



Tune Therapeutics Moves into Clinical Spotlight with TUNE-401: A First-in-Class Epigenetic Silencer for Hepatitis B

TUNE-401 will be the first epigenetic therapy to enter clinical trials for an infectious disease

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DURHAM, N.C. & SEATTLE--(BUSINESS WIRE)--Leading epigenome editing company Tune Therapeutics announced today that it has received clinical trial application (CTA) approval from the New Zealand Medicines and Medical Devices Safety Authority (Medsafe) to initiate a Phase 1b clinical trial for TUNE-401 – an investigational epigenetic silencing therapy designed to treat chronic Hepatitis B (HBV).

With this approval, TUNE-401 is expected to be the first epigenetic therapy to enter the clinic for the treatment of a common and infectious disease. Over 250 million people are currently living with chronic HBV infection, which is also the leading cause of hepatocellular carcinoma, or liver cancer – accounting for around 56% of cases worldwide.

The first-in-human study will evaluate the safety, tolerability, pharmacokinetics (PK), and pharmacodynamics (PD) of TUNE-401 in adult participants with chronic HBV. The initial clinical trial site will be in Auckland, New Zealand, and led by Principal Investigator Dr. Ed Gane.

“Tune-401 is designed to mimic and amplify a natural, innate immune response against HBV,” said Derek Jantz, Chief Scientific Officer at Tune Therapeutics. “Despite the well-established role of epigenetics in virus control, Tune-401 is the first treatment to employ direct epigenetic silencing to inactivate a virus. We feel confident that this unique mechanism of action will deliver long-awaited benefits for HBV patients and create renewed interest and momentum in the broader field of genetic medicine.”

Tune-401 employs lipid nanoparticles (LNPs) to deliver RNA encoding the active, HBV-targeting construct directly to liver cells. Inside these cells, the construct is translated into an epi-silencing protein that targets both integrated HBV DNA and cccDNA episomes - free-floating loops of HBV DNA that generate new viral particles and sustain chronic infection for years on end. Clinicians assert that shutting down these cccDNA ‘viral factories’ is an essential prerequisite to achieving a functional cure for HBV.

Critically, Tune-401 is the first treatment to reach the clinic that aims to silence both integrated HBV and HBV cccDNA at the epigenetic level, without cutting or editing DNA. Its active, epi-silencing protein binds to DNA without cutting, adding methyl groups that repress or inactivate viral genes while leaving the human genome intact. The protein is also highly specific – targeting a DNA target sequence unique to HBV, and highly conserved among HBV genomes.

"Hepatitis B remains a significant global health threat, with millions of people affected and in need of durable treatment solutions," said Dr. Ed Gane, Professor of Medicine at the University of Auckland. "Epigenetic silencing has the potential to achieve a long sought-after goal in the community: the promise of sustained disease remission after a finite course of treatment."

Tune Therapeutics will present data supporting its entry into clinical trials at the upcoming American Association for the Study of Liver Diseases (AASLD) Liver Meeting on Monday, November 18th.

About Tune Therapeutics

Armed with its powerful and innovative genetic tuning platform (TEMPO), Tune Therapeutics aims to bring gene, cell, and regenerative therapies into a new era of human medicine – expanding their range of application to common, chronic, and age-related diseases that are straining healthcare systems and limiting human healthspan on a global scale.

About TUNE-401

TUNE-401 is a first-in-class investigational product candidate for treating Hepatitis B (HBV) infection. TUNE-401 utilizes the company's versatile, modular TEMPO platform to epigenetically silence viral HBV intDNA and cccDNA necessary for sustained HBV infection. Lipid nanoparticle technology for TUNE-401 has been provided by Acuitas Therapeutics Inc.

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