Assertio Therapeutics Announces Favorable NUCYNTA® Patent Ruling

March 28, 2019

LAKE FOREST, Ill., March 28, 2019 (GLOBE NEWSWIRE) -- Assertio Therapeutics, Inc. (NASDAQ: ASRT) today announced that the United States Court of Appeals for the Federal Circuit has ruled in favor of Assertio with respect to the company's patent litigation against three filers of Abbreviated New Drug Applications (ANDAs) for the NUCYNTA® franchise. The Federal Circuit's ruling affirms the decision of the United States District Court (D.N.J.), which found U.S. patent No. 7,994,364 (the '364 Patent) to be valid and infringed by the defendants. The '364 Patent covers the entire NUCYNTA® franchise until December 2025.(1)

With the Court's ruling, the company expects market exclusivity until December 2025(1) for NUCYNTA® ER, NUCYNTA® and NUCYNTA® oral solution (an unmarketed form of NUCYNTA). The NUCYNTA® franchise is commercialized by Collegium Pharmaceutical, Inc. (Collegium). The Company receives royalties from Collegium based on net sales of the franchise. Based on Collegium's current 2019 NUCYNTA franchise revenue guidance, the Company currently expects such royalties to be approximately $120 million in 2019.

The Federal Circuit affirmed the District Court's ruling with regard to U.S. patent No. 8,536,130 (the '130 Patent), which upheld the validity of the '130 Patent but found that two of the three ANDA filers do not infringe the patent. The '130 Patent covers NUCYNTA ® ER until March 2029.(1)

The defendants in the appeal of the District Court's ruling in the patent litigation included Alkem Laboratories Limited, Hikma Pharmaceuticals International Limited and Actavis Elizabeth LLC, along with certain of their affiliated companies. Gibson, Dunn & Crutcher LLP represented Assertio in the litigation and appeal.

(1) Patent expiration dates reflect the addition of six months of pediatric patent term extension Assertio anticipates securing from the United States Food and Drug Administration.

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 royalties to be received based on sales of NUCYNTA and NUCYNTA ER, 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.

Investor and Media Contact:
John B. Thomas
SVP, Investor Relations and Corporate Communications
jthomas@assertiotx.com

Source: Assertio Therapeutics, Inc.