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SCYNEXIS' Oral SCY-635 Shows Potential as an Immune Acting Antiviral to Augment Current HCV Treatments

--SCY-635 Restores Sensitivity to PEG-IFN/RBV in Difficult to Treat Patients--

RESEARCH TRIANGLE PARK, N.C.--(BUSINESS WIRE)-- SCYNEXIS, Inc. announced today the results of a Phase 2a study of lead candidate SCY-635 in combination with pegylated interferon and ribavirin (Peg-IFN/RBV) for the treatment of the hepatitis C virus (HCV) that showed SCY-635 has the potential to play an important role in the reversal of immune exhaustion, restoring the immune systems of difficult to treat patients with HCV. The presentation "Short Duration Treatment with SCY-635 Restores Sensitivity to Peg-IFN/RBV in Difficult to Treat, IL28B TT/CT, HCV Genotype 1 Patients" was given by lead investigator Dr. Andrew J. Muir at the 63rd Annual Meeting of the American Association for the Study of Liver Diseases (AASLD) in Boston, Massachusetts. The results demonstrate that SCY-635 has the potential to open up a new frontier in immunotherapy for the treatment of HCV as a synergistic Direct Acting Antiviral (DAA) and a stimulator of the host immune system (Immune Acting Antiviral or IAA), augmenting existing treatments.

The Phase 2a study found that SCY-635 administered for only four weeks restored sensitivity to Peg-IFN/RBV therapy in a difficult to treat, HCV genotype 1 infected population. SCY-635 treated patients continued treatment with just Peg-IFN and RBV and at week 24 demonstrated a continued decline in viremia with 63% of patients having undetectable levels of HCV RNA as compared to placebo at 0%.

"The results of this study showed that SCY-635 by its effect on the immune response in HCV infected patients, could play an important role in future treatment regimens, shortening therapy timeframes, and simplifying treatment," said Yves Ribeill, PhD, Chief Executive Officer of SCYNEXIS. "A major hurdle we face in treating the virus is the difficult to treat population, whose immune system has been compromised by HCV. This candidate could be of great utility for all HCV infected patients by helping to restore the immune system."

The trial was a randomized, placebo-controlled, double-blind study with the primary objective of evaluating the effect of treatment with SCY-635 in combination with Peg-IFN α-2a and RBV on HCV viral replication in treatment-naive subjects with chronic genotype 1 infection who have an IL28B genotype of C/T or T/T. Eight patients were treated with 300 mg SCY-635 BID plus Peg-IFN and RBV for four weeks and two patients were treated with placebo plus Peg-IFN and RBV for four weeks. Patients continued treatment with just Peg-IFN and RBV for an additional 44 weeks. There were no deaths or serious adverse events (AEs) reported during the study and the most common AEs reported were neutropenia and anemia. No patients experienced an AE that led to discontinuation or interruption of the study.

Results of this and other studies have prompted SCYNEXIS to explore partnership opportunities with other companies to investigate the use of SCY-635 in an all oral regimen.

About HCV and Therapeutic Need

The World Health Organization estimates that about 3% of the world's population is infected with HCV and that there are more than 170 million chronic carriers who are at risk of developing liver cirrhosis and/or liver cancer. The recent introduction of protease inhibitors (Telaprevir and Boceprevir) has improved the response rate to interferon/ribavirin based therapy, however treatment options for difficult to treat (non-CC), HCV genotype 1a infected patients remain sub-optimal. Resistance issues, serious side effects, including black box labeling, and a significant population of patients who are contraindicated to interferon based therapy have created an urgent demand for new anti-HCV agents that can reduce or eliminate interferon based regimes.

While the majority of antiviral research remains focused on viral targets such as protease and polymerase enzymes, therapies such as SCY-635 that are based on immunomodulation to counteract viral immune evasion could be of great therapeutic value.

About SCY-635

SCY-635 is a novel oral Cyclophilin inhibitor in Phase 2 studies for the treatment for Hepatitis C (HCV) and in preclinical studies for the treatment of Hepatitis B (HBV). Studies to date have demonstrated that SCY-635 is unique in that it plays a dual role as a synergistic Direct Acting Antiviral (DAA) and a stimulator of the host immune system (Immune Acting Antiviral or IAA). The addition of SCY-635 to the repertoire of currently approved HCV therapies could breathe new life into the future of the immunotherapeutic options for treating HCV.

About SCYNEXIS

SCYNEXIS delivers innovative solutions to solve the toughest problems in drug discovery and development for our pharmaceutical, global health and life science partners. We have successfully delivered preclinical and clinical drug candidates to our customers across all major therapeutic indications and have developed our own proprietary cyclophilin inhibitor programs for the treatment of a broad range of diseases, including HCV, HBV and inflammation. www.scynexis.com

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