

## Neos Therapeutics Announces Submission of a New Drug Application for its Methylphenidate Extended Release Oral Disintegrating Tablet (XR-ODT) for the Treatment of ADHD

*Dallas-Fort Worth, TX (January 12, 2015) – Neos Therapeutics, Inc.* ("Neos"), a specialty pharmaceutical company with a late-stage pipeline of innovative extended release ("XR") products for Attention-Deficit Hyperactivity Disorder ("ADHD"), announced today that it has submitted a New Drug Application (NDA) for its methylphenidate XR-ODT drug candidate, NT-0102, an ADHD medication based on its patented XR-ODT technology.

Orally disintegrating tablets ("ODTs") differ from traditional tablets and capsules in that they are designed to quickly disintegrate on the tongue, rather than being swallowed whole. XR-ODTs provide a patient-friendly dosage form for those who have difficulty swallowing or do not like to swallow intact tablets or capsules and benefit from extended release formulations. NT-0102 is an extended release ODT formulation of methylphenidate that may be the first XR-ODT for the treatment of ADHD. The Neos XR-ODT formulation quickly disintegrates in the mouth without water, and has been shown to control ADHD symptoms through twelve hours post-dose in a pivotal clinical trial.

The pivotal clinical trial was a multicenter, randomized, double-blind, placebo-controlled laboratory classroom study in children (ages 6-12) with ADHD. NT-0102 met all primary and secondary efficacy endpoints, showing statistically significant improvement versus placebo on both the Swanson, Kotkin, Agler, M-Flynn, and Pelham (SKAMP) Scale ( $p < 0.0001$ ) and the Permanent Product Measure of Performance (PERMP) scale ( $p < 0.0001$ ). The SKAMP is a validated rating scale that measures classroom manifestations of inattention, hyperactivity, and impulsivity; the PERMP is a five-page math test that provides an objective assessment of effortful performance in the classroom. No serious adverse events were reported during the study and the adverse event profile was consistent with the drug's mechanism of action.

"The submission of the NDA for NT-0102 is a major milestone for Neos Therapeutics, and we look forward to working closely with the FDA during the review period," stated Vipin K. Garg, Ph.D., President and CEO of Neos. Dr. Garg further stated that "Neos is poised to submit additional NDAs for its ADHD pipeline drug candidates in 2015."

"ADHD is a condition that can result in significant academic and social impairment for patients. The burden on family members and caregivers can be enormous. The submission of NT-0102 NDA to the FDA brings us one step closer to having an easy to administer treatment option for those patients with ADHD who prefer not to swallow tablets or capsules," noted Dr. Ann Childress (Center for Psychiatry and Behavioral Medicine, La Vegas, NV), lead investigator for the study.

### About Neos Therapeutics

Neos Therapeutics, Inc. is a fully integrated specialty pharmaceutical company. The Company is initially focusing on ADHD with three proprietary products in late-stage development that provide patient-friendly dosage forms incorporating controlled and extended release oral disintegrating tablets (ODTs) and liquid suspensions. In addition, Neos manufactures and markets a generic of Tussionex® (hydrocodone and chlorpheniramine) extended-release oral suspension for the treatment of cough and

upper respiratory symptoms of a cold. The Company's products are developed and manufactured using its proprietary and patented ion resin technology. For more information, visit [www.neostx.com](http://www.neostx.com).

*This press release contains certain forward-looking statements that include projections and may also include words such as may, will, expects, believes, anticipates, plans, estimates, seeks, could, intends, and other similar expressions. These forward-looking statements involve risks, uncertainties, assumptions and other factors that are difficult to predict and that could cause actual results to vary materially from what is expressed in or indicated by the forward-looking statements.*

**CONTACTS:**

Vipin K. Garg, Ph.D.  
President and CEO  
Neos Therapeutics  
(919) 434-6643  
[vgarg@neostx.com](mailto:vgarg@neostx.com)

Richard I. Eisenstadt  
Chief Financial Officer  
Neos Therapeutics  
(972) 408-1389  
[reisenstadt@neostx.com](mailto:reisenstadt@neostx.com)

January 12, 2015