NEWS RELEASE

Enanta Pharmaceuticals Provides Update on NASH FXR Agonist Programs

10/4/2021

– EDP-305 1.0 mg Selected as Optimal Dose Following ARGON-2 Interim Analysis –

– EDP-297 Not Substantially Differentiated from EDP-305 Based on Recent Phase 1 Results –

– Company to Discontinue ARGON-2 Trial Evaluating EDP-305 as a Monotherapy and Prioritize Combination Approaches for FXR Agonists Through Out-Licensing Strategy –

WATERTOWN, Mass.--(BUSINESS WIRE)-- Enanta Pharmaceuticals, Inc., (NASDAQ: ENTA), a clinical stage biotechnology company dedicated to creating small molecule drugs for viral infections and liver diseases, today provides an update on its two clinical stage farnesoid X receptor (FXR) agonists, EDP-305 and EDP-297, for the treatment of non-alcoholic steatohepatitis (NASH). A pre-planned interim analysis of a subset of patients through week 12 in the Phase 2b ARGON-2 study of EDP-305 as a monotherapy and data from its Phase 1 clinical study of EDP-297 provided meaningful information on dose selection and characterization for these compounds. Enanta has made a business decision to prioritize combination approaches through an out-licensing strategy for further development of these two programs and does not plan to continue further development internally.

“Looking at a broad range of doses in NASH patients, our interim analysis of EDP-305 in ARGON-2, in comparison to clinical data from ARGON-1, indicates that the 1.0 mg dose of EDP-305 provides the best balance of efficacy and tolerability,” said Jay R. Luly, Ph.D., President and Chief Executive Officer of Enanta Pharmaceuticals. “We believe that the multiple mechanisms in development for NASH today, which reflect the complex pathophysiology of this disease, make it likely that a combination approach with FXR agonists will ultimately provide the optimal treatment regimen for patients. Given this evolving landscape, we have decided to discontinue the 72-week ARGON-2 study

early in favor of pursuing a combination regimen. Based on the significant data generated to date, we believe EDP-305, our lead, late-stage candidate, which has been administered in almost 600 patients for up to 12 weeks, and EDP-297, our follow-on candidate, are well-positioned to be an important component of a combination therapy to bring a much-needed treatment to patients with NASH. Going forward, we are eager to concentrate our resources on developing oral drug candidates for treating hepatitis B virus, and human respiratory diseases including respiratory syncytial virus and SARS-CoV-2."

EDP-305 Clinical Update

ARGON-2 is a Phase 2b randomized, double-blind, placebo-controlled, multicenter study evaluating safety and efficacy of 1.5 mg and 2.0 mg of EDP-305 in patients with liver biopsy proven NASH. The primary outcome at 72-weeks is the proportion of subjects who achieve ≥1 stage improvement in fibrosis without worsening of steatohepatitis and/or resolution of steatohepatitis and no worsening of liver fibrosis as determined by liver biopsy. Results from a planned internal interim analysis on a subset of patients at 12 weeks, as well as review of clinical data from all tested doses of EDP-305 demonstrated that the 1.0 mg dose of EDP-305 provides the best balance of efficacy and tolerability.

ARGON-1 was a 12-week Phase 2a randomized, double-blind, placebo-controlled study evaluating the safety, tolerability, pharmacokinetics and efficacy of 1.0 mg and 2.5 mg doses of EDP-305 in a NASH population. The primary objectives of the study were to evaluate change in ALT levels at week 12 and to evaluate the safety and tolerability of EDP-305. Key secondary objectives included change in liver fat content by MRI-PDFF, change in lipids, and pharmacokinetics and pharmacodynamic parameters, including C4 and FGF19.

In ARGON-1, EDP-305 1.0 mg dose resulted in good target engagement as measured by reduction in levels of C4, GGT and ALT after 12 weeks of treatment. Overall, EDP-305 was generally safe, with the majority of treatment-emergent adverse events being mild to moderate. The incidence of treatment discontinuation due to pruritus was 1.8%.

EDP-297 Clinical Update

EDP-297, Enanta's second FXR agonist designed for greater potency and tissue targeting, was evaluated in a Phase 1 randomized, double-blind, placebo-controlled study which assessed the safety, tolerability and pharmacokinetics of orally administered single (20-600 microgram) and multiple doses (5-90 microgram) of EDP-297 in healthy adult subjects. The first phase assessed single ascending doses of EDP-297 or placebo in healthy subjects. A "fasted" and "fed" two-part cohort also assessed food effect. The second phase assessed multiple ascending doses of EDP-297 or placebo for 14-days in healthy subjects. Each cohort within each phase enrolled a total of eight subjects who were randomized to receive EDP-297 or placebo. The cohort assessing food effect enrolled 10 subjects randomized to receive EDP-297 or placebo. While strong target engagement was observed at lower doses of EDP-297, the

overall balance of activity and tolerability was comparable to that of EDP-305. Data from this study will be submitted for presentation at a future medical conference.

About NASH and FXR Agonists

NASH is a serious form of non-alcoholic fatty liver disease (NAFLD) which is common in the United States and around the world and is closely associated with diabetes and obesity. Characterized by an excessive build-up of fat in the liver causing stress and damage to liver cells, NASH can lead to inflammation and fibrosis, causing permanent damage, including cirrhosis and impaired liver function, as well as cancer and eventually death. NASH is the leading cause of liver transplants in the United States and Europe and currently has no FDA-approved treatment. A farnesoid X receptor is a main regulator of bile acid levels in the liver and small intestine. It 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. EDP-305 and EDP-297 represent a non-bile-acid FXR agonist class that contains steroidal and non-steroidal components designed to take advantage of increased binding interactions with the receptor.

About Enanta

Enanta 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 have produced clinical candidates for the following disease targets: respiratory syncytial virus (RSV), hepatitis B virus (HBV), SARS-CoV-2 (COVID-19), and non-alcoholic steatohepatitis (NASH). Enanta is also conducting research in human metapneumovirus (hMPV).

Enanta's research and development activities are funded by royalties from hepatitis C virus (HCV) products developed under its collaboration with AbbVie. Glecaprevir, a protease inhibitor discovered by Enanta, is sold by AbbVie in numerous countries as part of its leading treatment for chronic HCV infection 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 out-licensing Enanta's FXR agonists. 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 impact of development, regulatory and

marketing efforts of others with respect to competitive treatments for NASH; the uncertainty of being able to achieve any out-licensing transaction for an Enanta's FXR agonist on favorable terms, if at all ; 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 June 30, 2021 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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