



Enanta Pharmaceuticals' HCV NS5A Inhibitor EDP-239 Advances into Combination Studies with Alisporivir (DEB025)

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WATERTOWN, Mass.--(BUSINESS WIRE)--Aug. 7, 2014-- Enanta Pharmaceuticals, Inc. (NASDAQ:ENTA) a research and development-focused biotechnology company dedicated to creating small molecule drugs in the infectious disease field, today announced that Novartis has advanced EDP-239, Enanta's NS5A inhibitor for hepatitis C virus (HCV), into drug combination studies with alisporivir (DEB025), a cyclophilin inhibitor being developed by Novartis. These combination studies are part of Enanta's existing collaboration with Novartis for the development of new combination therapies for the treatment of HCV using Enanta's NS5A inhibitors.

EDP-239 is a direct-acting anti-viral (DAA) that directly inhibits replication of HCV. Alisporivir (DEB025) blocks HCV replication by targeting proteins in the host cell that are critical to replication of the hepatitis C virus (HCV). As a host-targeting antiviral (HTA), alisporivir (DEB025) is expected to have a high barrier to HCV resistance. It has also demonstrated in vitro anti-HCV activity across multiple HCV genotypes. As the most advanced oral HTA¹, alisporivir (DEB025), when combined with EDP-239, may be an attractive drug combination for the next-generation of interferon-free HCV therapies.

The phase 1 combination study conducted by Novartis is investigating the pharmacokinetics, safety, and tolerability of alisporivir (DEB025) and EDP-239 when co-administered to healthy adult subjects and is scheduled to enroll 42 healthy subjects.

For more information on the complete study design, please visit www.clinicaltrials.gov.

"EDP-239 in combination with a cyclophilin inhibitor such as alisporivir provides a new combination of mechanisms to explore in the clinic," commented Jay R. Luly, Ph.D., President and CEO. "The advancement of EDP-239 in partnership with Novartis provides Enanta with another opportunity to participate in additional HCV regimens under development."

About EDP-239

EDP-239 is Enanta's lead NS5A inhibitor for HCV infection. NS5A is a non-structural (NS) viral protein that is essential to viral replication of HCV. EDP-239 has demonstrated potent activity against major HCV genotypes when tested in the replicon assay, which is a common in vitro test for determining potency of an active compound in reducing HCV replication. In addition, EDP-239 has additive or synergistic antiviral activity when used in combination with other anti-HCV therapeutics (DAA and HTA) in reducing HCV replication. Enanta's NS5A program and intellectual property estate in the HCV field were derived from its internal drug discovery efforts.

NS5A Collaboration with Novartis

On February 16, 2012, Enanta entered into a license and collaboration agreement with Novartis for the development, manufacture and commercialization of its lead development candidate, EDP-239, and other NS5A inhibitor compounds. Under the terms of the agreement, Enanta received an upfront payment of \$34 million and an \$11 million milestone payment and is eligible to receive up to a total of \$395 million in milestone payments if certain clinical, regulatory, and commercial milestones are met. Enanta is also eligible to receive tiered double-digit royalties on worldwide sales of products.

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 in the infectious disease field. Enanta is discovering, and in some cases developing, novel inhibitors designed for use against the hepatitis C virus (HCV). These inhibitors include members of the direct acting antiviral (DAA) inhibitor classes – protease (partnered with AbbVie), NS5A (partnered with Novartis) and nucleotide polymerase – as well as a host-targeted antiviral (HTA) inhibitor class targeted against cyclophilin. Additionally, Enanta has created a new class of antibiotics, called Bicyclobides, for the treatment of multi-drug resistant bacteria, with a focus on developing an intravenous and oral treatment for hospital and community MRSA (*Methicillin-resistant Staphylococcus aureus*) infections.

Forward Looking Statements Disclaimer

This press release contains forward-looking statements, including statements with respect to the prospects for clinical development of EDP-239 and the prospects for milestone payments to Enanta resulting from such development and any subsequent regulatory approvals and commercial sales. Statements that are not historical facts are based on our management's current expectations, estimates, forecasts and projections about our business and the industry in which we operate and our 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 that may affect actual results include the efforts of Novartis (our collaborator on EDP-239) to develop EDP-239 and obtain regulatory approvals and commercialize treatment regimens containing it, the development, regulatory and marketing efforts of others with respect to competitive HCV treatment regimens, and changes in the market for HCV therapies. 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 The Combination of Alisporivir plus an NS5A Inhibitor Provides Additive to Synergistic Anti-Hepatitis C Virus Activity without Detectable Cross-Resistance - Chatterji U, et.al. *Antimicrob Agents Chemother.* 2014 Jun;58(6):3327-3334. Epub 2014 Mar 31.



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