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

Topline data readout expected in the second quarter of 2018

New York, NY – September 27, 2017 – Avenue Therapeutics, Inc. (NASDAQ: ATXI) ("Avenue"), a Fortress Biotech (NASDAQ: FBIO) Company, today announced that the first patient has been dosed in the pivotal Phase 3 clinical trial of intravenous (IV) tramadol for the management of moderate to moderately severe pain in patients following bunionectomy surgery.

"The commencement of the pivotal Phase 3 program is a key step in the development of IV tramadol. Based on current enrollment projections, we expect to report topline data in the second quarter of 2018," said Lucy Lu, M.D., Avenue's President and Chief Executive Officer. "IV tramadol, if approved, would be the only Schedule IV intravenous opioid medicine in the United States. Currently, there is a significant gap in the acute care space between pain medications for mild to moderate pain with IV acetaminophen and NSAIDS, and those for moderate to severe pain with conventional narcotics. IV tramadol has the potential to fill this gap, and provide a new therapeutic alternative for moderate to moderately severe pain with less addiction potential than conventional narcotics and a convenient step-down option to oral tramadol."

The Phase 3, multicenter, randomized, double-blind, three-arm trial will evaluate the efficacy and safety of IV tramadol 50 mg and 25 mg versus placebo. Approximately 405 patients will be enrolled to IV tramadol 50 mg, IV tramadol 25 mg or placebo in a 1:1:1 ratio. The primary efficacy endpoint is the summed pain intensity difference over 48 hours (SPID48) compared to placebo. Additional information on the study can be found on www.clinicaltrials.gov using the identifier NCT03290378.

About Avenue Therapeutics

Avenue Therapeutics, Inc. ("Avenue"), a Fortress Biotech 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, a Schedule IV opioid, may provide less addiction potential than traditionally prescribed therapies, and 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 trial for the management of postoperative pain following bunionectomy surgery. 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 the timing of starting and completing clinical trials; uncertainties relating to preclinical and clinical testing; risks relating to our growth strategy; risks relating to the results of research and development activities; our ability to obtain, perform under and maintain financing and strategic agreements and relationships; 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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