Cotempla XR-ODT™ (methylphenidate) – New drug approval

- On June 19, 2017, Neos Therapeutics announced the FDA approval of Cotempla XR-ODT (methylphenidate) extended-release orally disintegrating tablets for the treatment of attention deficit hyperactivity disorder (ADHD) in pediatric patients 6 to 17 years of age.

- Cotempla XR-ODT is a schedule II controlled substance.

- According to the Centers for Disease Control and Prevention, ADHD is a common neurodevelopmental disorder of childhood and can continue through adolescence and adulthood. It affects 5% of children and 2.5% of adults in the U.S. Symptoms include inattentiveness, hyperactivity and impulsiveness.

- The approval of Cotempla XR-ODT was supported by a phase 3 clinical trial of 87 children with ADHD in a laboratory classroom setting. Treatment with Cotempla XR-ODT showed a statistically significant improvement in ADHD symptom control vs. placebo across the classroom day (placebo-subtracted difference of -11 [95% CI: -13.9, -8.2]).

- Similar to other methylphenidate-containing products, Cotempla XR-ODT carries a boxed warning for abuse and dependence.

- Cotempla XR-ODT is contraindicated in patients with known hypersensitivity to methylphenidate or other components of Cotempla XR-ODT and as concomitant treatment with monoamine oxidase inhibitors (MAOIs), or use of an MAOI within the preceding 14 days.

- Other warnings and precautions with Cotempla XR-ODT include serious cardiovascular reactions, blood pressure and heart rate increases, psychiatric adverse reactions, priapism, peripheral vasculopathy, including Raynaud's phenomenon, and long-term suppression of growth.

- Based on accumulated data from other methylphenidate products, the most common (> 5% and twice the rate of placebo) adverse reactions with Cotempla XR-ODT use are decreased appetite, insomnia, nausea, vomiting, dyspepsia, abdominal pain, weight decreased, anxiety, dizziness, irritability, affect lability, tachycardia, and increased blood pressure.

- The recommended starting dose of Cotempla XR-ODT is 17.3 mg once daily in the morning.

    - The Cotempla XR-ODT dose may be titrated weekly in increments of 8.6 mg to 17.3 mg. Daily doses above 51.8 mg have not been studied and are not recommended.
    - The Cotempla XR-ODT dose should be individualized according to the needs and responses of the patient.

- Neos Therapeutics plans to launch Cotempla XR-ODT in the fall of 2017. Cotempla XR-ODT will be available as 8.6 mg, 17.3 mg and 25.9 mg extended-release orally disintegrating tablets.