## Firdapse® (amifampridine) – Expanded indication

- On September 29, 2022, Catalyst Pharmaceuticals announced the FDA approval of Firdapse (amifampridine), for the treatment of Lambert-Eaton myasthenic syndrome (LEMS) in adults and pediatric patients 6 years of age and older.
    - Firdapse was previously approved for this indication in adults only.
- The approval of Firdapse for the expanded indication was supported by evidence from adequate and well-controlled studies of Firdapse in adults with LEMS, pharmacokinetic data in adult patients, pharmacokinetic modeling and simulation to identify the dosing regimen in pediatric patients, and safety data from pediatric patients aged 6 years and older.
- For pediatric patients, the recommended dosing regimen of Firdapse is dependent on body weight.
    - In pediatric patients weighing 45 kg or more, the recommended initial daily dosage is 15 mg to 30 mg daily, in 3 to 4 divided doses. The total daily dosage should be increased by 5 mg every 3 or 4 days. The maximum single dose is 20 mg, and the maximum total daily maintenance dosage is 80 mg given in divided doses.
    - In pediatric patients weighing less than 45 kg, the recommended initial daily dosage is 5 mg to 15 mg daily, in 3 to 4 divided doses. The total daily dosage should be increased by 2.5 mg every 3 or 4 days. The maximum single dose is 10 mg, and the maximum total daily maintenance dosage is 40 mg given in divided doses.
- Refer to the Firdapse drug label for adult dosing.