Motpoly XR™ (lacosamide) – New indication

- On June 7, 2024, the FDA approved Aucta Pharmaceuticals' Motpoly XR (lacosamide) extended-release capsules, as adjunctive therapy in the treatment of primary generalized tonic-clonic seizures in adults and in pediatric patients weighing at least 50 kg.
    - Additional pediatric use information is approved for UCB's Vimpat® (lacosamide) tablets, oral solution, and intravenous solution. However, due to UCB's marketing exclusivity rights, Motpoly XR is not labeled with that pediatric information.
- Motpoly XR is also approved for the treatment of partial-onset seizures in adults and in pediatric patients weighing at least 50 kg.
- The efficacy of Motpoly XR for the new indication was established based on data from Vimpat tablets.
- The recommended dosage for monotherapy and adjunctive therapy for partial-onset seizures and for adjunctive therapy for primary generalized tonic-clonic seizures in adults and in pediatric patients weighing at least 50 kg is included in the table below. Dosage should be increased based on clinical response and tolerability, no more frequently than once per week.

Age and body weight	Initial dosage	Titration regimen	Maintenance dosage
Adults (17 years and older)	Monotherapy*: 200 mg once daily Adjunctive Therapy: 100 mg once daily	Increase by 100 mg once daily every week	Monotherapy*: 300 mg to 400 mg once daily Adjunctive Therapy: 200 mg to 400 mg once daily
Pediatric patients weighing at least 50 kg	100 mg once daily	Increase by 100 mg once daily every week	Monotherapy*: 300 mg to 400 mg once daily Adjunctive Therapy: 200 mg to 400 mg once daily

* Monotherapy for partial-onset seizures only