April 17, 2023

Avenue Therapeutics Announces Regulatory Update Based on Type C Meeting with FDA and Next Steps in the Development of IV Tramadol

MIAMI, April 17, 2023 (GLOBE NEWSWIRE) -- Avenue Therapeutics, Inc. (Nasdaq: ATXI) ("Avenue" or the "Company"), a specialty pharmaceutical company focused on the development and commercialization of therapies for the treatment of rare and neurologic diseases, today announced that it has received official meeting minutes from the Type C meeting with the U.S. Food and Drug Administration ("FDA") conducted on March 9, 2023, regarding the development of intravenous ("IV") Tramadol for the treatment of post-operative pain. The purpose of this meeting was to discuss and reach agreement with the FDA on the proposed study protocol that would assess the risk of opioid-induced respiratory depression related to opioid stacking on IV Tramadol compared to IV morphine.

As disclosed in September 2022, Avenue received meeting minutes from the FDA regarding a Type A meeting conducted on August 9, 2022, for IV Tramadol. At that meeting, Avenue presented a study design for a single safety clinical trial that the Company believes could address the concerns regarding risks related to opioid stacking and the FDA stated that the proposed study design appeared reasonable and agreed on various study design aspects with the expectation that additional feedback would be provided to Avenue upon review of a more detailed study protocol. Subsequent to the August 9 meeting, the Company incorporated the FDA's suggestions from the meeting minutes and submitted a Type C Meeting Request and a briefing book that included a detailed study protocol as the basis for further discussion with the FDA on the requirements for a complete response to the second Complete Response Letter for IV Tramadol.

The Type C meeting minutes from the FDA indicate that the FDA and Avenue Therapeutics are in agreement with a majority of the proposed protocol items and are in active discussion about remaining open items. The minutes indicate that the FDA also agrees that a successful study will support the submission of a complete response to the second Complete Response Letter for IV Tramadol pending final agreement on a statistical analysis plan and a full review of the submitted data in the complete response as well as concurrence from the Division of Anesthesia, Analgesia and Addiction Products (DAAAP).

"Our meeting with the FDA was very productive and led to agreement on many of the outstanding items regarding the proposed study protocol that would assess the risk of

opioid-induced respiratory depression related to opioid stacking on IV Tramadol relative to an approved opioid analgesic," said Alexandra MacLean, M.D., Avenue's Chief Executive Officer. "We are finalizing the protocol based on the FDA's feedback and look forward to the continued collaborative discussions with the FDA with the goal of partnering or initiating a Phase 3 safety study this year to assess the risk of opioid-induced respiratory depression related to opioid stacking on IV Tramadol relative to an approved opioid analgesic when treating post-operative pain. We expect that a positive study outcome could result in the approval of IV Tramadol. Additionally, we plan to provide updates on our other two programs later this year including the AJ201 clinical trial to treat spinal and bulbar muscular atrophy and the continued development of BAER-101 for epilepsy and acute anxiety. Avenue continues to stay true to its mission of developing impactful therapies to treat patients with rare and neurologic diseases, while generating shareholder value."

About Avenue Therapeutics

Avenue Therapeutics, Inc. (Nasdaq: ATXI) is a specialty pharmaceutical company focused on the development and commercialization of therapies for the treatment of neurologic and rare diseases. It is currently developing three assets including AJ201, a first-in-class asset for spinal and bulbar muscular atrophy, BAER-101, an oral small molecule selective GABA-A α2/3 receptor positive allosteric modulator for CNS diseases, and IV Tramadol, which is in Phase 3 clinical development for the management of moderate-to-moderately-severe pain in adults in a medically supervised healthcare setting. Avenue is headquartered in Miami, FL and was founded by Fortress Biotech, Inc. (Nasdaq: FBIO). For more information, visit www.avenuetx.com.

Forward-Looking Statements

This press release contains predictive or "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. All statements other than statements of current or historical fact contained in this press release, including statements that express our intentions, plans, objectives, beliefs, expectations, strategies, predictions or any other statements relating to our future activities or other future events or conditions are forward-looking statements. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "predict," "project," "will," "should," "would" and similar expressions are intended to identify forward-looking statements. These statements are based on current expectations, estimates and projections made by management about our business, our industry and other conditions affecting our financial condition, results of operations or business prospects. These statements are not guarantees of future performance and involve risks, uncertainties and assumptions that are difficult to predict. Therefore, actual outcomes and results may differ materially from what is expressed or forecasted in, or implied by, the forward-looking statements due to numerous risks and uncertainties. Factors that could cause such outcomes and results to differ include, but are not limited to, risks and uncertainties arising from: expectations for increases or decreases in expenses; expectations for the clinical and pre-clinical development, manufacturing, regulatory approval, and commercialization of our pharmaceutical product candidate or any other products we may acquire or in-license; our use of clinical research centers and other contractors; expectations for incurring capital expenditures to expand our research and development and manufacturing capabilities; expectations for generating revenue or becoming profitable on a sustained basis; expectations or ability to enter into marketing and other partnership agreements; expectations or ability to enter into product acquisition and in-licensing transactions; expectations or ability to build our own commercial infrastructure to

manufacture, market and sell our product candidates; acceptance of our products by doctors, patients or payors; our ability to compete against other companies and research institutions; our ability to secure adequate protection for our intellectual property; our ability to attract and retain key personnel; availability of reimbursement for our products; estimates of the sufficiency of our existing cash and cash equivalents and investments to finance our operating requirements, including expectations regarding the value and liquidity of our investments; the volatility of our stock price; expected losses; expectations for future capital requirements; and those risks discussed in our filings which we make with the SEC. Any forward-looking statements speak only as of the date on which they are made, and we undertake no obligation to publicly update or revise any forward-looking statements to reflect events or circumstances that may arise after the date of this press release, except as required by applicable law. Investors should evaluate any statements made by us in light of these important factors.

Contact:
Jaclyn Jaffe
Avenue Therapeutics, Inc.
(781) 652-4500
ir@avenuetx.com

Source: Avenue Therapeutics