

NEWS RELEASE

ClearB Therapeutics Announces First Patient Dosed in a Phase 1b

10/12/2023

First in Human Study of CLB-3000 and a Presentation at AASLD 2023 of Preclinical data both for the Treatment of Chronic Hepatitis B Infection

CONCORD, Mass.--(BUSINESS WIRE)-- ClearB Therapeutics, Inc., now a clinical-stage biotechnology company committed to developing therapies to drive functional cure in patients with chronic hepatitis B (CHB) infection, announced that the first patient has been dosed in the Phase 1b clinical study evaluating the therapeutic vaccine CLB-3000 ([ACTRN1263000841673](#)). Satisfactory review of safety data for this patient supported opening enrollment for the remainder of the cohort.

CLB-3000 is a bivalent subunit therapeutic vaccine comprised of CLB-405 and CLB-505 proteins, adjuvanted with Alhydrogel®. CLB-405 and CLB-505 were designed to over-represent clearance profile epitopes that were identified from the functional cure patients. The Phase 1b study is an open label dose escalation design enrolling up to 36 CHB patients in as many as 3 cohorts. The objectives of the study are safety, tolerability, and anti-viral activity of CLB-3000. Results from the two ascending dose cohorts are expected in 2H 2024.

"We are beyond thrilled to be able to advance our therapeutic vaccine candidate, CLB-3000, toward first in human trials in patients with CHB. We look forward to sharing emerging clinical data with the Hepatitis B community as it becomes available" said Aileen Rubio, PhD, CEO for the company. "CHB infection remains a substantial global health care problem in need of safe and effective therapies. We believe that boosting of patients' own immune system with ClearB's therapeutic vaccine, CLB-3000, could become an important component of evolving combination treatment regimens."

In addition, ClearB Therapeutics announced the acceptance of an abstract including new preclinical data for a humanized monoclonal antibody as serotherapy for the treatment of CHB for presentation at the American Association for the Study of Liver Diseases (AASLD) The Liver Meeting 2023, taking place in Boston, MA November 10 – 14, 2023.

“We are also excited to continue to showcase new preclinical data on an additional novel immune based serotherapy approach at the upcoming AASLD The Liver Meeting,” Dr. Rubio added. For more information regarding AASLD The Liver Meeting 2023, please visit **The Liver Meeting | AASLD**.

Abstract number: 1541

Abstract title: A humanized monoclonal antibody 4G2 exhibits anti-viral activity in a mouse model of persistent hepatitis B virus (HBV) infection

Presenter name: Aditi Deshpande

About Hepatitis B

The World Health Organization defines hepatitis B as a “potentially life-threatening liver infection caused by Hepatitis B virus (HBV). It is a major global health problem. It can cause chronic infection and puts people at high risk of death from cirrhosis and liver cancer.” Approximately 2 billion people are infected with HBV and ~250 million living with CHB. Viral hepatitis is the 7th ranked cause of human death and liver cancer is the 3rd most common cause of cancer related death globally.

About ClearB Therapeutics

ClearB Therapeutics was co-founded in 2017 with Professor Stephen Locarnini and the Victoria Infectious Diseases Reference Laboratory in Melbourne, Australia. ClearB is working to develop immune based therapies designed to drive functional cure of hepatitis B infection. The work is grounded in proprietary insights derived from studying rare-event infection resolution in patients who suffer from CHB. For more information, please visit <https://clearbtherapeutics.com/>.

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