Neos Therapeutics Initiates and Completes Dosing in a Phase 1 Trial of NT0502 for the Treatment of Chronic Sialorrhea

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New chemical entity and selective muscarinic receptor antagonist targeting large unmet need for a new treatment that can meaningfully improve the lives of patients with neurological conditions

DALLAS and FORT WORTH, Texas, Jan. 13, 2020 (GLOBE NEWSWIRE) -- Neos Therapeutics, Inc. (NASDAQ: NEOS), a commercial-stage pharmaceutical company developing and manufacturing central nervous system-focused products, today announced that it has initiated and completed dosing in a Phase 1 pilot pharmacokinetic study evaluating the safety and tolerability of NT0502 in healthy volunteers. NT0502 is a new chemical entity and selective anticholinergic agent that, based on preclinical data, is preferential for blocking muscarinic receptors in the salivary glands. The Company is developing NT0502 for the treatment of chronic sialorrhea, which is defined as prevalent and excessive drooling from the mouth resulting from the inability to control and swallow oral secretions, a common problem in patients with a variety of debilitating neurological conditions. Top-line pharmacokinetic data from the study is expected in the first quarter of 2020.

"There is significant market need for new treatments for chronic sialorrhea that can improve the quality of life for the millions of patients with neurological conditions, such as Parkinson's disease, cerebral palsy and amyotrophic lateral sclerosis (ALS), who must also live with the associated burden of excessive drooling," said Jerry McLaughlin, President and Chief Executive Officer. "NT0502 has a novel mechanism that offers the promise of an effective treatment with an improved tolerability profile for patients relative to existing pharmacologic options for chronic sialorrhea. We are looking forward to the results of this pilot pharmacokinetic study and the continued progress of NT0502 through the clinic."

The Phase 1 trial for NT0502 is a single-dose open-label, randomized study to assess the systematic exposure and safety of four ion-resin, modified-release orally disintegrating tablet formulations of NT0502 and oxybutynin in 30 healthy adults. Data from this study will provide insights into the pharmacokinetic profile of the four formulations and provide guidance on final formulation selection and dosing for future clinical trials.

About NT0502

NT0502 (N-desethyloxybutynin) is a new chemical entity being developed as an oral, once- or twice-daily treatment to reduce chronic sialorrhea in patients with neurological and other conditions associated with drooling and excessive salivation. Based on preclinical data, the Company believes that NT0502 offers the potential for an improved tolerability profile and an easier-to-dose oral formulation, without the need for complex titration, compared to existing treatment options. NT0502 is an active metabolite of oxybutynin, an approved drug to treat a urological condition.

About Sialorrhea

Sialorrhea is defined as prevalent and excessive drooling from the mouth as a result of limitations in a person's ability to control and swallow oral secretions. Sialorrhea can lead to significant physical and psychosocial complications, including perioral chapping, aspiration, dehydration, infection, foul odor, stigmatization, and increased dependency and level of care, all of which can create an additional burden for these medically complicated patients. In the U.S., more than 1.4 million patients – including those suffering from Parkinson's disease, cerebral palsy, stroke, traumatic brain injury, ALS and other neurological conditions – experience sialorrhea due to neuromuscular/sensory dysfunction.[1] Many of these patients remain untreated today because existing non-selective anticholinergic agents are associated with treatment-limiting side effects and cumbersome dosing schedules.

About Neos Therapeutics

Neos Therapeutics, Inc. (NASDAQ: NEOS) is a fully-integrated pharmaceutical company focused on developing, manufacturing, and commercializing innovative medicines utilizing its proprietary modified-release microparticle, drug delivery technology. Adzenys XR-ODT® (amphetamine) extended-release orally disintegrating tablets (see Full Prescribing Information, including Boxed WARNING), Cotempla XR-ODT® (methylphenidate) extended-release orally disintegrating tablets (see Full Prescribing Information, including Boxed WARNING), and Adzenys-ER® (amphetamine) extended-release oral suspension (see Full Prescribing Information, including Boxed WARNING), all for the treatment of ADHD, are the first three branded, approved products using the Company's modified-release microparticle, drug delivery technology. In addition, Neos manufactures and markets its generic version of the branded product Tussionex®[2], an extended-release oral suspension of hydrocodone and chlorpheniramine for the relief of cough and upper respiratory symptoms of a cold (see Full Prescribing Information, including Boxed WARNING). Additional information about Neos is available at www.neostx.com.

Forward-Looking Statements

Any statements in this press release about future expectations, plans and prospects for the Company, including statements about the Company's strategy, future operations, commercial products, clinical development of its therapeutic candidates (including NT0502), plans for potential future product candidates, financial condition and outlook, and other statements containing the words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "suggest," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the net sales, profitability, and growth of the Company's commercial products; the status, timing, costs, results and interpretation of the Company's clinical trials or any future trials, including the Phase 1 study of NT0502, whether NT0502 preferentially blocks muscarinic receptors in the salivary glands, and whether NT0502 will be an effective treatment with an improved tolerability profile and a more acceptable dosing regimen for patients compared to existing treatment options; the

uncertainties inherent in conducting clinical trials, including the timing and results of the Phase 1 study of NT0502; expectations for regulatory interactions, submissions and approvals; the financial condition and outlook for the Company; availability of funding sufficient for the Company's foreseeable and unforeseeable operating expenses and capital expenditure requirements; uncertainties related to the Company's intellectual property; other matters that could affect the availability or commercial potential of the Company's commercial products or therapeutic candidates; and other factors discussed in the Risk Factors set forth in the Company's Annual Report on Form 10-K and Quarterly Reports on Form 10-Q filed with the Securities and Exchange Commission (SEC) and in other filings the Company makes with the SEC from time to time. In addition, the forward-looking statements included in this press release represent the Company's views only as of the date hereof. The Company anticipates that subsequent events and developments may cause the Company's views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to do so, except as may be required by law.

References

1. Mozaffarian. AHA Circulation. 2016; Taylor. MMWR Surveill Summ. 2017; Laskowitz. CRC Press; 2016; Alhashemi. Neurosciences (Riyadh). 2010; Cohen. Int J Stroke. 2016; Maenner. Ann Epidemiol 2016; Marras. NPJ Parkinsons Dis. 2018; Kalf. J Neurol. 2009; Reid. Dev Med Child Neurol. 2012; McGrath Epidemiol Rev. 2008; 2015 Clozapine for Treating Schizophrenia – A comparison of the States; Maher. Ther Adv Psychopharmacol. 2016.
2. Tussionex® is a registered trademark of the UCB Group of Companies.

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