Palisades Therapeutics Receives FDA Clearance to PROCEED with Phase 2a PTSD Trial of PT150 in U.S. Veterans

DoD-Funded Study Accelerates Novel PTSD Mechanism into Trials; Proven Alcohol Safety Profile De-Risks Program for Patients with Comorbid Alcohol Use Disorder

Pop Test/Palisades Therapeutics

CLIFFSIDE PARK, NJ, UNITED STATES, February 19, 2026 /EINPresswire.com/ -- Pop Test Oncology LLC, operating as Palisades Therapeutics, today announced that the U.S. Food and Drug Administration (FDA) has granted permission to PROCEED with a Phase 2a clinical trial entitled “Efficacy and Safety of PT150 in U.S. Veterans with Post Traumatic Stress Disorder (PTSD)." The dual-site, double-blind, placebo-controlled study is funded by the Department of Defense Congressionally Directed Medical Research Programs and will enroll 120 Veterans at VA medical centers in San Diego, California and Houston, Texas.

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> *Randi Altschul, CEO*

PT150, an orally dosed selective glucocorticoid receptor (GR) antagonist, represents one of the first novel pharmacological mechanisms investigated for PTSD in over two decades, directly targeting dysregulated stress biology underlying trauma symptomatology and addiction relapse.

An Urgent Unmet Need

PTSD affects up to 20% of military personnel and approximately 6-8% of the civilian population, yet no new medications have been approved for PTSD since 2001. The disorder's high comorbidity with alcohol use disorder—affecting 30-50% of PTSD patients—creates an urgent clinical challenge. Existing FDA-approved treatments (sertraline and paroxetine) provide limited symptom relief and fail to address shared neurobiological mechanisms driving trauma memory dysfunction and stress-triggered relapse.

The impact is staggering: the Veterans Affairs system treats over 1 million Veterans with PTSD annually, while AUD costs the nation over $249 billion in healthcare and productivity losses. This nearly quarter‑century gap in new PTSD medications reflects the complexity of PTSD neurobiology and limitations of traditional monoamine‑based approaches in engaging core stress‑response pathways.

PT150: A Novel Mechanism Targeting Stress Biology
PT150 addresses this gap by modulating glucocorticoid receptor (GR) signaling, a central component of the hypothalamic-pituitary-adrenal (HPA) axis dysregulation characteristic of PTSD. Evidence suggests that GR hypersignaling disrupts trauma memory consolidation and extinction while increasing vulnerability to stress-triggered relapse. Short-term GR antagonism is hypothesized to "reset" this dysregulated system, normalizing emotional memory processing and stress resilience, potentially improving both core PTSD symptoms and relapse risk.

PT150 is part of an extended Palisades Therapeutics platform of next‑generation GR‑modulating compounds designed to address a spectrum of stress‑ and immune‑mediated CNS and systemic disorders. This platform approach supports lifecycle expansion and follow‑on indications for PT150 and related compounds that can be pursued in partnership with leading pharmaceutical companies.

Groundbreaking Alcohol Safety Data: De-Risking Development
A critical differentiation for PT150 is its validation for populations with active alcohol consumption—a hallmark of PTSD/AUD comorbidity. Palisades Therapeutics has completed two peer-reviewed studies demonstrating PT150 is safe and well-tolerated when co-administered with alcohol:

Study 1: Pharmacodynamic Safety (Scientific Reports, 2021)
A Phase 1 randomized trial at Michael E. DeBakey VA Medical Center evaluated safety and pharmacodynamic interactions between PT150 and ethanol in healthy, alcohol-experienced volunteers. Key findings included:

- No significant differences in vital signs (heart rate, blood pressure) during alcohol challenges
- No clinically significant electrocardiogram changes or serious adverse events
- No meaningful differences in alcohol craving or subjective intoxication

Conclusion: "Administration of PT150 with concurrent alcohol use is safe and well-tolerated."

Study 2: Pharmacokinetic Interactions (Journal of Addiction Medicine, 2025)
A Phase 1 drug-drug interaction study evaluated whether ethanol alters PT150 pharmacokinetics or vice versa. Rigorous analysis of peak plasma concentrations (Cmax), time to peak (Tmax), elimination half-life (t½), and area under the concentration curve (AUC) revealed:
- No statistically significant PK interactions between PT150 and ethanol on any parameter
- No serious adverse events or abnormal electrocardiograms

Conclusion: "Coadministration of PT150 and alcohol does not produce significant pharmacokinetic interactions, supporting feasibility of evaluating PT150 in future clinical trials for alcohol use disorder."

This alcohol safety profile is unprecedented among novel CNS therapeutics and positions PT150 as uniquely suited for Veteran populations and civilians with PTSD/AUD comorbidity, where active alcohol use is prevalent.

Dual Government-Validated Development Pathway
The FDA-cleared PTSD trial complements ongoing National Institute on Alcohol Abuse and Alcoholism (NIAAA)-funded Phase 2 research at the University of Kentucky, now in its second year of enrollment. This dual government backing—DoD for PTSD, NIAAA for AUD—provides exceptional de-risking for prospective pharmaceutical partners, as both federal agencies have independently validated the clinical rationale and study designs supporting PT150's development.

Phase 2a PTSD Trial Design
Study Endpoints:
- Primary: Change in PTSD symptoms from baseline to 4 weeks post-treatment (Clinician Administered PTSD Scale for DSM-5)
- Secondary: Safety and tolerability (Frequency, Intensity, Burden of Side Effects rating scale)
- Exploratory: Fear potentiated startle extinction/recall testing, a PTSD-specific biomarker sensitive to glucocorticoid signaling

Study Leadership:
- Principal Investigator: Victoria Risbrough, Ph.D., VA Research Career Scientist, Professor and Vice Chair of Academic Affairs in Psychiatry at University of California San Diego
- Co-Investigator: Christopher D. Verrico, Ph.D., Michael E. DeBakey VA Medical Center and Baylor College of Medicine; more than 20 years of experience in addiction pharmacology
- Consulting Team: Dr. Dewleen Baker (PTSD researcher, former Director of Neuroscience, San Diego CESAMH); Dr. Thomas R. Kosten (Waggoner Chair, Psychiatry/Neuroscience/Pharmacology, Baylor); Dr. Katia Harlé (lead biostatistician, UCSD)
- Laboratory support provided by TPM Laboratories, Inc., a Cormica Lab

Platform Opportunity Beyond PTSD
While PTSD and AUD are the initial focus, PT150 has demonstrated preliminary efficacy signals in multiple CNS and systemic indications including neurodegeneration (Parkinson's disease models), glioblastoma, and GLP-1 adjunctive therapy for metabolic set-point modulation.

"PT150 offers a rare, dual-validated opportunity: a novel GR-targeted mechanism in PTSD with an unprecedented alcohol safety package, backed by both DoD and NIAAA, creating a highly de-risked CNS asset with clear partnering and lifecycle expansion potential." said Randi Altschul,

CEO of Palisades Therapeutics

About Palisades Therapeutics

Pop Test Oncology LLC, operating as Palisades Therapeutics, is a clinical-stage pharmaceutical company developing novel therapeutics for CNS disorders, oncology, and metabolic diseases. The company operates as a "brain trust" of 100+ scientists, physicians, and professionals collaborating across leading academic institutions and federal agencies.

Forward-Looking Statements

This press release contains forward-looking statements regarding PT150 development, trial outcomes, and commercial potential. These statements are based on current expectations and involve risks and uncertainties.

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