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Avenue Therapeutics Announces Publications in Peer-Reviewed Journals

NEW YORK, June 05, 2020 (GLOBE NEWSWIRE) -- Avenue Therapeutics, Inc. (NASDAQ: ATXI) ("Avenue"), a company focused on the development of intravenous ("IV") tramadol for the U.S. market, today announced the following publications in peer-reviewed journals.

The publication titled "Intravenous Tramadol is Effective in the Management of Postoperative Pain Following Abdominoplasty: A Three-Arm Randomized Placebo- and Active-Controlled Trial" has been published in *Drugs in R&D* and can be accessed here.

The objective of this Phase 3 study was to evaluate the safety, tolerability and efficacy of IV tramadol 50 mg versus placebo in patients following abdominoplasty surgery, a soft-tissue surgical model. The study included an active comparator arm, IV morphine 4mg. While the study was not powered to provide statistical comparison of the two active arms, its sample size allowed for assessment of the general comparability of the treatment regimens. The results of the study demonstrated that IV tramadol was statistically superior to placebo and comparable to IV morphine for the primary and all key secondary efficacy outcomes. IV tramadol also demonstrated numerically lower rates of incidence of the most common treatment-emergent adverse events than IV morphine.

The publication titled "IV Tramadol – A New Treatment Option for Management of Post-Operative Pain in the U.S.: An Open-Label, Single-Arm, Safety Trial Including Various Types of Surgery" has been published in *Journal of Pain Research* and can be accessed here.

This safety study was a Phase 3, single-arm, open-label safety study performed in patients undergoing a variety of elective bone and soft tissue surgeries to evaluate the safety and tolerability of IV tramadol 50 mg. The study enrolled 251 patients with both orthopedic and soft tissue surgeries well represented. Dosing was completed in 95% of the patients. IV tramadol was well tolerated, and the adverse events were consistent with known tramadol pharmacology. At the end of treatment, approximately 95% of the patients reported that study medication was good, very good, or excellent for controlling pain.

The publication titled "Misuse of Tramadol in the United States: An Analysis of the National Survey of Drug Use and Health 2002-2017" has been published in *Substance Abuse: Research and Treatment* and can be accessed here.

The objective of the study was to analyze the rates of misuse – use in any way not directed by a doctor – of products containing oral tramadol, a Schedule IV opioid, as compared to comparator Schedule II opioids (morphine, oxycodone, and hydrocodone) and alprazolam, a commonly prescribed Schedule IV controlled substance in the U.S. from the National Survey of Drug Use and Health ("NSDUH"). NSDUH is an annual, congressionally mandated household survey of self-reported alcohol, drug and tobacco use among non-institutionalized persons (≥12 years old) in the U.S. The study showed a low prevalence of oral tramadol

misuse as compared to other commonly prescribed opioids when adjusted for prescription volume. Estimates of reported oral tramadol misuse remained relatively stable over time. Reports of oral tramadol misuse were also much less than alprazolam, another Schedule IV drug.

About Avenue Therapeutics

Avenue Therapeutics is a specialty pharmaceutical company whose mission is to develop IV tramadol, a potential alternative that could reduce the use of conventional opioids, for patients suffering from acute pain in the U.S. 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 related to us obtaining regulatory approval from the FDA for our product candidate, risks relating to the COVID-19 outbreak and its potential impact on our employees' and consultants' ability to complete work in a timely manner, 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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