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Avenue Therapeutics Completes the Acquisition of Baergic Bio and its Selective GABA-A α 2/3 Receptor Positive Allosteric Modulator for the Treatment of Central Nervous System Disorders

NEW YORK, Nov. 08, 2022 (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 central nervous system ("CNS") diseases, today announced the closing of the acquisition of Baergic Bio, Inc. ("Baergic Bio") pursuant to the previously disclosed Share Contribution Agreement with its parent company, Fortress Biotech, Inc.

Founded in December 2019, Baergic Bio, now a subsidiary of Avenue, is a clinical-stage pharmaceutical company that focuses on the development of a pharmaceutical product for the treatment of CNS disorders. Its pipeline currently includes a single compound, BAER-101, an oral small molecule selective GABA-A α 2/3 receptor positive allosteric modulator, which was in-licensed from AstraZeneca Plc.

The potential therapeutic value of selective modulators of GABA-A receptors has recently been recognized, with multiple assets moving forward since the 2019 U.S. Food and Drug Administration approval of brexanolone. These compounds are being developed for a host of therapeutic indications including epilepsy, anxiety, pain, depression and other related conditions. Preclinical data have substantiated the efficacy of BAER-101 as a novel anxiolytic and antiepileptic.

Benzodiazepines interact non-selectively with GABA-A receptor (GABA-AR) subunits, especially the α 1 subunit. By selectively targeting the α 2/3 subunits of the GABA-A receptor, BAER-101 may spare the adverse effects associated with benzodiazepine use. Consistent with its selectivity over α 1-preferring GABA-ARs, BAER-101 may have a reduced propensity to produce sedation and memory impairment. To date, clinical experience in over 700 patients has shown that BAER-101 is safe and side effects were mild to moderate.

Alexandra MacLean, M.D., Chief Executive Officer of Avenue, said, "The acquisition of Baergic Bio is a step forward in our plan to build Avenue into a leader in the development of drugs targeting unmet needs in the CNS field. BAER-101 has the potential to address

various orphan indications as well as larger markets with a favorable profile relative to current therapeutic options. Combined with our recent capital raise and potential regulatory path forward for IV tramadol, we believe Avenue has the foundational portfolio to continue to deliver and expand meaningful therapies for patients with CNS 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 central nervous system diseases. 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 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 candidate; 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; ability to successfully integrate Baergic Bio in the Company’s operations; 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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