

Palisades Therapeutics PT150 for treatment of “long haul COVID” neuro-psychiatric conditions

PT150 for depression, fatigue, memory dysfunction, and “brain fog” associated with long haul COVID syndrome

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Neuroinflammatory changes have been implicated in [long haul COVID](#) syndrome, these changes include underlying symptoms such as

depression, fatigue, memory dysfunction, and “brain fog.” Data for PT150 indicates it is a likely modulator of neuroinflammation that may be expected to therapeutically impact on these symptoms.



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I am excited to test PT150 for depression, fatigue, memory dysfunction, and brain fog associated with long haul COVID syndrome. PT150 is an exciting novel drug with far reaching implications.”

Craig R. Rush, PhD, University of Kentucky

Hypothalamic-pituitary-adrenal (HPA) axis dysfunction has also been demonstrated in the neurologic and psychological aspects of long haul COVID. Excessive acute activation of the HPA stress axis or its chronic activation can lead to feedback loop distributions that contribute to numerous human disorders and stress conditions, including anxiety, post-traumatic stress disorder, major depressive disorder, and occupational burnout.

Intriguingly, in autopsied patients with SARS, following the lung, the adrenal glands belonged to the organs with the highest concentration of virus particles. Effects of [SARS-CoV-2](#) in adrenal glands have been confirmed. In addition,

the pituitary was affected, making it clear that the HPA axis is targeted during a coronavirus infection.

In a proof of concept study in normal human males, 900 mg/day of PT150 was shown to significantly decrease cerebrospinal fluid corticotropin-releasing factor (CRF) levels suggesting a

“reset” of the HPA-axis at this dose. Human data from multi-site PT150 phase 1 and phase 2 clinical trials for treatment of depression show that PT150 has equivalent symptom reduction compared to the SSRI paroxetine and clomipramine, a tricyclic antidepressant. However, in subsets of depressed patients displaying HPA-axis dysfunction – (as measured by high levels of serum cortisol and/or response to dexamethasone suppression tests) – PT150 showed significantly increased efficacy over the other anti-depressants. In keeping with the pre-clinical data, the clinical data suggest that PT150 accomplishes a “reset” of HPA axis functioning even after short term use.

[HPA-axis dysregulation](#) has also been associated with addiction and withdrawal mechanisms in animals and in humans. Glucocorticoid receptor (GR) antagonists have been proposed as short-term (7 or 14 day) treatments to “reset” the hypothalamic–pituitary–adrenal (HPA) axis in these conditions. It remains unclear whether the reset occurs peripherally via feedback mechanisms or centrally via direct GR antagonism within key circuits, but efficacy has been observed pre-clinically and clinically in Alcohol Use Disorder (AUD).

This mechanism of HPA axis functional restoration in humans is thus expected to complement the expected neuroinflammatory modulation by PT150 for therapeutic benefit in patients with long haul COVID neurological and psychological symptoms. For these reasons, a clinical trial is designed with PT150 as a monotherapy at the University of Kentucky led by Principal Investigator Craig R. Rush, PhD for neuropsychiatric symptoms associated with long haul COVID syndrome. Dr. Rush stated “I am excited to test PT150 for depression, fatigue, memory dysfunction, and “brain fog” associated with long haul COVID syndrome. PT150 is an exciting novel drug. Besides long haul COVID syndrome, neuroinflammation and HPA disruption is common in other psychiatric conditions such as alcohol, methamphetamine and opioid abuse. The initial clinical trial we propose could have far reaching implications”.

Palisades invites leading companies such as Eli Lilly and Company (NYSE: LLY), Johnson & Johnson (NYSE: JNJ) and Pfizer Inc. (NYSE: PFE) to review our data.

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