Assertio Therapeutics Provides Regulatory Update on Long-Acting Cosyntropin

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LAKE FOREST, Ill., Oct. 21, 2019 (GLOBE NEWSWIRE) -- Assertio Therapeutics, Inc. (NASDAQ: ASRT), today announced that its development partner West Therapeutic Development, LLC (West) has received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) for its New Drug Application (NDA) for its injectable formulation of long-acting cosyntropin (synthetic adrenocorticotropic hormone, or ACTH). West is seeking approval for use as a diagnostic drug in the screening of patients presumed to have adrenocortical insufficiency.

The primary focus of the CRL relates to the FDA determination that certain pharmacodynamic parameters were not adequately achieved.

“West and Assertio will work together to determine how best to address the CRL,” said Arthur Higgins, President and CEO of Assertio. “In the meantime, we continue to focus on driving robust adjusted EBITDA performance and generating strong cash flows.”

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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