Novira Therapeutics Announces Successful Completion of Phase 1a Clinical Study of NVR-1221 and Commencement of Phase 1b Clinical Studies

Pharmacokinetics, Safety and Tolerability of NVR-1221 Support Advancement to Phase 1b Clinical Studies in Patients with Chronic HBV Infection

DOYLESTOWN, Pa., September 4, 2014 – Novira Therapeutics, Inc., a privately held biopharmaceutical company developing novel therapies for curative treatment of chronic hepatitis B virus (HBV) infection, today announced successful completion of a Phase 1a clinical study of NVR-1221. The results for the Phase 1a clinical study demonstrated NVR-1221 was safe and well-tolerated at all doses in 40 healthy volunteers. The complete safety and pharmacokinetics (PK) analysis of the Phase 1a data will be presented at an upcoming scientific conference.

Novira also announced that it has commenced enrollment of its Phase 1b clinical studies of NVR-1221. The Phase 1b clinical studies are planned to test the safety, PK and initial antiviral activity of NVR-1221 in patients with chronic HBV infection as mono-therapy and in combination with approved therapy. The Phase 1b clinical studies are expected to enroll up to 48 patients with chronic HBV infection in the mono-therapy dose-ranging study, followed by up to an additional 48 HBV patients in the combination clinical study of NVR-1221 with approved therapy.

“We are very pleased with the results of the Phase 1a clinical study and look forward to advancing NVR-1221 into Phase 1b clinical studies and patients with chronic HBV infection,” said Christian S. Schade, Novira’s Chief Executive Officer. “Either as mono-therapy or in combination with current standards of care, NVR-1221 represents a new class of small molecule to potentially offer HBV patients the opportunity for sustained viral suppression leading to higher functional cure rates.”

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 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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