

Enanta Pharmaceuticals Completes Enrollment in Two Ongoing Phase 2 Studies

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- Respiratory Syncytial Virus (RSV) Human Challenge Study with EDP-938
- ARGON-1 Study in Non-alcoholic Steatohepatitis (NASH) with EDP-305

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, today announced it has completed enrollment in two Phase 2 studies.

The Phase 2 study of EDP-938 in RSV is a randomized, double-blind, placebo-controlled, human challenge study in healthy adult subjects randomized into 1 of 2 dosing arms or a placebo arm. Subjects are dosed for 5 days and receive a once-daily 600 mg dose, a single 500 mg loading dose followed by 300 mg twice daily, or placebo. Primary and secondary outcome measures include changes in viral load measurements and changes in baseline symptoms. Topline data is expected mid-calendar 2019.

The ARGON-1 study in NASH is a 12-week, randomized, double-blind, placebo-controlled Phase 2 study evaluating the safety, tolerability, pharmacokinetics and efficacy of EDP-305 in subjects with NASH. The primary endpoint in the study is ALT reduction and safety. Subjects receive placebo or a 1 mg or 2.5 mg dose once daily for 12-weeks. Topline data is expected by the end of the third quarter of calendar 2019.

More information on the designs of these studies can be found at www.clinicaltrials.gov.

About EDP-938

EDP-938, Enanta's lead N-protein inhibitor, is being developed for the treatment of RSV infection. Enanta believes

EDP-938 is differentiated from fusion inhibitors currently in development by others for RSV because this N-protein inhibitor targets the virus' replication machinery and has demonstrated high barriers to resistance against the virus in vitro. EDP-938 has also been shown to reduce viral load below the level of detection in vivo. Additionally, it is possible that N-protein inhibitors may be effective treatments at later stages of infection.

About RSV

Respiratory syncytial virus (RSV) is a virus that infects the lungs and represents a serious unmet medical need in infants and children, as well as immune-compromised individuals and the elderly. RSV is the most common cause of bronchiolitis (inflammation of the small airways in the lung) and pneumonia in children under 1 year of age in the United States. Each year, 57,000 to 125,000 children in this group are hospitalized due to RSV infection. Also, at increased risk of a severe RSV infection, are children with compromised (weakened) immune systems due to a medical condition or medical treatment, adults with compromised immune systems and those 65 and older. There is currently no safe and effective therapy for already established RSV infection.

About EDP-305, a Farnesoid X Receptor (FXR) Agonist

EDP-305 is a potent FXR agonist and Enanta's lead product candidate being developed for the treatment of NASH and PBC. EDP-305 represents a new class of FXR agonists that has been designed to take advantage of increased binding interactions with the receptor. Further, this non-bile acid class contains steroidal and non-steroidal components and does not contain the carboxylic acid group that can lead to the formation of taurine and glycine conjugates normally associated with bile acids, which may also be present in other classes of FXR agonists.

About NAFLD, NASH, and FXR

Non-alcoholic fatty liver disease (NAFLD) is the accumulation of excessive fat in the form of triglycerides in patients' liver cells (steatosis) that is not associated with alcohol abuse. NAFLD is widely considered to be the liver expression of metabolic disease associated with type 2 diabetes, insulin resistance, obesity, and hyperlipidemia. A subgroup of NAFLD patients has liver cell injury and inflammation (steatohepatitis) in addition to excessive fat. Progression of this condition leads to non-alcoholic steatohepatitis (NASH). Patients with NASH can develop fibrosis and ultimately cirrhosis of the liver, potentially leading to hepatocellular carcinoma (HCC) or requiring a liver transplant. Farnesoid X receptor (FXR) is a nuclear receptor and a main regulator of bile acid levels in the liver and small intestine. FXR responds to bile acids by regulating gene transcription of key enzymes and transporters, many of which play important roles in lipid metabolism, insulin resistance, inflammation, and fibrosis.

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-938 for RSV and EDP-305 for NASH/PBC. 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 RSV, NASH and PBC; the impact of development, regulatory and marketing efforts of others with respect to competitive treatments for RSV, NASH and PBC; 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-K for the fiscal year ended September 30, 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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