



Assertio Therapeutics Announces Submission of NDA for FDA Approval of Cosyntropin Depot

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-- Submission Advances Company's Strategy to Build A New Orphan/Specialty Business and Aligns with Company's Mission of Putting Patients First --

LAKE FOREST, Ill., Dec. 20, 2018 (GLOBE NEWSWIRE) -- Assertio Therapeutics, Inc. (NASDAQ: ASRT) today announced that it has submitted to the U.S. Food and Drug Administration a 505(b)(2) New Drug Application for its novel injectable formulation of cosyntropin (synthetic adrenocorticotrophic hormone, or ACTH) depot with its partner, West Therapeutic Development, LLC. The application seeks approval for the use of this product as a diagnostic drug in the screening of patients presumed to have adrenocortical insufficiency.

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

"Our filing strategy for cosyntropin depot is the most efficient and expeditious way to make this important medical product available to patients -- and is a significant milestone as we build a new orphan/specialty business," said Arthur Higgins, President and Chief Executive Officer of Assertio. "This filing represents the first indication in our clinical development program for a long-acting formulation of cosyntropin. If successful, we'll have the opportunity to offer patients in the U.S. an alternative depot formulation to immediate-release cosyntropin by early 2020."

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 cosyntropin depot, 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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Source: Assertio Therapeutics, Inc.