epm Therapeutics

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FOR IMMEDIATE RELEASE

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epm Therapeutics Secures FDA Pre-IND Meeting to Advance EPM301 for Prader-Willi Syndrome

Meeting marks a key step toward Phase 1 development of a potential new therapy for PWS

FLORENCE, Ky. – EPM Group Inc., a preclinical-stage biotechnology company doing business as (dba) epm Therapeutics, has been granted a Pre-Investigational New Drug (Pre-IND) meeting with the U.S. Food and Drug Administration. This meeting represents a critical step in the regulatory process for EPM301, a first-in-class therapy being developed by epm for the treatment of hyperphagia and other symptoms experienced by individuals with Prader-Willi syndrome (PWS). The meeting is currently scheduled for Feb. 25, 2026.

The pre-IND meeting is intended to facilitate early dialogue with the FDA regarding epm's proposed development plans for using EPM301 to treat patients with PWS. The meeting is expected to address key aspects of the development program, including nonclinical data, clinical pharmacology and manufacturing considerations. Regulatory feedback from FDA reviewers across multiple disciplines will also be provided to help guide next steps for the program.

More specifically, the pre-IND meeting is expected to provide epm with an opportunity to seek FDA feedback on the design of its planned Phase 1 clinical study for EPM301, as well as to better understand regulatory requirements for the broader clinical development program. Based on this feedback, epm plans to continue advancing toward submission of an Investigational New Drug application (IND), currently anticipated in the fourth quarter of 2026.

The planned Phase 1 study is a randomized, placebo-controlled, single-ascending dose and multiple-ascending dose trial designed to evaluate the safety of EPM301 in healthy volunteers and individuals with PWS.

"Prader-Willi syndrome presents significant daily challenges for individuals and their families, and there remains a substantial unmet need for new therapeutic options," said Dr. Peter Welburn, President and CEO of epm Therapeutics. "This milestone represents an important step forward in our efforts to advance EPM301 and to develop therapies that may one day improve the lives of people living with PWS and those who care for them."

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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.