March 25, 2024

Avenue Therapeutics to Host Virtual Key Opinion Leader (KOL) Event on April 4, 2024

MIAMI, March 25, 2024 (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 neurologic diseases, today announced that it will host a virtual key opinion leader ("KOL") event highlighting expert perspectives on spinal bulbar muscular atrophy ("SBMA"), also known as Kennedy's Disease, on Thursday, April 4, 2024 at 11:00am ET.

The virtual event will focus on the potential of AJ201 in SBMA, including KOL perspectives on the SBMA treatment landscape, an overview of the Phase 1b/2a study evaluating AJ201 for the treatment of SBMA and outcome considerations for the upcoming topline data read-out for the Phase 1b/2a trial expected in the second quarter of 2024. The event will be moderated by Alexandra MacLean, M.D., Chief Executive Officer of Avenue Therapeutics, and will feature presentations from the following experts:

- **Christopher Grunseich**, M.D., Lasker Clinical Research Scholar and Investigator and Head of the Inherited Neuromuscular Diseases Unit at the National Institute of Neurological Disorders and Stroke
- **Tahseen Mozaffar**, M.D., Professor of Neurology, Pathology and Laboratory Medicine, Director of the Division of Neuromuscular Diseases and Director of the ALS and Neuromuscular Center at the University of California, Irvine.

To access the conference call, please register using the audio conference linkhere. A webcast replay of the event will be available on the Events page of Avenue's website at https://avenuetx.com/.

About Spinal and Bulbar Muscular Atrophy

Spinal and bulbar muscular atrophy ("SBMA") is a rare, X-linked genetic neuromuscular disease primarily affecting men. The condition is caused by the trinucleotide CAG repeat expansion in the androgen receptor ("AR") which leads to production of a mutant polyglutamine ("polyQ") AR protein that forms aggregates responsible for muscular atrophy focused in the limbs and bulbar region of the body. The weakening of the bulbar muscles affects chewing, speech and swallowing, with patients prone to choking or inhaling foods or liquids, resulting in airway infection. SBMA also affects muscles in the limbs, leading to

difficulty walking and injury caused by falling. Although there is a range of cited prevalence rates in scientific literature, a recent study used genetic analysis to estimate disease prevalence of 1:6,887 males. Currently, there are no treatments approved by the U.S. Food and Drug Administration or European Medicines Agency available for patients. For more information about SBMA, also known as Kennedy's Disease, please visit https://kennedysdisease.org/.

About AJ201

AJ201 is a novel, first-in-class asset in development for the treatment of spinal and bulbar muscular atrophy. It was designed to modify SBMA through multiple mechanisms including degradation of the mutant androgen receptor protein and stimulation of the Nrf1 and Nrf2 pathways, which are involved in protecting cells from oxidative stress that can lead to cell death. AJ201 is currently being studied in a Phase 1b/2a multicenter, randomized, double-blind clinical trial in six clinical sites across the U.S., which aims to evaluate the safety, PK/PD data and clinical response of AJ201 in patients suffering from SBMA. AJ201 has been granted Orphan Drug Designation by the FDA for multiple polyQ diseases, including SBMA, Huntington's disease and spinocerebellar ataxia. Avenue exclusively licensed AJ201 from AnnJi Pharmaceuticals in the United States, Canada, European Union, Great Britain, and Israel.

About Polyglutamine diseases

Polyglutamine diseases are a group of neurodegenerative disorders caused by expanded CAG repeats encoding a long polyQ tract in the affected proteins. To date, a total of nine polyQ disorders have been described. Mutant protein aggregation in affected tissues is the pathological hallmark of polyQ diseases. Neuroinflammation, oxidative stress and dysregulated protein quality control are thought to be key pathological factors that are either direct results of mutant protein aggregations and/or exacerbate the severity and progression of the diseases. Modulating multiple cellular pathways in enhancing degradation of mutant AR aggregates, inducing antioxidant and heat shock responses, and increasing proteasome expression simultaneously provide the rationale to develop AJ201 for the treatment of SBMA and potentially other polyQ diseases.

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 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, α3 receptor positive allosteric modulator for CNS diseases, and IV tramadol, which is in Phase 3 clinical development for the management of acute postoperative 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.

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