Enanta Pharmaceuticals Presents New Preclinical Data on Compounds Targeting Hepatitis B Virus and Non-Alcoholic Steatohepatitis at The International Liver Congress™ 2019

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WATERTOWN, Mass.--(BUSINESS WIRE)-- Enanta Pharmaceuticals, Inc. (NASDAQ: ENTA), a research and development-focused biotechnology company dedicated to creating small molecule drugs for viral infections and liver diseases, announced that new preclinical data from Enanta's wholly-owned development programs for hepatitis B virus (HBV) and non-alcoholic steatohepatitis (NASH) will be presented at The International Liver Congress™ (ILC) 2019, in Vienna, Austria.

New data include a presentation on development candidate EDP-514, Enanta's core inhibitor for HBV that is expected to enter into a Phase 1 clinical study in the second half of 2019. Presentations also focus on Enanta's NASH program, featuring new data on the FXR agonist EDP-305, and including in vivo data on EP-027315 and EP-026856, two prototype compounds from Enanta's ASK-1 (apoptosis signal-regulating kinase 1) inhibitor project.

“Enanta continues to generate an abundance of preclinical and clinical data on our development candidates EDP-514 for HBV, and EDP-305 for NASH,” stated Jay R. Luly, President and CEO, Enanta. “Our extensive scientific research provides us the knowledge and confidence to move forward our best candidates with the highest likelihood of success. We look forward to announcing clinical results of EDP-305 in our ARGON-1 Phase 2 study in NASH patients in the third quarter and to initiating a phase 1 study with EDP-514 during the second half of 2019.”

A summary of the poster presentations at The International Liver Congress™ (ILC) 2019 are below.
Full abstracts can be found at [http://ilc-congress.eu](http://ilc-congress.eu).

April 11, 2019 - 09:00 - 19:00
THU-084: “A comparative study of anti-Fibrotic therapeutics using aptamer-based quantitative proteomics in a rat model of non-alcoholic steatohepatitis cirrhosis,” Smitha Krishnan, United States

Data in this poster demonstrate that in a preclinical rat model of NASH cirrhosis utilizing an aptamer-based proteomics assay, it was possible to identify non-invasive biomarkers of treatment response and potential pathways activated by different mechanisms currently under study in clinical trials by Enanta and others. Three anti-fibrotic compounds were evaluated: two ASK-1 inhibitors, Enanta compound EP-026856 and Gilead’s selonsertib, and one FXR agonist, Enanta compound EDP-305. While all three drugs were effective in inhibiting fibrosis development in this 12-week treatment model, EP-026856 showed the greatest effect on returning non-invasive serum markers back to baseline.

April 12, 2019 - 09:00 - 17:00
FRI-191: “EDP-514, a novel HBV core inhibitor with potent antiviral activity both in vitro and in vivo,” Kai Lin, United States

Data in this poster demonstrate that EDP-514, a novel class II HBV core inhibitor, is a potent inhibitor of HBV replication, and prevents the de novo formation of new cccDNA in primary human hepatocytes when given early during infection. Data also show that EDP-514 is pan-genotypic, and that combinations of EDP-514 with nucleoside reverse-transcriptase inhibitors (NRTIs, current anti-viral therapies for HBV) or a class I core inhibitor result in additive to synergistic antiviral effects in vitro. In vivo, EDP-514 demonstrates excellent in vivo efficacy with >4-log viral load reduction in HBV-infected PXB mice.

FRI-340: “In vivo effects of a novel inhibitor of apoptosis signal-regulating kinase 1 in mouse models of liver injury and metabolic disease,” Manuel Roqueta-Rivera, United States

Data in this poster demonstrate that EP-027315 is a potent and highly selective inhibitor of ASK-1. It inhibits hepatic ASK-1 and decreases liver pJNK (one of the stress-activated protein kinase signaling pathways influencing inflammation in liver cells), plasma ALT (a common marker of potential liver damage), and apoptosis (cell death) in a dose-dependent manner in a mouse acute injury model. EP-027315 also protects against liver injury in a diet-induced obesity model. Suppression of markers of liver injury, inflammation, and apoptotic pathways are observed at both a transcriptional and protein level.

About Enanta
Enanta Pharmaceuticals is using its robust, chemistry-driven approach and drug discovery capabilities to become a leader in the discovery and development of small molecule drugs for the treatment of viral infections and liver diseases. Enanta's research and development efforts are currently focused on the following disease targets: respiratory syncytial virus (RSV), non-alcoholic steatohepatitis (NASH)/primary biliary cholangitis (PBC), and hepatitis B virus (HBV).

Enanta's research and development activities are funded by royalties from HCV products developed under its collaboration with AbbVie. Glecaprevir, a protease inhibitor discovered by Enanta, is now sold by AbbVie in numerous countries as part of its newest treatment for chronic hepatitis C virus (HCV) infection. This leading HCV regimen is sold under the tradenames MAVYRET™ (U.S.) and MAVIRET™ (ex-U.S.) (glecaprevir/pibrentasvir). Please visit www.enanta.com for more information.

Forward Looking Statements Disclaimer
This press release contains forward-looking statements, including statements with respect to the prospects for further developments with respect to EDP-305 for NASH/PBC and EDP-514 for HBV. Statements that are not historical facts are based on management’s current expectations, estimates, forecasts and projections about Enanta’s business and the industry in which it operates and management’s beliefs and assumptions. The statements contained in this release are not guarantees of future performance and involve certain risks, uncertainties and assumptions, which are difficult to predict. Therefore, actual outcomes and results may differ materially from what is expressed in such forward-looking statements. Important factors and risks that may affect actual results include: the development risks of early stage discovery efforts in the disease areas in Enanta’s research and development pipeline, such as NASH, PBC and HBV; the impact of development, regulatory and marketing efforts of others with respect to competitive treatments for NASH, PBC and HBV; Enanta’s limited clinical development experience; Enanta’s need to attract and retain senior management and key scientific personnel; Enanta’s need to obtain and maintain patent protection for its product candidates and avoid potential infringement of the intellectual property rights of others; and other risk factors described or referred to in “Risk Factors” in Enanta’s most recent Form 10-Q for the quarter ended December 31, 2018 and other periodic reports filed more recently with the Securities and Exchange Commission. Enanta cautions investors not to place undue reliance on the forward-looking statements contained in this release. These statements speak only as of the date of this release, and Enanta undertakes no obligation to update or revise these statements, except as may be required by law.

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