



NodThera Announces Progress of NT-0796, a Novel NLRP3 Inflammasome Inhibitor, into a Phase 1 First-in-Human Study

-Study of lead candidate to provide important information on safety, pharmacokinetics and pharmacodynamics to inform further clinical development in chronic inflammatory diseases-

-Highlights continued progress advancing a differentiated portfolio of novel NLRP3 inflammasome inhibitors to treat both peripheral- and neuro- inflammatory diseases-

BOSTON, SEATTLE and CAMBRIDGE, UK – November 4, 2021 – [NodThera](#), a clinical-stage biotechnology company developing a new class of medicines that inhibit the NLRP3 inflammasome to treat chronic inflammation, today announced that the first healthy volunteers have been dosed in a Phase 1 clinical trial of its lead investigational candidate, NT-0796.

NT-0796 is a small molecule NLRP3 inflammasome inhibitor with differentiated novel chemistry that provides unprecedented potency and potential for prolonged pharmacodynamic (PD) effect, with the ability to cross the blood brain barrier in preclinical species. NT-0796 selectively inhibits NLRP3, the upstream regulator of the body's inflammation response, to reduce levels of both IL-1 β and IL-18 – pro-inflammatory cytokines known to play a role in chronic inflammation underlying a wide range of chronic diseases. Pharmacokinetic (PK) and PD data from an *ex vivo* IL-1 β /IL-18 stimulation assay and cerebrospinal fluid (CSF) sampling in the Phase 1 study will inform further clinical development.

“The recent convergence of key insights into innate immunity, IL-1 β /IL-18 and the NLRP3 inflammasome have revolutionized our understanding of chronic disease,” said Adam Keeney, Ph.D., CEO of NodThera. “As one of the first companies to recognize the importance of NLRP3 in the inflammation cascade, we look forward to gathering important human data from the Phase 1 clinical study of our lead candidate NT-0796 so we can accelerate innovation for patients with limited treatment options.”

The primary objective of this study is to assess the safety and tolerability of NT-0796, while secondary objectives include assessment of PK and PD (ability to lower IL-1 β and IL-18 levels) and CSF sampling to assess NLRP3 target engagement and compound exposure after single and multiple ascending doses.

“NT-0796 leverages novel chemistry that is unlike any other NLRP3 inflammasome inhibitor in the field. It is designed to deliver key advantages in PK and PD, with the potential to cross the blood brain barrier,” said Donald Johns, M.D., Chief Medical Officer of NodThera. “The NLRP3 inflammasome is a key driver of diseases that span different parts of the body, from common ailments such as osteoarthritis, to cardiovascular disease, Alzheimer’s Disease, cancer, and beyond. Unlocking this treatment potential provides the opportunity to impact many patients whose quality of life is negatively affected by chronic inflammatory disease.”

About NodThera

NodThera is a clinical-stage biotechnology company developing a new class of potent and selective NLRP3 inflammasome inhibitors for the treatment of diseases driven by chronic inflammation. Led by an experienced management team, NodThera is leveraging new insights into inflammasome biology and chemistry to build a portfolio of highly differentiated small molecule NLRP3 inflammasome inhibitors. The company was founded in 2016 and financed by 5AM Ventures, Cowen Healthcare Investments, Epidarex Capital, F-Prime Capital, Novo Holdings, Sanofi Ventures and Sofinnova Partners. NodThera is headquartered in Lexington, MA, with additional locations in Cambridge, UK and Seattle, WA. Learn more at www.nodthera.com or follow us on [LinkedIn](#).

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