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Avenue Therapeutics Announces Dosing of First Patient in Phase 3 Safety Trial of Intravenous Tramadol for the Management of Postoperative Pain

NEW YORK, Jan. 02, 2018 (GLOBE NEWSWIRE) -- Avenue Therapeutics, Inc. (NASDAQ:ATXI) ("Avenue"), a company focused on the development and commercialization of intravenous (IV) tramadol, today announced that it has dosed the first patient in its Phase 3 safety trial of IV tramadol for the management of moderate to moderately severe pain.

"We are pleased to announce the dosing of the first patient in our Phase 3 safety trial of IV tramadol. This safety study is a key component of our pivotal Phase 3 development program and will be used to support our planned new drug application (NDA), which we hope to submit to the U.S. Food and Drug Administration in late 2019," said Lucy Lu, M.D., Avenue's President and Chief Executive Officer. "We believe that IV tramadol, which has been used widely outside the U.S., has the potential to fill the gap between IV acetaminophen/NSAIDs and conventional IV narcotics, and may help circumvent the use of conventional narcotics. We look forward to rapidly advancing our pivotal program, which will bring us closer to our goal of making available the first Schedule IV intravenous opioid in the U.S."

The Phase 3, multicenter, open-label trial will evaluate the safety of IV tramadol 50 mg in the management of postoperative pain following surgery. The trial will enroll approximately 250 patients to receive 50 mg of IV tramadol over 15 minutes at zero, two and four hours, then once every four hours thereafter.

Avenue Therapeutics is currently evaluating IV tramadol in a Phase 3 trial in patients following bunionectomy surgery, and expects to report topline data in the second quarter of 2018. The Company expects to initiate a second Phase 3 trial in patients following abdominoplasty surgery in the third quarter of 2018.

About Avenue Therapeutics
Avenue Therapeutics, Inc. ("Avenue"), a Fortress Biotech (NASDAQ:FBIO) Company, is a specialty pharmaceutical company focused on the development and commercialization of intravenous (IV) tramadol for the management of moderate to moderately severe postoperative pain. IV tramadol may fill a gap in the acute pain market between IV acetaminophen/NSAIDS and IV conventional narcotics. Avenue is currently evaluating IV tramadol in a pivotal Phase 3 program for the management of postoperative pain. Avenue is headquartered in New York City. For more information, visit www.avenuetx.com.

About Fortress Biotech
Fortress Biotech, Inc. ("Fortress") is a biopharmaceutical company dedicated to acquiring, developing and commercializing novel pharmaceutical and biotechnology products. Fortress

develops and commercializes products both within Fortress and through certain of its subsidiary companies, also known as Fortress Companies. In addition to its internal development programs, Fortress leverages its biopharmaceutical business expertise and drug development capabilities and provides funding and management services to help the Fortress Companies achieve their goals. Fortress and the Fortress Companies may seek licensings, acquisitions, partnerships, joint ventures and/or public and private financings to accelerate and provide additional funding to support their research and development programs. For more information, visit www.fortressbiotech.com.

Forward-Looking Statements

This press release may contain "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, each as amended. Such statements include, but are not limited to, any statements relating to our growth strategy and product development programs and any other statements that are not historical facts. Forward-looking statements are based on management's current expectations and are subject to risks and uncertainties that could negatively affect our business, operating results, financial condition and stock value. Factors that could cause actual results to differ materially from those currently anticipated include: risks relating to our growth strategy; risks relating to the results of research and development activities; risks relating to the timing of starting and completing clinical trials; our ability to obtain, perform under and maintain financing and strategic agreements and relationships; uncertainties relating to preclinical and clinical testing; our dependence on third-party suppliers; our ability to attract, integrate and retain key personnel; the early stage of products under development; our need for substantial additional funds; government regulation; patent and intellectual property matters; competition; as well as other risks described in our SEC filings. We expressly disclaim any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in our expectations or any changes in events, conditions or circumstances on which any such statement is based, except as required by law.

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