

Invero Pharma Submits IND Application to FDA for Xenon-Based Therapy in Traumatic Brain Injury

BUFFALO, NY, UNITED STATES, November 25, 2025

/EINPresswire.com/ -- Invero Pharma, through its affiliate Invero Health, LLC, a clinical-stage biopharmaceutical company developing neuroprotective therapies for acute brain injuries, today announced the submission of an Investigational New Drug (IND) application to the U.S. Food and Drug Administration (FDA) for XENEX®, its proprietary xenon gas-based therapy for severe traumatic brain injury (TBI).



XENEX is an inhaled treatment designed to limit neuronal damage after TBI by acting on multiple injury pathways, including NMDA receptor modulation. Invero's proprietary delivery system enables precise, scalable administration in critical care settings—overcoming limitations of earlier gas delivery devices.

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The IND submission is supported by extensive preclinical data demonstrating safety and efficacy in validated models of brain trauma. Pending FDA clearance, Invero plans to

initiate a Phase II clinical trial in patients with severe TBI to evaluate safety and potential clinical benefit. The company has partnered with a leading international medical gas supplier to provide highly purified (99.999%) xenon for the trial.

“This IND submission represents a key milestone toward addressing one of medicine’s most pressing unmet needs,” said Douglas Stefanelli, Chief Executive Officer of Invero Pharma. “With no approved therapies for severe TBI, XENEX has the potential to significantly improve outcomes and redefine the standard of care.”

“For decades, clinicians have lacked a therapy that can truly alter the trajectory of severe traumatic brain injury,” said Dr. Amelia Maiga, Principal Investigator of the upcoming trial at Vanderbilt University Medical Center. “Xenon’s unique multi-modal mechanism, combined with

Invero's delivery innovation, offers a promising new path forward."

Each year, 70,000–90,000 Americans experience long-term disability from severe TBI. (CDC, 2019). The burden is also high among military personnel, where about 20% of service members deployed to Iraq and Afghanistan have reported TBI (AAPM&R, 2013).

About Invero Pharma

Invero Pharma is a Buffalo, NY-based biopharmaceutical company pioneering neuroprotective treatments for acute brain injuries such as traumatic brain injury (TBI), cardiac arrest, and subarachnoid hemorrhage (SAH). Its lead program, XENEX®, is a novel xenon-based therapy designed to improve outcomes following severe brain trauma.

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