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epm Therapeutics Announces Successful Pre-IND Meeting with FDA for EPM301

Milestone represents a step forward for treatment of patients with Prader-Willi syndrome

FLORENCE, Ky. – epm Therapeutics ("EPM" or the "Company"), a biopharmaceutical company developing a synthetic cannabinoid acid derivative (EPM301) for the treatment of patients with **Prader-Willi syndrome (PWS)**, announced the successful outcome of a Type B pre-Investigational New Drug (IND) meeting with the U.S. Food and Drug Administration (FDA). The meeting provided a clear regulatory roadmap for the Company's investigational new drug application for EPM301. EPM301 is designated Orphan Drug (ODD) and Rare Pediatric Disease (RPD) for the treatment of hyperphagia (insatiable appetite) in patients with PWS.

The FDA's pre-IND guidance included a review of epm's Chemistry, Manufacturing and Controls (CMC) program, plan for nonclinical safety pharmacology and toxicology studies, and proposed Phase 1 clinical trial design. The FDA's written responses allows EPM to confirm and finalize its clinical and regulatory development strategy, complete the nonclinical program, and file an IND in early 2027.

With the approved IND, EPM plans to initiate a Phase 1a/b clinical trial that will evaluate orally administered EPM301 in healthy volunteers and two cohorts of patients with PWS.

"The FDA's constructive feedback validates our development pathway moving forward and confirms the design of our Phase 1a/b clinical study," said Peter Welburn, CEO of epm Therapeutics. "This represents a significant milestone for EPM301 and the development of a potential new treatment option for the substantially unmet needs of patients and families living with PWS."

About epm Therapeutics

EPM Group, Inc., doing business as epm Therapeutics, is a privately held biotechnology company dedicated to the discovery and development of cannabinoid acid-based therapeutics for diseases with high unmet needs. Founded in 2017 in collaboration with Dr. Raphael Mechoulam, epm's lead asset, EPM301, is a first-in-class oral therapy in development for the treatment of hyperphagia and other symptoms common in Prader-Willi Syndrome (PWS). To learn more about epm, visit epmtherapeutics.com, or find us on [Facebook](#) and [LinkedIn](#).

About Prader-Willi Syndrome

Prader-Willi syndrome (PWS) is a rare genetic neurodevelopmental disorder. The Prader-Willi Syndrome Association USA estimates that PWS occurs in one in every 15,000 live births. The defining symptom of PWS is hyperphagia, a chronic and life-threatening condition characterized by an intense, persistent sensation of hunger accompanied by food preoccupations, an extreme drive to consume food, food-related behavior problems, and a lack of normal satiety, which can severely diminish the quality of life for individuals with PWS and their families.

Forward-Looking Statements

This press release contains forward-looking statements regarding epm Therapeutics' future operations, development plans, and potential market opportunities. All statements other than historical facts are forward-looking statements. Forward-looking statements involve risks and uncertainties, including the risk that the company may not receive required regulatory approvals, commercialize its product candidates, or realize the market potential of its pipeline. Actual results may differ materially.