

December 1, 2023



Avenue Therapeutics to Present at American Epilepsy Society 2023 Annual Meeting

MIAMI, Dec. 01, 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 neurologic diseases, today announced that Amy Chappell, M.D., FAAN, will be presenting preclinical *in vivo* data evaluating BAER-101 using the SynapCell's Genetic Absence Epilepsy Rat from Strasbourg ("GAERS") model of absence epilepsy at the American Epilepsy Society (AES) 2023 Annual Meeting in Orlando, FL on December 2, 2023.

The Company's presentation details are as follows:

Title: A Phase 2- Ready Potentiator of $\alpha 2/3$ -Containing GABA_A Receptors Potently and Fully Blocks Seizures in Rats with Genetic Absence Epilepsy

Poster Session and Location: Session 1; West Hall C, Level 2

Session Date/Time: Saturday, December 2, 2023, 12:00 p.m. ET

Board Number: 1.444

"We are pleased with the progress made with BAER-101, a molecule with unique pharmacology which has demonstrated that it can significantly suppress seizures in a translational animal model of absence epilepsy," said Alexandra MacLean, M.D., Chief Executive Officer of Avenue. "The presentation of preclinical results from this trial showcase BAER-101's selectively targeting of GABA_A $\alpha 2$ and $\alpha 3$ subtypes more than $\alpha 1$ and $\alpha 5$, potentially improving anticonvulsant and anxiolytic activity while minimizing the risk of tolerance and abuse associated with existing treatments in this drug class. With these compelling preclinical results in-hand, along with the drug's proven safety profile in numerous clinical trials, we are encouraged by BAER-101's potential to address the unmet needs of epilepsy patients."

BAER-101 underwent preclinical *in vivo* evaluation in SynapCell's Genetic Absence Epilepsy Rat from Strasbourg ("GAERS") model of absence epilepsy. The GAERS model, which is a proven, early, informative indicator of efficacy in anti-seizure drug development with high predictability of response in humans, mimics behavioral, electrophysiological and pharmacological features of human absence seizures. In the model, BAER-101 demonstrated full suppression of seizure activity with a minimal effective dose of 0.3 mg/kg, PO. The effect was fast in onset and stable throughout the duration of testing. The combination of safety and tolerability in hundreds of patients and the preclinical efficacy data support BAER-101's continued development in a Phase 2a trial.

The Company's poster at AES 2023 will be available on the Publications section of Avenue's website at <https://avenuetx.com/publications/>.

About BAER-101

Avenue is developing BAER-101 via its subsidiary Baergic Bio for epilepsy disorders. BAER-101 is a positive allosteric modulator of $\alpha 2,3$ subunit-containing GABA_A receptors with minimal activity at $\alpha 1$ or $\alpha 5$ -containing receptors, which are believed to mediate many of the issues impacting the medical use of benzodiazepines such as those noted with diazepam use (tolerance, dependence, abuse, sedation and impaired cognition). As a result, BAER-101 may have the potential to treat epilepsy, anxiety and other disorders in which benzodiazepines are currently used, while minimizing the benzodiazepine associated adverse effects. BAER-101 was licensed in from AstraZeneca with a large safety database in over 700 patients and an efficacy signal in a subset of patients with anxiety.

About Epilepsy

Absence epilepsy is a form of epileptic syndrome where patients show generalized non-convulsive seizures characterized by a brief unresponsiveness to environmental stimuli and cessation of activity. In human, typical absence seizures are associated with bilateral, synchronous and regular spike-and-wave discharges ("SWD"). SynapCell's world-exclusive model, the GAERS, displays spontaneous SWD and has become the "state of the art" translational reference model for the past thirty years. Most of the drugs that have been studied in the GAERS model show efficacy in focal as well as generalized seizures in humans.

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. The Company 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 $\alpha 2/3$ 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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