Neos Therapeutics Announces Positive Phase 3 Study Results for its Methylphenidate Extended-Release (XR) Oral Disintegrating Tablet (ODT) in ADHD Patients

Dallas/Fort Worth, TX (July 15, 2014) - Neos Therapeutics, Inc. ("Neos" or "the Company"), a highly differentiated oral drug delivery company with a portfolio of proprietary technologies and a late-stage pipeline of innovative controlled release (CR) products for ADHD, announced today that it has completed a positive Phase 3 study for its methylphenidate XR-ODT drug candidate, NT-0102, in children with ADHD.

The trial was a multicenter, randomized, double-blind, placebo-controlled laboratory classroom study in 87 children with a diagnosis of ADHD. NT-0102 met primary and secondary efficacy endpoints, showing statistically significant improvement on both the Swanson, Kotkin, Agler, M-Flynn, and Pelham Scale (SKAMP) and the Permanent Product Measure of Performance (PERMP) scale, through 12 hours postdose. No serious adverse events were reported during the study and the adverse event profile was consistent with the drug's mechanism of action.

"ADHD is a condition that causes significant distress for patients and caregivers. Although, there are a number of effective long-acting medications currently on the market, most formulations consist of tablets or capsules that can be difficult for children to swallow. The positive data from this study is exciting. Hopefully, soon we will have a once-daily oral disintegrating tablet option that is easy to administer to patients," said Dr. Ann Childress (Center for Psychiatry and Behavioral Medicine, La Vegas, NV), lead investigator for the study.

"We are very pleased to have worked with Dr. Childress on this study. Having a potential treatment option for those who cannot swallow other dosage forms is important, especially in a chronic disorder like ADHD, in which children may struggle to take their medication or develop pill fatigue," noted Dr. Carolyn Sikes, Vice President of Clinical Development at Neos.

Stimulant medications, such as methylphenidate, have been available for the treatment of ADHD for decades. Extended-release formulations of these medications allow for once-daily dosing, however recent data suggest that a significant percentage of children and adolescents struggle to ingest tablets or capsules. An XR-ODT formulation, which does not require swallowing an intact tablet or capsule and can be dosed once daily, may offer a practical alternative.

Dr. Vipin Garg, President and CEO of Neos, added that "We are delighted with these robust clinical results, as this data validates our XR-ODT technology. We believe that our methylphenidate and amphetamine XR-ODT formulations could provide a patient-friendly dosage form for both children and adults with ADHD. We are looking forward to filing the NDA for our NT-0102 drug candidate in the near future."

About ADHD

Attention-Deficit/Hyperactivity Disorder (ADHD) is a neurobehavioral disorder characterized by excessive levels of inattention and/or hyperactivity/impulsivity for an individual's age and level of development, which causes significant functional and social impairment. The disorder begins in childhood and up to 9.5% of children (ages 4-17) have received a diagnosis of ADHD (about 5.4 million school-aged children). For up to 50% of these individuals, the condition or symptoms of the condition persist into adulthood.

About Neos Therapeutics

Neos Therapeutics, Inc. is a specialty pharmaceutical company focused on the development and manufacture of FDA approved drug products that utilize the Company's proprietary and patented delivery technologies. The Neos drug products are being developed using the Dynamic Time Release Suspension® (DTRS®) and Rapidly Disintegrating Ionic Masking™ (RDIM™) technologies that deliver controlled release (CR) small molecule active pharmaceutical ingredients (APIs) in either liquid or oral disintegrating tablet (ODT) dosage forms. By utilizing APIs that are already FDA-approved, Neos can reduce development and regulatory risk and efficiently advance targeted proprietary Rx products through the FDA's New Drug Application (NDA) approval process. For more information, visit www.neostx.com.

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