Praxis Precision Medicines Announces Extension Period for Relutrigine for Treatment of SCN2A and SCN8A Developmental and Epileptic Encephalopathies

June 29, 2026 at 4:30 PM EDT

FDA sets updated PDUFA date of December 27, 2026

BOSTON, June 29, 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) notified Praxis that it has extended by three months the review period for its New Drug Application (NDA) for relutrigine for the treatment of SCN2A and SCN8A developmental and epileptic encephalopathies (DEEs), setting an updated PDUFA target action date from September 27, 2026 to December 27, 2026. The extension follows Praxis's submission of additional sensitivity analyses of existing clinical data, which the FDA has deemed a "major amendment," allowing additional time for the FDA to review. No new clinical studies were requested, and the FDA did not cite any safety or manufacturing concerns. The review remains active and ongoing, and Praxis is continuing its preparations to bring relutrigine to a patient community with significant unmet need. Praxis remains confident in the strength of the relutrigine application and continues to collaborate with the FDA to support the completion of its review.

“Relutrigine has demonstrated a compelling profile, and we have every confidence in the strength of the data package to benefit patients with SCN2A and SCN8A DEEs,” said Marcio Souza, president and chief executive officer. “We appreciate and will continue to collaborate with the FDA review team. We are also continuing to advance our preparations to deliver relutrigine to a patient community that currently has no treatment options approved for these DEEs.”

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, Instagram, LinkedIn and Twitter/X.

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 regulatory submissions and interactions and the commercial potential of Praxis’ product candidates, as well as other statements containing the words “anticipate,” “believe,” “continue,” “could,” “endeavor,” “estimate,” “expect,” “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 submissions for regulatory approval or review by governmental authorities; 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.

Investor Contact:
Praxis Precision Medicines
investors@praxismedicines.com
857-702-9452

Media Contact:
Dan Ferry
LifeSci Advisors
Daniel@lifesciadvisors.com
617-430-7576