## Dyanavel® XR (amphetamine) – New formulation approval

- On November 5, 2021, Tris Pharma announced the FDA approval of Dyanavel XR (amphetamine) extended-release tablets, for the treatment of attention deficit hyperactivity disorder (ADHD) in patients 6 years and older.
- Dyanavel XR is a Schedule II controlled substance.
- Dyanavel XR was previously available as an extended-release oral suspension.
- Dyanavel XR carries a boxed warning for abuse and dependence.
- Dyanavel XR is contraindicated:
    - In patients known to be hypersensitive to amphetamine, or other components of Dyanavel XR.
    - Patients taking monoamine oxidase inhibitors (MAOIs), or within 14 days of stopping MAOIs.
- Additional warnings and precautions for Dyanavel XR include serious cardiovascular reactions, blood pressure and heart rate increases, psychiatric adverse reactions, long-term suppression of growth, peripheral vasculopathy (including Raynaud's phenomenon), and serotonin syndrome.
- The most common adverse reactions with amphetamine products are dry mouth, anorexia, weight loss, abdominal pain, nausea, insomnia, restlessness, emotional lability, dizziness, and tachycardia.
- The recommended starting dosage of Dyanavel XR is 2.5 mg or 5 mg once daily in the morning. The dosage may be increased in increments of 2.5 mg to 10 mg per day every 4 to 7 days based on clinical response. The maximum recommended dosage is 20 mg once daily.
    - Pharmacological treatment of ADHD may be needed for extended periods. Healthcare providers should periodically re-evaluate the long-term use of Dyanavel XR, and adjust dosage as needed.
    - Dyanavel XR extended-release oral suspension can be substituted with Dyanavel XR extended-release tablets on a milligram per milligram basis.
- Tris Pharma plans to launch Dyanavel XR extended-release tablets in first quarter 2022. Dyanavel XR extended-release tablets will be available as a 5 mg (functionally scored), 10 mg, 15 mg, and 20 mg strength.