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Avenue Therapeutics Announces FDA Advisory Committee Meeting to Review IV Tramadol NDA Tentatively Scheduled for February 15, 2022

NEW YORK, Nov. 29, 2021 (GLOBE NEWSWIRE) -- Avenue Therapeutics, Inc. (NASDAQ: ATXI) ("Avenue" or the "Company"), a company focused on the development of intravenous ("IV") tramadol for the U.S. market, today announced that the FDA has informed the Company that a joint meeting of the Anesthetic and Analgesic Drug Products Advisory Committee and the Drug Safety and Risk Management Advisory Committee is tentatively scheduled for February 15, 2022. The committees will discuss the IV tramadol New Drug Application.

The FDA has previously stated that input from an Advisory Committee is needed for the Office of New Drugs ("OND") to reach a decision on Avenue's formal dispute resolution request and that the OND will respond to Avenue's appeal within 30 calendar days after the Advisory Committee meeting.

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. 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; 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, and we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995.

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Source: Avenue Therapeutics