# Assertio Therapeutics Announces FDA Notification of Acceptance for Filing of 505(b)(2) NDA for Long-acting Cosyntropin

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**Company Anticipates Potential Market Launch by Early 2020**

LAKE FOREST, Ill., Feb. 19, 2019 (GLOBE NEWSWIRE) -- Assertio Therapeutics, Inc. (NASDAQ: ASRT) announced today that it has received notification of acceptance for filing from the U.S. Food and Drug Administration (FDA) for its 505(b)(2) New Drug Application for its injectable formulation of long-acting cosyntropin (synthetic adrenocorticotropic hormone, or ACTH). The Company, together with its partner West Therapeutic Development, seeks approval for the use of this product as a diagnostic drug in the screening of patients presumed to have adrenocortical insufficiency.

“We are pleased to announce another positive milestone in the development of long-acting cosyntropin and in the advancement of our strategy to build a new orphan/specialty business,” said Arthur Higgins, President and Chief Executive Officer of Assertio. “The FDA’s acceptance of our filing positions us one step closer to launching a synthetic long-acting cosyntropin into the U.S. market by early 2020.”

The PDUFA (Prescription Drug User Fee Act) goal date for the completion of the FDA’s review of long-acting cosyntropin is set for October 19, 2019. This date reflects a standard 10-month review period and is consistent with management’s expectations for the 505(b)(2) filing.

Long-acting cosyntropin is an alcohol-free formulation of a synthetic analogue of ACTH, a hormone secreted from the pituitary gland that is responsible for the stimulation of the adrenal cortex. Cosyntropin is composed of the first 24 of 39 amino acids of natural ACTH, and retains the full steroidogenic activity of natural ACTH.

**About Assertio Therapeutics, Inc.**
Assertio Therapeutics is committed to providing responsible solutions to advance patient care in the Company’s core areas of neurology, orphan and specialty medicines. Assertio currently markets three FDA-approved products and continues to identify, license and develop new products that offer enhanced options for patients that may be underserved by existing therapies. To learn more about Assertio, visit www.assertiotx.com.

**"Safe Harbor" Statement under the Private Securities Litigation Reform Act of 1995**
This news release contains forward-looking statements. These statements involve inherent risks and uncertainties that could cause actual results to differ materially from those projected or anticipated, including risks related to regulatory approval and clinical development of long-acting cosyntropin, expectations regarding potential business opportunities and other risks outlined in the Company's public filings with the Securities and Exchange Commission, including the Company's most recent annual report on Form 10-K and subsequent Quarterly Reports on Form 10-Q. All information provided in this news release speaks as of the date hereof. Except as otherwise required by law, the Company undertakes no obligation to update or revise its forward-looking statements.

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