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Avenue Therapeutics Announces Publication of IV Tramadol Phase 1 Clinical Data in Clinical Pharmacology in Drug Development

NEW YORK, Oct. 28, 2019 (GLOBE NEWSWIRE) -- Avenue Therapeutics, Inc. (NASDAQ: ATXI) ("Avenue"), a company focused on the development of intravenous ("IV") tramadol for the U.S. market, announced today that its Phase 1 data on intravenous (IV) tramadol has been published in the peer-reviewed journal *Clinical Pharmacology in Drug Development*. Based on the results of the study, Avenue chose the IV tramadol 50 mg dosing regimen for Phase 3 development.

The objective of this Phase 1, open-label, single investigational center, three-treatment, three-period, multidose crossover study was to compare the pharmacokinetics of two novel IV tramadol dosing regimens to oral tramadol 100 mg given every six hours, the highest approved oral dosage in the United States. Compared to the oral regimen, IV tramadol 50 mg administered at hours 0, 2, and 4 and every 4 hours thereafter reached initial tramadol peak serum concentration (Cmax) more rapidly, while resulting in similar overall steady-state Cmax and area under the plasma concentration–time curve, and that the primary metabolite, M1, had lower area under the plasma concentration–time curve and Cmax than for the oral regimen. The IV tramadol 50 mg dosing regimen was well tolerated, with adverse event profiles consistent with the known pharmacological effects of tramadol.

The paper titled "Comparing the Pharmacokinetics of 2 Novel Intravenous Tramadol Dosing Regimens to Oral Tramadol: A Randomized 3-Arm Crossover Study", can be accessed here.

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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