

Palisades Therapeutics Announces Groundbreaking Clinical Results for its PT150 Drug, the Exemplar of its Platform

Oral Glucocorticoid Receptor Antagonist Demonstrates Superior Efficacy and Safety Profile for Multiple Therapeutic Applications

CLIFFSIDE PARK, NJ, UNITED STATES, August 19, 2025 /EINPresswire.com/ --Pop Test Oncology LLC, operating as <u>Palisades Therapeutics</u>, a pioneering biopharmaceutical company



developing next-generation therapeutics, today announced the publication of landmark Phase I pharmacokinetic study results for PT150 in the Journal of <u>Addiction Medicine</u>.

https://journals.lww.com/journaladdictionmedicine/abstract/9900/pharmacokinetic interactions

_between ethanol and.561.aspx



These results represent more than successful safety data—they validate a potentially revolutionary approach to treating one of America's most devastating public health challenges"

Dr. Christopher Verrico, Baylor College of Medicine This groundbreaking study, funded by the Department of Defense, demonstrates that PT150, the company's lead selective glucocorticoid receptor antagonist, can be safely administered in alcoholic patients who have substantial alcohol exposure without clinically significant drug interactions—a crucial regulatory milestone that validates the compound's therapeutic potential across multiple indications such as AUD (alcohol use disorder) and post-traumatic stress disorder (PTSD) in patients with co-morbid AUD. PT150 crosses the blood brain barrier and thus has

an ideal profile for these clinical settings.

Breakthrough Platform Technology with Unprecedented Therapeutic Advantages

PT150 is the flagship compound of Palisades Therapeutics' extensive proprietary platform of novel glucocorticoid and androgen receptor modulators. The platform's crown jewel is PT157, a

potent dimer of PT150 that demonstrates significantly enhanced efficacy with lower required dosages for equivalent or greater clinical effect. This innovative drug platform addresses critical unmet medical needs across multiple clinical indications.

Exceptional Safety Profile Validates Clinical Development Strategy

This important Phase I drug-drug interaction study enrolled 16 healthy volunteers and clearly established PT150's safety when combined with alcohol consumption. The study's remarkable safety results include:

- No statistically significant pharmacokinetic interactions between PT150 and ethanol
- No serious adverse events reported throughout the study period
- All electrocardiograms remained normal, demonstrating cardiovascular safety

"These results represent more than successful safety data—they validate a potentially revolutionary approach to treating one of America's most devastating public health challenges," said Dr. Christopher Verrico, lead investigator and corresponding author from Baylor College of Medicine and the Michael E. DeBakey VA Medical Center. "PT150's demonstrated safety when combined with alcohol clears the path for larger Phase II efficacy trials and brings us significantly closer to providing patients with a truly innovative treatment option for Alcohol use Disorder (AUD)."

Superior Efficacy Profile Validated by Academic Research

Groundbreaking research conducted at the University of Kentucky is demonstrating PT150's superior therapeutic profile compared to current standard treatments for alcohol use disorder. PT150 represents a paradigm shift in AUD treatment by targeting the underlying stress pathophysiology rather than just blocking reward mechanisms like Vivitrol injections. Through HPA axis normalization, PT150 addresses the root causes of stress-induced drinking, abnormal stress responses, impaired fear extinction, and alcohol craving. Its superior selectivity, safety profile, shorter treatment duration (14 days vs. monthly injections), and ability to address comorbid conditions make it a potentially transformative advance that may offer more durable recovery outcomes than current opioid receptor-based approaches.

Comprehensive Mechanism of Action Targeting Root Causes

PT150 and PT157 operate through multiple synergistic mechanisms that address fundamental disease pathways:

- Anti-inflammatory Action: Both compounds effectively cross the blood-brain barrier and halt inflammation at its source, providing systemic protection against inflammatory cascades.
- Rebound Prevention: As adjunctive treatment to GLP-1 therapeutics, PT compounds prevent weight rebound by resetting metabolic set points and blocking stress-induced eating behaviors.

- Organ Protection: The compounds demonstrate remarkable efficacy in preventing pancreatitis, particularly as adjunctive therapy to GLP-1 treatments where pancreatitis risk remains elevated.
- Dual Mechanism: Unlike existing treatments, <u>PT150/PT157</u> simultaneously address both GLP-1 enhancement and alcohol use disorder, providing comprehensive therapeutic coverage for these indications when comorbidly present.

Robust Clinical Development Portfolio Across Multiple Indications

Palisades Therapeutics has established a comprehensive clinical development program supported by leading federal agencies and academic institutions:

Department of Defense (DoD)

• PTSD with Alcohol Use Disorder Subset: DoD-funded Phase II clinical trial evaluating PT150 in U.S. Veterans with post-traumatic stress disorder, including a significant subset with co-occurring alcoholism, addressing the critical need for dual-diagnosis treatment approaches.

National Institute on Alcohol Abuse and Alcoholism (NIAAA)

• University of Kentucky AUD Study: NIAAA-funded clinical research specifically focused on PT150's efficacy in alcohol use disorder treatment, building on preclinical data showing superiority to current standard-of-care options.

Metabolic and Weight Management Applications at MUSC

• Adjunctive GLP-1 Studies: Groundbreaking research at the Medical University of South Carolina (MUSC) investigating PT150/PT157 as adjunctive therapy to GLP-1 therapeutics, targeting the critical unmet need of weight rebound prevention and pancreatitis risk reduction.

National Institute on Drug Abuse (NIDA) Collaboration

• PT157 Substance Use Disorder Development: Recently signed agreement with NIDA for the development of PT157, the enhanced dimer compound of PT150, specifically targeting substance use disorders with improved potency and reduced dosing requirements

"This diverse portfolio of federally funded clinical studies validates the transformative potential of our PT150/PT157 platform across multiple therapeutic areas," noted the Palisades Therapeutics research team. "The simultaneous advancement of these studies positions us to address some of healthcare's most challenging unmet needs through a single, innovative platform approach."

Robust Intellectual Property Estate

Strong Patent Protection Through 2040s Ensures Market Exclusivity. Composition of matter patents providing fundamental protection as well as 5-7 years of regulatory data exclusivity as New Chemical Entities (NCE). High-barrier NCE scaffold resistant to generic competition.

Addressing Several of America's Most Critical Healthcare Crisis Situations: AUD & Obesity

The clinical need for PT150/PT157 cannot be overstated. America faces a staggering addiction crisis:

- 28.8 million adults suffer from alcohol use disorder.
- Current FDA-approved medications demonstrate poor adherence rates, with most achieving less than 25% optimal adherence.
- PT150/PT157 represent the first oral therapies specifically designed to address the critical limitations of GLP-1 therapeutics: weight rebound and pancreatitis risk.

Partnering Opportunities

Industry leaders and partners seeking solutions that combine scientific rigor, entrepreneurial spirit, and a mission to protect public health. Together, we can create the next generation of therapeutics that save lives. "Please, contact us today!"

"Hoping that big pharma will join us @AbbVie @Johnson-Johnson @Alkermes @Bristol-Myers-Squibb @Astellas-Pharma @Pfizer."

#Biotech #Addiction #PharmaNews #ClinicalTrials #Breakthrough

Forward-Looking Statements

This press release contains forward-looking statements regarding business prospects based on current expectations and involve risks and uncertainties that could cause actual results to differ from those expressed or implied.

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