Novira Therapeutics Announces Presentation of Phase 1a Safety and Pharmacokinetic Data for NVR 3-778

Phase 1b Clinical Studies Ongoing in Patients with Chronic HBV Infection

DOYLESTOWN, Pa., November 10, 2014 – Novira Therapeutics, Inc., a privately held biopharmaceutical company developing novel therapies for curative treatment of chronic hepatitis B virus (HBV) infection, today announced the presentation of Phase 1a safety and pharmacokinetic data for its lead HBV antiviral candidate, NVR 3-778 (also known as NVR-1221), in a late-breaking poster presentation at the 2014 annual meeting of the American Association for the Study of Liver Diseases in Boston. Dr. Edward J. Gane, Chief Hepatologist and Deputy Director of the New Zealand Liver Transplant Unit at Auckland City Hospital in Auckland, New Zealand is the lead author on the poster and the principal clinical investigator for the study.

The randomized, placebo-controlled Phase 1a trial enrolled 40 healthy adult volunteers to assess the safety and tolerability of NVR 3-778 after single oral doses of 50 to 800 mg/day, followed by an assessment of 200 mg once-daily dosing for 14 days. The study results indicated that NVR 3-778 was well-tolerated at all doses. There was no pattern of treatment-related or dose-related clinical adverse events (AEs), and no serious or severe AEs. All AEs were of common types, and most were not attributed to study drug treatment. The AEs were all transient and mild (grade 1) in severity except for two grade 2 AEs not attributed to study treatment (sprain and tooth pain). The pharmacokinetic profile of NVR 3-778 indicated substantial dose-related plasma levels that were consistent across the subjects within each dosing cohort. At doses of 200 mg or more, plasma concentrations of NVR 3-778 remained above *in vitro* HBV-inhibitory concentrations for more than 24 hours, supporting evaluation of once-daily dosing in HBV patients.

"These encouraging Phase 1a results indicate that NVR 3-778 was well-tolerated at all dose levels in human volunteers, and once-daily doses of 200 mg or more provided systemic levels of NVR 3-778 high enough to potentially be associated with antiviral efficacy in hepatitis B patients," said Nathaniel Brown MD, Novira's Chief Medical Officer. "The Phase 1a results support advancement to Phase 1b testing in patients with chronic HBV infection, which is now underway. The Phase 1b clinical study is designed to evaluate the safety and antiviral efficacy of NVR 3-778 in HBV patients as both a single agent and in combination with current HBV therapies after a four week dosing period."

About NVR 3-778

NVR 3-778 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 3-778 offers the potential for more efficient suppression of the virus leading to improved durable viral suppression and functional 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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