Onyda™ XR (clonidine) – New drug approval

- On May 24, 2024, the FDA approved Tris Pharma's Onyda XR (clonidine) extended-release oral suspension, for the treatment of attention deficit hyperactivity disorder (ADHD) as monotherapy and as adjunctive therapy to central nervous system (CNS) stimulant medications in pediatric patients 6 years of age and older.

- The efficacy of Onyda XR is based upon adequate and well-controlled studies of clonidine hydrochloride extended-release tablets.

- Warnings and precautions for Onyda XR include hypotension/bradycardia; sedation and somnolence; rebound hypertension; allergic reactions; and cardiac conduction abnormalities.

- The most common adverse reactions (≥ 5% and twice the rate of placebo) with Onyda XR use as monotherapy for ADHD were somnolence, fatigue, irritability, nightmare, insomnia, constipation, and dry mouth.

- The starting dosage of Onyda XR is 0.1 mg orally once daily at bedtime with or without food. The dose should be titrated in increments of 0.1 mg per day at weekly intervals depending on clinical response up to the maximum recommended dosage of 0.4 mg once daily at bedtime.

    — Doses of Onyda XR higher than 0.4 mg once daily were not evaluated in clinical trials for ADHD and are not recommended.
    — For patients switching from another clonidine product, discontinue that treatment, and titrate with Onyda XR using the titration schedule. Onyda XR should not be substituted for other clonidine products on a milligram-per-milligram basis because of differing pharmacokinetic profiles.

- Tris Pharma's launch plans for Onyda XR are pending. Onyda XR will be available as a 0.1 mg/mL oral suspension.