



Nocion Therapeutics Announces Dosing Underway in Participants with Chronic Cough

- *Studying inhaled NTX-1175, A First-In-Class, Charged Sodium Channel Blocker*
- *Phase 2a Study Expected to Enroll 40 Chronic Cough Patients; Enrolling in UK and Germany*

Waltham, MA –(BUSINESS WIRE)—August 31, 2021 – Nocion Therapeutics, a clinical-stage biopharmaceutical company developing novel small molecule charged sodium channel blockers, called nocions, that selectively affect actively firing nociceptors for the treatment of serious conditions involving cough, itch, and pain, announced today that the first ten participants have been dosed in the company’s Phase 2a study of an inhaled form of NTX-1175. Nocion’s first-in-class proprietary molecule is being developed as a treatment for cough indications including Chronic Cough. Part 1 of the Phase 2a study is designed to assess the efficacy, safety, and tolerability of NTX-1175 in approximately 40 adult participants with refractory or unexplained Chronic Cough and is enrolling in the UK and Germany.

“We are excited to begin this study, which is the first randomized, controlled study of NTX-1175 in the chronic cough population and will help us assess the safety and efficacy of our nociceptor-targeted treatments,” said Dr. Richard Batycky, Chief Executive Officer of Nocion. “We believe that our unique pharmacology, with broad antitussive potential, may be highly differentiated from currently available and investigational approaches, and may improve the lives of chronic cough patients.”

Jacky Smith MB, ChB, FRCP, PhD, Professor of Respiratory Medicine at the University of Manchester and an Honorary Consultant at Manchester University NHS Foundation Trust, the global research lead for the Phase 2a study and a leader in the development of treatments for Chronic Cough commented, “Long-term chronic cough can have a huge negative impact on someone’s life, which can include anxiety, depression and exhaustion. When inhaled, NTX-1175 may be able to mitigate cough by directly targeting and reducing the activation of the sensory nerves in airways, which represents a unique approach to tackling the problem of cough in general, including Chronic Cough.”

Earlier this year, Nocion completed its First-in-Human Phase 1 study of inhaled NTX-1175 in 80 healthy participants. Nocion’s program received COVID-19-related priority review status through the UK’s Medicines and Healthcare products Regulatory Agency (MHRA) and through Germany’s Federal Institute for Drugs and Medical Devices (BfArM), as NTX-1175 has the potential to treat both Chronic and Acute Cough, including postinfectious cough associated with COVID-19.

The ongoing Phase 2a trial is a two-part study being conducted first in participants with Chronic Cough and then in participants with Acute Cough, including postinfectious cough following COVID-19. Part 1 is a randomized, double-blind, placebo-controlled, two-period crossover study evaluating three dose levels of NOC-100 (1, 3, and 10 mg) in participants with refractory or unexplained Chronic Cough. Participants are randomized to receive either active or matching placebo at escalating doses (2 days of once-daily dosing at each dose level) in period 1 before crossing over to the opposite treatment condition in period 2, with approximately 7 days of washout between the treatment periods. Part 2 of the Phase 2a study, to be initiated following completion of Part 1, will enroll participants with Acute Cough.

ABOUT COUGH

Chronic Cough is cough lasting more than eight weeks and is associated with significant, debilitating physical, social and psychosocial impact. It is estimated that approximately 26 million adults in the United States suffer from Chronic Cough, of which 8 million suffer from refractory or unexplained Chronic Cough, for which there are currently no approved pharmacological treatments available.

Acute Cough is cough lasting less than eight weeks and is one of the most common ailments for which patients seek medical treatment, accounting for approximately 21 million patients annually in the US. Of these, approximately 17 million can be attributed to acute viral or post-viral cough. Additionally, cough is one of the most common symptoms associated with COVID-19.

ABOUT NTX-1175

NTX-1175 is a proprietary molecule in the novel class of permanently charged sodium channel blockers (CSCBs) that allows for specific silencing of activated/inflamed nociceptors. Unlike other investigative cough therapies such as P2X3 antagonists which target a specific Large Pore Channel (LPC), NTX-1175 gains access to the nociceptor through any open LPC whereupon it inhibits the sodium channels responsible for initiating the pathological cough response. This broad mechanism has shown significant antitussive effects in preclinical models of cough, superior to that of P2X3 antagonists, and forms the basis for its use in cough indications beyond Chronic Cough.

ABOUT NOCION

Nocion Therapeutics is a biopharmaceutical company developing novel small molecule charged sodium channel blockers, "nocions", that selectively affect actively firing nociceptors for the treatment of serious conditions involving cough, itch, and pain. The company's mission is to safely alleviate suffering for millions of patients with conditions arising from activated sensory neurons. For more information, visit: www.nociontx.com.

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