedical Engineering at the University of California Irvine, California, USA

Dr. Hamid Djalilian is an Otolaryngologist with expertise in the treatment of the diseases of the ear and skull base. He has published over 120 peer-reviewed, and over a 100 invited papers and chapters, as well as an edited book. He has presented over 150 papers at national and international meetings and has been an invited lecturer nationally and internationally. His research focus is on the diagnosis and treatment of chronic otitis media in adults and children, novel methods of cholesteatoma treatment, the role of migraine in otologic disease, hearing preservation in acoustic neuroma and cochlear implantation, and treatment of tinnitus. In addition to his busy clinical practice, Dr. Djalilian has co-invented several medical devices that are undergoing clinical trial or commercialization.

### • Paola Marchisio, M.D.

Associate Professor of Pediatrics and Director of the Pediatric Unit at Fondazione IRCSS Cà Granda Ospedale Maggiore Policlinico, Milan, Italy

Dr. Paola Marchisio is a Pediatrician whose research focuses mainly on pediatric infectious diseases, and specifically the optimization of antibiotic therapy in children, the etiology of upper respiratory tract infections, otitis media and strategies for its prevention, the role of nasopharyngeal flora in determining middle ear infection, the prevalence of otitis media with cranio-facial abnormalities and the impact of influenza vaccine.

Since 1984 Prof. Marchisio has participated in clinical trials as a sub-investigator, as co-investigator and principal investigator. She authored a great number of papers published in national and international scientific journals. As the President of the School of Pediatric Nursing, she has been teaching Pediatrics at University of Milan since 1986. Prof. Marchisio is member of prestigious national and international boards of Pediatrics.

# • Tal Marom, M.D.

Associate Professor, Department of Otolaryngology-Head and Neck Surgery, Samson Assuta Ashdod University Hospital, Ben Gurion University Faculty of Health Sciences, Ashdod, Israel

Dr. Tal Marom is a University Associate Professor of Otolaryngology-Head and Neck Surgery, at the Department of Otolaryngology-Head and Neck Surgery, Samson Ashdod University Hospital, affiliated with the Ben Gurion University Faculty of Health Sciences in Israel. After obtaining his specialist degree in Otolaryngology-Head and Neck Surgery, he successfully completed his Pediatric Infectious Diseases Fellowship in ear, nose and throat diseases in Children, at the Department of Pediatrics, University of Texas Medical Branch, Texas, USA.

Over the past 10 years, Dr. Marom has dedicated his career to studying different aspects of otitis media in children and adults, and published many original articles, state-of-the-art reviews and invited commentaries on the epidemiology, bacteriology, pathophysiology, diagnosis, treatment and complication of otitis media in esteemed peer-reviewed journals. Dr. Marom is an active member of the Israeli Association of Otolaryngologists-Head and Neck Surgeons and the European Society of Pediatric Otolaryngology. In 2021, he will co-direct the 21st Symposium of the International Society of Otitis Media.

# • Michael E. Pichichero, M.D.

Director, Rochester General Hospital Research Institute, Rochester, New York, USA

For further information please see: https://www.urmc.rochester.edu/people/20996550-michael-e-pichichero

# • Seth Pranksy, M.D.

Pediatric Otolaryngology, Head and Neck Surgery, Rady Children's Hospital San Diego, California, USA

Dr. Seth Pransky has been a Pediatric Otolaryngologist on staff at Rady Children's Hospital San Diego since 1985. He was the Chief of Pediatric Otolaryngology from 1997-2017 and served on the Executive Board of the Rady Children's Hospital Specialists for 18 years, was the Medical Director of Satellite Services for the hospital for 16 years and has also been a Professor of Surgery in the Division of Otolaryngology at University of California, San Diego. Dr. Pransky has served as President of the Society for Ear, Nose and Throat Advances in Children (SENTAC); on the board of directors of the American Society of Pediatric Otolaryngology (ASPO) and on the Pediatric Otolaryngology Committee of the American Academy of Otolaryngology (AAO) for six years and the Executive Committee of the American Academy of Pediatrics (AAP) Section of Otolaryngology for six years.

His research in pediatric otolaryngology has resulted in numerous publications in peer-reviewed journals and multiple book chapters. His current research interests include an ongoing involvement with and study of recurrent respiratory papillomatosis as well as issues related to otitis media, tympanostomy tubes and otorrhea and operative management of nasal and sinus disease in children.

# • Anne GM Schilder, M.D., Ph.D.

Professor of Otolaryngology at University College London (UCL) Ear Institute, London, United Kingdom and University Medical Centre Utrecht (UMCU), Netherlands.

Dr. Anne GM Schilder is a Pediatric Otolaryngologist at the Royal National Throat, Nose and Ear Hospital, London and the Primary Care Centre 'Binnenstad', Utrecht, Netherlands. At UCL, she leads a program of translational hearing research supported by large grants from the UK National Institute of Health Research (NIHR) and EU Horizon 2020. At UMCU, she has led a series of trials of medical and surgical interventions for upper respiratory and middle ear infections in children. These trials have been influential in the way global health-care systems think about the management of children with these conditions and have been translated into national and international evidence-based guidelines and health policies.

Prof. Schilder has served as President of the European Society of Pediatric Otorhinolaryngology (ESPO) and is a Board Member of the International Society for Otitis Media. She is joint Coordinating Editor of Cochrane ENT, National Lead of the NIHR Clinical Research Network, and holds a Visiting Chair at Macquarie University, Sydney, and the University of Oxford.

### 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 and drainage 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 (OP01), 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 <u>www.sec.gov</u>. 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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Source: Novus Therapeutics, Inc.

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