



Novira Therapeutics Begins Phase 1a Clinical Study of NVR-1221 for the Treatment of Chronic Hepatitis B (HBV) Infection

DOYLESTOWN, Pa., May 8, 2014 – Novira Therapeutics, Inc., a privately held biopharmaceutical company developing novel therapies for curative treatment of chronic hepatitis B virus (HBV) infection, today announced that it initiated a Phase 1a clinical study of NVR-1221. The Phase 1a clinical study is designed to assess the pharmacokinetic profile and dose-related safety and tolerability of NVR-1221 in healthy volunteers.

“We are thrilled to begin the clinical development NVR-1221,” said Lalo Flores, Ph.D., the co-Founder, President and Chief Scientific Officer at Novira. “NVR-1221 belongs to a new class of antiviral agents that target the viral core or capsid protein of the hepatitis B virus. Achievement of this important milestone positions NVR-1221 to be the first agent to test the curative potential of HBV core inhibitors in the clinic.”

The Phase 1a clinical study follows successful completion of the Clinical Trial Application (CTA) regulatory process in New Zealand. The clinical study will investigate the dose-related safety/tolerance and pharmacokinetics (PK) of NVR-1221 in approximately 40 healthy volunteers. Upon completion and satisfactory outcome of the Phase 1a clinical study, Novira will commence a Phase 1b clinical study to test the safety, PK and initial antiviral activity of NVR-1221 in patients with chronic HBV infection.

“The initiation of this Phase 1a clinical study marks an important milestone for Novira as it moves closer to bringing innovative and potentially curative approaches to patients with chronic HBV infection,” said Christian S. Schade, Chief Executive Officer at Novira. “We look forward to completing this Phase 1a trial over the coming months and commencing a Phase 1b clinical study to test NVR-1221 in chronic HBV patients as mono-therapy and in combination with approved agents.”

About NVR-1221

NVR-1221 is a small molecule, direct acting antiviral, for oral administration in patients with Chronic Hepatitis B (CHB) that inhibits the HBV core or capsid protein. HBV core is a novel and promising drug target with multiple activities required for viral replication and persistence. Inhibition of HBV core protein function by NVR-1221 offers the potential for a more efficient suppression of the virus leading to improved durable viral suppression and cure rates.

About HBV

Hepatitis B infection presents a significant unmet medical need with an estimated 350 million people worldwide living with chronic HBV infection. A significant number of patients with chronic infection incur a higher risk of developing cirrhosis and cancer. It is estimated that 60% of hepatocellular carcinoma (liver cancer) is a direct consequence of HBV infection. Current drugs approved for the management of CHB include PEG-Interferon and nucleot(s)ides which can effectively suppress virus replication, but rarely lead to a cure.

About Novira Therapeutics

Novira Therapeutics, Inc., is a privately held biopharmaceutical company focused on discovery and development of first-in-class antiviral drugs for the treatment of chronic HBV infection (CHB), a global disease with a high level of unmet medical need. The company is employing innovative chemistry and biology technologies to discover small molecule inhibitors of the HBV core or capsid protein as well as other drugs with novel mode of action. The company's novel antivirals will offer the potential to address the limitations of current CHB therapies when used either as mono-therapy or in combination with existing standards of care.

For more information, visit www.noviratherapeutics.com.

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