

## Neos Therapeutics Presents Data at ASCP Annual Meeting for Investigational XR-ODT for Treatment of ADHD

*Dallas/Fort Worth, TX (June 24, 2015)* – **Neos Therapeutics, Inc.** (“Neos” or “the Company”), a pharmaceutical company with three late-stage innovative, extended-release (“XR”) product candidates for the treatment of attention deficit hyperactivity disorder (“ADHD”), today announced the presentation of new data at the American Society of Clinical Psychopharmacology Annual Meeting (“ASCP”) in Miami, Florida. The results from two clinical trials of the Company’s methylphenidate XR orally disintegrating tablet (“ODT”) drug candidate, Cotempla XR-ODT™ (formerly NT-0102), and one clinical trial of its amphetamine XR-ODT drug candidate, NT-0202, were presented. The data confirm that both formulations have a concentration-time profile that is consistent with once daily dosing, and that they maintain their extended-release properties in the presence of a high fat meal and varying concentrations of alcohol. Tolerability data were also presented.

“These studies offer valuable insights into Neos’ two extended-release orally disintegrating tablet drug candidates for ADHD, and demonstrate a pharmacokinetic profile similar to a marketed capsule product,” said Ann Childress M.D., University of Nevada School of Medicine and President, Center for Psychiatry and Behavioral Medicine, Las Vegas, Nevada. “The breadth of XR-ODT candidate data presented at ASCP reinforce that these formulations appear to provide a pharmacokinetic profile consistent with once daily dosing, maintain their extended-release properties in the presence of a high-fat meal and alcohol and are generally well-tolerated.”

Up to 54% of pediatric patients and 40% of adult patients in the general population are reported to have difficulty swallowing tablets and capsules, which may result in skipped doses or discontinuance of their medication altogether. Cotempla XR-ODT™ and NT-0202 disintegrate in the mouth without water and provide a pharmacokinetic (“PK”) profile that is consistent with once-daily dosing.

“We are pleased that the results of the studies presented at ASCP suggest that Cotempla XR-ODT™ can be dosed with or without food and has a similar pharmacokinetic profile to a marketed methylphenidate capsule product,” said Vipin K. Garg, Ph.D., President and CEO of Neos Therapeutics. “We are also encouraged to see that the modified-release properties of NT-0202 are maintained in the presence of alcohol. We believe that this is the first public presentation of data from a study on the effects of alcohol on the PK parameters of an extended-release amphetamine formulation.”

In January 2015, Neos announced the submission of a New Drug Application (“NDA”) for Cotempla XR-ODT™ to the U.S. Food and Drug Administration (“FDA”). The NDA was accepted for filing by the FDA on March 10, 2015, and has a Prescription Drug User Fee Act (“PDUFA”) goal date of November 9, 2015. If approved, the Company believes Cotempla XR-ODT™ will be the first methylphenidate extended-release orally disintegrating tablet for the treatment of ADHD, potentially providing patients the combination of two key drug delivery attributes – an extended-release profile which allows for once-daily dosing and an ODT dosage form which disintegrates in the mouth without water – in one formulation.

### Three Key Data Presentations at ASCP

Title: Pharmacokinetics of Novel Methylphenidate Extended-Release Oral Disintegrating Tablets for ADHD

Date: 6/23/2015; Session Time: 11:15:00 AM to 1:00:00 PM; Poster Board # 18

In a Phase 1 study of healthy adults comparing the oral bioavailability and absorption of methylphenidate XR-ODT™ 60 mg to a reference marketed product, Metadate CD® (methylphenidate HCL extended-release capsules) 60 mg, the PK profile of methylphenidate XR ODT was generally similar to that of Metadate CD; however MPH XR-ODT had a 25% higher Cmax.

27% of adult volunteers receiving methylphenidate XR-ODT reported an adverse event (“AE”) compared to 30% of patients receiving Metadate CD®, with no AEs leading to discontinuation of the study drug. The most common AE was nausea, which was similar in the two treatment groups.

