July 21, 2020

Avenue Therapeutics Announces Publication of Phase 3 Bunionectomy Study Results

Publication highlights IV tramadol 50 mg demonstrated a statistically significant benefit (p-value < 0.05) over placebo for primary and all key secondary efficacy endpoints

NEW YORK, July 21, 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 that the results from its Phase 3 study of IV tramadol in patients undergoing bunionectomy have been published in the peer-reviewed journal, *Pain and Therapy.*

The objective of this Phase 3 study was to compare the analgesic benefit and tolerability of two doses of IV tramadol (50 mg and 25 mg) to placebo in adult patients undergoing bunionectomy, an orthopedic surgical model. Eligible patients were randomized (1:1:1 ratio) to IV tramadol 50 mg, 25 mg or placebo. The primary endpoint was the summary of pain intensity differences ("SPID") over 48 hours. Key secondary endpoints included SPID over 24 hours, total consumption of rescue analgesia, and patient global assessment of efficacy. Safety assessments included treatment emergent adverse events ("TEAEs"), clinical laboratory tests, vital signs, and electrocardiograms ("ECG"). Assessment of the dose-response was an important objective of the study. The study established a clear dose response, with IV tramadol 50 mg demonstrating a statistically significant benefit ($p < 0.05$) over placebo for primary and all key secondary efficacy endpoints, whereas IV tramadol 25 mg demonstrated intermediate results between the 50 mg and placebo arms. IV tramadol 50 mg was well-tolerated. The most common TEAEs were nausea and vomiting, and there were no meaningful differences among the treatments for vital signs, ECG, and laboratory assessments. The largest proportion of patients completed IV tramadol 50 mg (98.6%) compared to IV tramadol 25 mg (91.8%) and placebo (88.2%). The study concluded that IV tramadol 50 mg was effective and well-tolerated as a treatment for postoperative pain following bunionectomy surgery, while IV tramadol 25 mg, although well-tolerated, was judged to be an ineffective dose for the treatment of pain in this setting.

Based on the results of the study, IV tramadol 50 mg was further developed in Avenue's Phase 3 program. The publication titled "Efficacy and Safety of Intravenously Administered Tramadol in Patients with Moderate to Severe Pain Following Bunionectomy: A

Randomized, Double-Blind, Placebo-Controlled, Dose-Finding Study" can be accessed here.

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.

Contacts:
Jaclyn Jaffe and William Begien
Avenue Therapeutics, Inc.
(781) 652-4500
ir@avenuetx.com

Source: Avenue Therapeutics