Mydayis™ (mixed salts of a single-entity amphetamine product) – New drug approval

- On June 20, 2017, Shire announced the FDA approval of Mydayis (mixed salts of a single-entity amphetamine product) extended-release capsules for the treatment of attention deficit hyperactivity disorder (ADHD) in patients 13 years and older.
    - Mydayis is a Schedule II controlled substance.
    - Pediatric patients ≤ 12 years of age experienced higher plasma exposure than patients ≥ 13 years of age at the same dose, and experienced higher rates of adverse reactions, mainly insomnia and decreased appetite
- ADHD is a neurodevelopmental disorder characterized by inattentiveness, hyperactivity and impulsiveness. An estimated 4.4% of adults have ADHD in the U.S. Approximately 50% to 66% of children with ADHD may continue to have ADHD symptoms as adults.
- The approval of Mydayis was supported by several clinical studies of over 1,600 adolescents and adults with ADHD. The studies demonstrated that a morning dose of Mydayis was superior in improving ADHD symptoms vs. placebo.
- Similar to other amphetamine-containing products, Mydayis carries a boxed warning for abuse and dependence.
- Mydayis is contraindicated in patients with known hypersensitivity to amphetamine or other components of Mydayis and as concomitant treatment with monoamine oxidase inhibitors (MAOIs), or use of an MAOI within the preceding 14 days.
- Other warnings and precautions with Mydayis include serious cardiovascular reactions, blood pressure and heart rate increases, psychiatric adverse reactions, long-term suppression of growth, peripheral vasculopathy, including Raynaud's phenomenon, seizures, serotonin syndrome, and potential for overdose due to medication errors.
- The most common adverse reactions in patients with ADHD (≥ 5% and at a rate at least twice placebo) were:
    - Children ≥ 13 years of age: insomnia, decreased appetite, decreased weight, irritability, and nausea
    - Adults: insomnia, decreased appetite, decreased weight, dry mouth, increased heart rate, and anxiety
- The recommended starting dose of Mydayis for adults and children is 12.5 mg once daily upon awakening.
    - The dose should be individualized according to the needs and response of the patient.
    - For adults, initial doses of 25 mg once daily may be considered for some patients.
    - The dose may be adjusted in increments of 12.5 mg for both adults and children.
    - The maximum daily dose is 50 mg for adults and 25 mg for children.

Continued . . .

- Shire plans to launch Mydayis in the third quarter of 2017. Mydayis will be available as 12.5 mg, 25 mg, 37.5 mg, and 50 mg extended-release capsules.