## Neos Therapeutics Announces Trade Name Cotempla XR-ODT™ for its Methylphenidate Extended-Release Orally Disintegrating Tablets

Dallas/Fort Worth, TX (May 20, 2015) – **Neos Therapeutics, Inc.** ("Neos" or "the Company"), a pharmaceutical company with three late-stage extended-release ("XR") product candidates for the treatment of attention deficit hyperactivity disorder ("ADHD") currently in development, today announced that the U.S. Food and Drug Administration ("FDA") has provisionally accepted the trade name Cotempla XR-ODT™ for its methylphenidate extended-release orally disintegrating tablets ("ODT").

Cotempla XR-ODT™ may be the first XR-ODT for the treatment of ADHD. The Cotempla XR-ODT™ formulation quickly disintegrates in the mouth, and in a pivotal clinical trial of children with ADHD, was shown to have a statistically significant improvement versus placebo with respect to attention and behavior, with onset-of-effect observed within one hour and a12-hour duration. Cotempla XR-ODT™ combines two key drug delivery attributes into one formulation, an extended-release profile which allows for once daily dosing and an ODT dosage form which can facilitate administration and ingestion.

It has been reported that up to 54% of pediatric patients have difficulty swallowing tablets and capsules. For many of these patients, swallowing difficulties can persist into adolescence and adulthood, with 40% of the adult population reporting pill-swallowing difficulties which may result in skipping doses or discontinuing their medication altogether. Cotempla XR-ODT™ disintegrates in the mouth without water and thus may provide a more patient- and caregiver-friendly once-daily dosage form for these patients.

Neos submitted a 505(b)(2) NDA for Cotempla XR-ODT<sup>m</sup> in January of this year. The NDA was accepted for a standard 10-month review by the FDA on March 10, 2015.

## **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.

## **CONTACTS:**

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