Avenue Therapeutics to Present Phase 3 Bunionectomy Study of IV Tramadol at the American Society of Anesthesiologists Annual Meeting

New York, NY – October 18, 2019 – Avenue Therapeutics, Inc. (NASDAQ: ATXI) ("Avenue"), a company focused on the development of intravenous ("IV") tramadol for the U.S. market, today announced an eAbstract presentation at ANESTHESIOLOGY® 2019, the Annual Meeting of the American Society of Anesthesiologists in Orlando, FL from October 19-23, 2019.

The eAbstract (A2170) entitled "Tramadol Hydrochloride Injection: Effective Relief of Postsurgical Pain in Patients Undergoing Bunionectomy Surgery", is scheduled to be presented on Sunday, October 20th at 10:45 a.m. EDT. The eAbstract will highlight the Phase 3 data for IV tramadol in the management of post-surgical pain in patients undergoing bunionectomy, an orthopedic model.

"Patients are often treated with Schedule II narcotics due to a lack of other options," said David Leiman, M.D., Director, HD Research Corp. and Clinical Assistant Professor of Surgery at The University of Texas at Houston, an investigator in IV tramadol's Phase 3 program. "These data suggest that IV tramadol, if approved, may become an important new therapy for managing postoperative pain and offer a potential alternative that could reduce the use of Schedule II narcotics."

This Phase 3, multicenter, double-blind, placebo-controlled trial evaluated the efficacy and safety of IV tramadol in 409 patients following bunionectomy surgery. Patients were randomized in a 1:1:1 ratio to a postoperative regimen of 50 mg of IV tramadol, 25 mg of IV tramadol or placebo administered over 15 minutes at hours 0, 2, 4 and once every 4 hours thereafter, for up to 13 doses. The primary endpoint of the bunionectomy study assessed the analgesic efficacy of IV tramadol compared to placebo as measured by SPID48. The key secondary endpoints included SPID24, total consumption of rescue medicine and Patient Global Assessment, which captures the patient's perception of the treatment. As previously announced, IV tramadol 50 mg met the primary as well as all of the key secondary endpoints.

About Avenue Therapeutics

Avenue 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 has completed its Phase 3 program of IV tramadol for the management of postoperative pain and plans to submit a New Drug Application to the U.S. Food and Drug Administration by year-end. Avenue is headquartered in New York City and was founded by Fortress Biotech, Inc. (NASDAQ: FBIO). For more information, visit www.avenuetx.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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