Title: No Food Effect for a Novel Oral Disintegrating Tablet Formulation of Extended-Release Methylphenidate for the Treatment of ADHD

Date: 6/24/2015; Session Time: 12:00:00 PM to 2:00:00 PM; Poster Board # 1

A Phase 1 study of Cotempla XR-ODT™ 60 mg in healthy adults determined a standard FDA high-fat meal did not significantly alter the rate of oral absorption or the extent of exposure to methylphenidate XR-ODT, suggesting that this formulation can be taken with or without food. Similar mean maximum plasma concentrations (Cmax) and overall exposure (AUC0-inf, AUC0-last) were observed in both fed and fasted patients. Time to peak plasma concentration (Tmax) was similar under both conditions.

58% of adult volunteers reported an AE, with similar incidence across the fed and fasted groups. The most common AEs were anxiety and nausea.

Title: The Controlled-Release Properties and Exposure Levels of a Novel Orally Disintegrating Tablet Formulation of Amphetamine for Treatment of ADHD are Maintained in the Presence of Alcohol

Date: 6/24/2015; Session Time: 12:00:00 PM to 2:00:00 PM; Poster Board # 2

A Phase 1 study of NT-0202 (amphetamine XR-ODT) 30 mg found varying concentrations of alcohol (0% to 40% ethanol) did not significantly alter the rate, extent of absorption or exposure of the active drug in healthy fasted adult volunteers.

66% of adult volunteers reported an AE, with no AEs leading to discontinuation of NT-0202. The most common AEs were catheter site inflammation, headache, nausea and intoxication.

### **About XR-ODT Technology**

Stimulant medications such as methylphenidate and amphetamine are the standard of care for treating ADHD, and XR formulations of these medications allow for once-daily dosing. However, recent data suggest that a significant percentage of children in the general population are unable to easily swallow solid dosage forms, and many remain uncomfortable doing so through adolescence. ODTs differ from traditional tablets and capsules in that they are designed to disintegrate on the tongue, rather than being swallowed whole.

### **About ADHD**

According to the National Institute of Mental Health, ADHD is one of the most common childhood disorders and can continue through adolescence and adulthood. Symptoms include difficulty staying focused and paying attention, difficulty controlling behavior and hyperactivity (over-activity).

## About Neos Therapeutics

Neos Therapeutics, Inc. is a pharmaceutical company focused on developing, manufacturing and commercializing products utilizing its proprietary modified-release drug delivery technology platform. The Company is initially focusing on ADHD and has developed three branded product candidates that are XR medications in patient-friendly ODT or liquid suspension dosage forms. In addition, Neos manufactures and markets its generic equivalent of the branded product Tussionex®, an XR liquid suspension of hydrocodone and chlorpheniramine indicated for the relief of cough and upper respiratory symptoms of a cold.

### Special Note Regarding Forward-Looking Statements:

*This press release contains forward-looking statements within the meaning of the federal securities laws and these statements involve substantial risks and uncertainties. Forward-looking statements generally relate to future events or our future financial or operating performance. In some cases, you can identify forward-looking statements because they contain words such as "may," "will," "should," "expects," "plans," "anticipates," "could," "intends," "target," "projects," "contemplates," "believes," "estimates," "predicts," "potential" or "continue" or the negative of these words or other similar terms or expressions that concern our expectations, strategy, plans or intentions. Forward-looking statements contained in this press release include, but are not limited to, statements about the PDUFA date for Cotempla XR-ODT™ and PK profile, extended-release properties and tolerability of our product candidates, including Cotempla XR-ODT™ and NT-0202. We caution you that the foregoing may not be the only the forward-looking statements made in this press release. You should not rely upon forward-looking statements as predictions of future events. These forward-looking statements involve risks, uncertainties, assumptions and other factors that are difficult to predict and that could cause actual results to differ materially from what is expressed in or indicated by the forward-looking statement.*

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June 24, 2015