Harmony Biosciences to Present New 18-Month Open-Label Extension Data from the EPX-100 Phase 3 Dravet Syndrome Trial at the 2026 American Epilepsy Society Annual Meeting

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PLYMOUTH MEETING, Pa., Nov. 24, 2026 (GLOBE NEWSWIRE) -- Harmony Biosciences Holdings, Inc. (Nasdaq: HRMY) today announced that it will present two posters at the 2026 American Epilepsy Society Annual Meeting being held December 4-8 in Denver, CO. The posters include new 18-month open-label extension data from the company's investigational drug EPX-100 (clemizole hydrochloride) in the ongoing Phase 3 ARGUS trial for the treatment of Dravet syndrome, as well as operational experience from the decentralized at-home trial model being used in the Phase 3 ARGUS and LIGHTHOUSE trials.

Harmony is investigating EPX-100 for the treatment of Dravet syndrome and Lennox-Gastaut syndrome in the ongoing ARGUS and LIGHTHOUSE trials, respectively. These trials are currently enrolling, and more information can be found at argustrial.com and lighthouselgsstudy.com.

Poster presentation details are listed below:

- Title: "EPX-100 as Adjunctive Therapy in Participants with Dravet Syndrome: Updated Preliminary Results from the Open-Label Extension Phase of the ARGUS Study"
  Poster Number: 2.218
  Poster Session 2; Sunday, December 6, Noon - 2 pm MT

- Title: "Implementation of a Decentralized At-Home Clinical Trial Model in Rare Epilepsy Studies: Operational Experience from the Phase 3 ARGUS and LIGHTHOUSE Trials"
  Poster Number: 2.219
  Poster Session 2; Sunday, December 6, Noon - 2 pm MT

About Clemizole Hydrochloride (EPX-100)
EPX-100 (clemizole hydrochloride) is an investigational treatment in development for Dravet syndrome (DS) and Lennox-Gastaut syndrome (LGS). EPX-100 targets central 5-hydroxytryptamine receptors to modulate serotonin signaling and is administered orally twice daily as a liquid formulation. Open-label extension (OLE) data for EPX-100 in Dravet syndrome presented at AES 2025 demonstrated an approximately 50% median reduction in countable motor seizure frequency per 28 days (CMS-28), with half of participants achieving at least a 50% reduction, along with favorable long-term safety and tolerability.

About Dravet Syndrome
Dravet syndrome (DS) is a severe and progressive epileptic encephalopathy that begins in infancy and causes significant impact on patient functioning. DS begins in the first year of life and is characterized by high seizure frequency and severity, intellectual disability, and a risk of sudden unexpected death in epilepsy. Approximately 85% of Dravet syndrome cases are caused by de novo loss-of-function (LOF) mutations in the *SCN1A* gene, which codes for a voltage-gated sodium channel. DS affects approximately 8,000 patients in the U.S.

About Lennox-Gastaut Syndrome
Lennox-Gastaut syndrome (LGS) is a rare and drug-resistant epileptic encephalopathy characterized by onset in children between 3-5 years of age. The underlying cause of LGS is unknown and can be related to a wide range of factors including genetic differences and structural differences in the brain. As a result, patients experience multiple seizure types, including drop seizures, in addition to developmental, cognitive, and behavioral issues. LGS affects approximately 48,000 patients in the U.S.

About Harmony Biosciences
Harmony Biosciences is developing and commercializing innovative medicines for both rare and broad CNS disorders, and we are becoming an enduring leader in neuroscience. Our first medicine, WAKIX® (pitolisant), is the first and only FDA-approved non-scheduled treatment for excessive daytime sleepiness or cataplexy in patients 6 years of age and older with narcolepsy. Its launch ranks among the most successful in the history of orphan drugs. Building on our success and profitability, we are continuing to advance our novel clinical-stage pipeline, led by BP-205, an investigational orexin-2 receptor agonist with best-in-class potential across a broad range of CNS disorders. With a strong balance sheet, we have the capacity and conviction to pursue strategic business development opportunities. Harmony is guided by an unwavering commitment to patients and driven to create long-term value for shareholders. For more information, visit: www.harmonybiosciences.com.

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