Enanta Pharmaceuticals Announces AbbVie's Investigational HCV Regimen Receives U.S. FDA Breakthrough Therapy Designation

September 30, 2016

- *Investigational regimen includes Enanta's protease inhibitor glecaprevir (ABT-493)*
- *Breakthrough Therapy Designation granted based on Phase 2 clinical data for genotype 1 (GT1) patients who failed previous therapy with direct-acting antivirals (DAAs)*
- *Currently in Phase 3 clinical trials, glecaprevir/pibrentasvir (G/P) is an investigational, pan-genotypic regimen being evaluated for the treatment of chronic hepatitis C virus (HCV) genotypes 1-6*
- *Breakthrough Therapy Designation is granted to investigational treatments for serious or life-threatening conditions with preliminary clinical evidence that may demonstrate substantial improvement over existing therapies*

WATERTOWN, Mass.--(BUSINESS WIRE)--Sep. 30, 2016-- 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 that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy Designation (BTD) for AbbVie's investigational, pan-genotypic regimen of glecaprevir (ABT-493)/pibrentasvir (ABT-530) (G/P) for the treatment of patients with chronic hepatitis C virus (HCV) who failed previous therapy with direct-acting antivirals (DAAs) in genotype 1 (GT1), including previous therapy with an NS5A inhibitor and/or protease inhibitor.

The BTD is supported by positive results seen in AbbVie's Phase 2 MAGELLAN-1 clinical study. According to the FDA, BTD is intended to expedite the development and review of an investigational therapy for a serious or life threatening condition when there is preliminary clinical evidence that the therapy may demonstrate substantial improvement over any existing therapy.[1]

"The FDA's Breakthrough Therapy Designation is an important step for AbbVie's efforts to bring to market its pan-genotypic HCV medicine containing our second-generation protease inhibitor," stated Jay R. Luly, Ph.D., CEO of Enanta. "AbbVie is also investigating an eight-week regimen of G/P for the majority of patients. We look forward to release of additional clinical data on G/P in the coming months."

Glecaprevir (GLE) is Enanta's second protease inhibitor being developed through its collaboration with AbbVie. AbbVie's investigational regimen includes GLE, an NS3/4A protease inhibitor, and pibrentasvir (PIB), an NS5A inhibitor, which are co-formulated and dosed once daily as three oral tablets.

AbbVie will present new Phase 3 data evaluating the safety and efficacy of G/P across all major HCV genotypes (genotypes 1-6) at an upcoming scientific congress. There is additional information on the clinical trials for G/P conducted by AbbVie available at www.clinicaltrials.gov.

About Enanta

Enanta Pharmaceuticals is a research and development-focused biotechnology company that uses its robust chemistry-driven approach and drug discovery capabilities to create small molecule drugs for viral infections and liver diseases. Enanta's research and development efforts are currently focused on four disease targets: Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), Non-alcoholic Steatohepatitis (NASH) and Respiratory Syncytial Virus (RSV).

Enanta has discovered novel protease inhibitors and NS5A inhibitors that are members of the direct-acting-antiviral (DAA) inhibitor classes designed for use against the hepatitis C virus (HCV). Enanta's protease inhibitors, developed through its collaboration with AbbVie, include paritaprevir, which is contained in AbbVie's marketed DAA regimens for HCV, and ABT-493, Enanta's second protease inhibitor, which AbbVie is developing in Phase 3 studies in combination with ABT-530, AbbVie's NS5A inhibitor. Enanta has also discovered a cyclophilin inhibitor, EDP-494, a novel host-targeting mechanism for HCV, which is now in a clinical proof of concept study in HCV patients, and EDP-305, a non-bile acid FXR agonist for NASH, currently in Phase 1 clinical development. Please visit www.enanta.com for more information on our programs and pipeline.

Forward Looking Statements Disclaimer

This press release contains forward-looking statements, including statements with respect to the prospects for AbbVie's investigational HCV treatment regimen containing glecaprevir. 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 efforts of AbbVie (our collaborator developing glecaprevir) to develop and obtain regulatory approval of any regimens containing glecaprevir and successfully commercialize them; the development, regulatory and marketing efforts of others with respect to competitive HCV treatment regimens; regulatory and reimbursement actions affecting any glecaprevir-containing HCV regimen, any competitive regimen, or both; 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, 2015 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.

1 U.S. Food and Drug Administration. Fact Sheet: Breakthrough Therapies. http://www.fda.gov/RegulatoryInformation/Legislation/SignificantAmendmentstotheFDCAct/FDASIA/ucm341027.htm. Accessed September 1, 2016.

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Source: Enanta Pharmaceuticals, Inc.

Investor Contact
Enanta Pharmaceuticals, Inc.
Carol Miceli, 617-607-0710
cmiceli@enanta.com

or

Media Contact
MacDougall Biomedical Communications
Kari Watson, 781-235-3060
kwatson@macbiocom.com