Evrysdi® (risdiplam) – New formulation approval

- On February 11, 2025, Roche announced the FDA approval of Evrysdi (risdiplam) 5 mg tablet, for the **treatment of spinal muscular atrophy (SMA) in pediatric and adult patients**.
- **Evrysdi tablet is a new formulation of risdiplam**. Evrysdi is also approved as a 60 mg powder for constitution to provide a 0.75 mg/mL oral solution.
- The approval of the Evrysdi tablet was based on the results of a bioequivalence study, which demonstrated that the 5 mg tablet, whether swallowed whole or dispersed in non-chlorinated drinking water (eg, filtered water), and original oral solution provide comparable exposure to risdiplam.
- The Evrysdi oral solution will remain available for those on other doses of Evrysdi and for those who may prefer the oral solution.
- In patients 2 years of age and older weighing 20 kg or more, the recommended dose for Evrysdi tablet is **5 mg once daily**.
    - Refer to the Evrysdi drug label for dosing with the oral solution.
- Roche plans to launch Evrysdi tablet in the coming weeks.