



Protagenic Therapeutics Advances PT00114 into Multiple-Dose Phase 1 Trial; Positioning for Phase 2 in Stress & Mood Disorders

Dosing Completion Expected by End of August; Phase 2 Trial Expected to Begin in 1Q 2026

NEW YORK, NY / [ACCESS Newswire](#) / August 21, 2025 / Protagenic Therapeutics, Inc. (NASDAQ:PTIX), a biopharmaceutical company developing novel neuro-active peptide therapies, today announced completion of first dose injection for all study subjects in the multiple-dose portion of its ongoing Phase I clinical trial of PT00114. The company expects to complete dosing by the end of August, with topline safety data anticipated by the end of September, supporting advancement into Phase 2 efficacy studies planned for the first quarter of 2026.

PT00114 is the first investigational therapy based on Teneurin C-terminus Associated Peptide (TCAP), a naturally occurring brain hormone localized in the amygdala and hippocampus that regulates stress and emotional balance. Unlike existing therapies that blunt symptoms, PT00114 is thought to directly modulate the brain's maladaptive responses to stress-offering a differentiated approach to treating anxiety, depression, addiction, and Post Traumatic Stress Disorder (PTSD).

Current treatments leave more than half of patients without adequate relief and are burdened by significant side effects.

"Initiating the multiple-dose trial of PT00114 marks a pivotal step in our clinical program," said Robert Stein, M.D., Ph.D., Chief Medical Officer. "With dosing on track to complete this month, we are preparing to transition rapidly into Phase 2 efficacy trials."

The multiple-dose study follows a successful single ascending dose trial that confirmed PT00114's favorable safety and tolerability profile. Data from this trial will contribute to Phase 2 studies designed to demonstrate PT00114's therapeutic potential in stress-related and mood disorders.

About Protagenic Therapeutics, Inc.:

Protagenic Therapeutics, Inc. (NASDAQ:PTIX) is committed to pioneering neuro-active peptides into therapeutics to mitigate stress-related disorders. For more information, visit www.protagenic.com.

About PT00114:

PT00114, a 41-amino-acid synthetic peptide, holds promise in treating various neuro-psychiatric conditions, including depression, anxiety, and PTSD. It operates with a novel mechanism, mirroring the active part of the natural brain hormone TCAP, thereby reducing circulating cortisol levels.

Forward-Looking Statements:

This press release contains forward-looking statements concerning Protagenic Therapeutics' product candidates and clinical trial plans. Forward-looking statements include words such as "expects," "anticipates," "intends," "plans," "could," "believes," "estimates" and similar expressions. Investors are urged to exercise caution and not place undue reliance on such statements, because they are subject to risks and uncertainties that could cause actual results to differ materially.

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8/21/2025 8:12:00 AM