



Results from Phase 1 Multiple-Dose Study of PT00114

Findings support advancement into Phase 2 to explore a first-in-class pathway aimed at stress-related neuropsychiatric conditions

NEW YORK CITY, NEW YORK / [ACCESS Newswire](#) / December 9, 2025 / Protagenic Therapeutics Inc. (NASDAQ:PTIX), a biopharmaceutical company developing therapeutics that target the biology of chronic stress and its downstream psychiatric and neurologic effects, today reported positive topline safety results from its Phase 1 Multiple Dose (MD) study of PT00114.

PT00114 is a synthetic analogue of a naturally occurring brain peptide thought to be involved in restoring homeostasis following prolonged exposure to stress. Its mechanism of action-rooted in rebalancing dysfunctional stress-response circuits-represents a departure from conventional neurotransmitter-focused approaches and may offer a new pathway for patients whose conditions remain insufficiently treated with existing therapies.

Phase 1 MD Study Overview

The study was conducted in healthy volunteers and was designed to evaluate the safety, tolerability, and pharmacokinetic profile of PT00114 across multiple dose levels. All planned cohorts have completed dosing.

Preliminary analyses show:

- PT00114 was well tolerated across all dose ranges studied.
- Reported adverse events were consistent with expectations for a peptide-based injectable therapy, including expected injection-site reactions.
- No serious adverse events were observed, and all participants completed the assigned dosing schedules.

"These results provide a clear safety foundation for advancing PT00114," said Dr. Garo Armen, Executive Chairman of Protagenic Therapeutics. "The Phase 1 study achieved what it was designed to do-establish tolerability and characterize the compound's behavior in humans. In addition, several participants who received PT00114 reported an improved sense of well-being, a finding that, while anecdotal at this stage, aligns with the compound's intended biological activity."

Dr. Armen added, "There is significant unmet need in stress-related psychiatric conditions, where many patients cycle through multiple therapies without adequate relief. PT00114's upstream mechanism-modulating the stress axis rather than solely neurotransmitter release-offers a fundamentally different approach. The safety profile emerging from Phase 1 gives us confidence to proceed."

Next Steps

Protagenic Therapeutics is finalizing its detailed analysis of the full Phase 1 dataset, including pharmacokinetic modeling to support dose selection. A comprehensive report will be released once analyses are complete.

The company expects to initiate a Phase 2 study in early 2026 to evaluate PT00114 in a targeted patient population affected by chronic stress-related psychiatric disorders. Additional details on study design and endpoints will be communicated in the coming months.

About Protagenic Therapeutics, Inc.

Protagenic Therapeutics, Inc. (NASDAQ:PTIX) is a biopharmaceutical company focused on developing innovative peptide-based therapeutics targeting the biological pathways underlying stress-related neurological and mood disorders. The company's lead compound, PT00114, is a synthetic analog of a naturally occurring brain peptide that helps regulate the body's stress response and emotional equilibrium.

Forward-Looking Statements

Statements in this press release contain "forward-looking statements" within the meaning of the U.S. federal securities laws. Forward-looking statements can be identified by words such as "projects," "may," "will," "could," "would," "should," "believes," "expects," "anticipates," "estimates," "intends," "plans," "potential," "promise" or similar references to future periods. Examples of forward-looking statements in this current report include, without limitation, statements regarding the Company's expected filing of its Quarterly Report on Form 10-Q, the Company's planned appeal before the Panel, and the continued listing of the Company's securities pending the appeal. Forward-looking statements are statements that are not historical facts nor assurances of future performance. Instead, they are based on the Company's current beliefs, expectations and assumptions regarding the future of its business, future plans, strategies, projections, anticipated events and trends, the economy and other future conditions. Because forward-looking statements relate to the future, they are subject to inherent risks and uncertainties, and actual results may differ materially from those set forth in the forward-looking statements. Important factors that could cause actual results to differ include, without limitation, that there can be no assurance that the Company will file the Form 10-Q, that there can be no assurance that the Company will otherwise meet Nasdaq compliance standards, that there can be no assurance that Nasdaq will grant the Company any relief from delisting as necessary or whether the Company can agree to or ultimately meet applicable Nasdaq requirements for any such relief, and the other important factors described under the caption "Risk Factors" in the Company's filings with the SEC. Any forward-looking statement made by the Company in this current report is based only on information currently available and speaks only as of the date on which it is made. Except as required by applicable law, the Company expressly disclaims any obligation to publicly update any forward-looking statements, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

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