Praxis Precision Medicines Announces FDA Acceptance of New Drug Application for Ulixacaltamide HCl in Patients with Essential Tremor

April 14, 2026 at 7:30 AM EDT

FDA assigned PDUFA target action date of January 29, 2027

No advisory committee meeting expected

BOSTON, April 14, 2026 (GLOBE NEWSWIRE) -- Praxis Precision Medicines, Inc. (NASDAQ: PRAX), a fully integrated, leading central nervous system (CNS) precision neuroscience biopharmaceutical company, today announced that the U.S. Food and Drug Administration (FDA) has accepted for review its New Drug Application (NDA) for ulixacaltamide HCl for the treatment of essential tremor (ET) in adults. The FDA has set a target action date under the Prescription Drug User Fee Act (PDUFA) of January 29, 2027 and is not planning to hold an advisory committee meeting.

"Today's announcement brings us one step closer to delivering something patients living with essential tremor have been waiting for, a therapy developed specifically for their condition," said Marcio Souza, president and chief executive officer. "We look forward to continuing to work with the FDA through the review process while we prepare for the commercial launch."

Ulixacaltamide for treatment of essential tremor

The NDA is supported by positive results from the Essential3 Phase 3 program, which comprised two simultaneously enrolled pivotal studies in adults with essential tremor. The statistically and clinically significant results from the Essential3 program provide the primary evidence of effectiveness for the NDA submission. Ulixacaltamide was generally well tolerated, with a safety profile consistent with previous trials and no drug-related serious adverse events. Ulixacaltamide received Breakthrough Therapy Designation (BTD) from the FDA in December 2025.

About Ulixacaltamide
Ulixacaltamide is a differentiated and highly selective small molecule inhibitor of T-type calcium channels designed to block abnormal neuronal burst firing in the Cerebello-Thalamo-Cortical (CTC) circuit correlated with tremor activity. Ulixacaltamide has received Breakthrough Therapy Designation from the FDA and is the most advanced program within Praxis' Cerebrum™ small molecule platform.

About Praxis
Praxis Precision Medicines is a fully integrated, leading central nervous system (CNS) precision neuroscience biopharmaceutical company, translating insights from genetic epilepsies into the development of therapies for CNS disorders characterized by neuronal excitation-inhibition imbalance. Praxis is applying genetic insights to the discovery and development of therapies for rare and more prevalent neurological disorders through our proprietary small molecule platform, Cerebrum™, and antisense oligonucleotide (ASO) platform, Solidus™, using our understanding of shared biological targets and circuits in the brain. Praxis has established a diversified, multimodal CNS portfolio including multiple programs across movement disorders and epilepsy, with four late-stage product candidates. For more information, please visit www.praxismedicines.com and follow us on Facebook, LinkedIn and X/Twitter.

Forward-Looking Statements
This press release contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995 and other federal securities laws, including express or implied statements regarding Praxis' future expectations, plans and prospects, including, without limitation, statements regarding the anticipated timing of clinical trials, the anticipated timing of regulatory submissions and interactions and potential market opportunity and commercial potential of Praxis' product candidates, as well as other statements containing the words "anticipate," "believe," "continue," "could," "endeavor," "estimate," "expect," "anticipate," "intend," "may," "might," "plan," "potential," "predict," "project," "seek," "should," "target," "will" or "would" and similar expressions that constitute forward-looking statements under the Private Securities Litigation Reform Act of 1995.

The express or implied forward-looking statements included in this press release are only predictions and are subject to a number of risks, uncertainties and assumptions, including, without limitation: uncertainties inherent in clinical trials; the expected timing of clinical trials, data readouts and the results thereof, and submissions for regulatory approval or review by governmental authorities; regulatory approvals to conduct trials; and other risks concerning Praxis' programs and operations as described in its Annual Report on Form 10-K for the year ended December 31, 2025 and other filings made with the Securities and Exchange Commission. Although Praxis' forward-looking statements reflect the good faith judgment of its management, these statements are based only on information and factors currently known by Praxis. As a result, you are cautioned not to rely on these forward-looking statements. Any forward-looking statement made in this press release speaks only as of the date on which it is made. Praxis undertakes no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future developments or otherwise.

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