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Avenue Therapeutics Announces Publication of a Review of IV Tramadol

NEW YORK, Sept. 09, 2020 (GLOBE NEWSWIRE) -- Avenue Therapeutics, Inc. (NASDAQ: ATXI) ("Avenue"), a company focused on the development of intravenous ("IV") tramadol for the U.S. market, today announced that a publication entitled "IV tramadol: A novel option for US patients with acute pain—A review of its pharmacokinetics, abuse potential and clinical safety record" has been published in the peer-reviewed journal, *Journal of Opioid Management*, and can be accessed [here](#).

This paper provides a review of the pharmacokinetics ("PK") of the IV tramadol dosing regimen intended for the U.S., its abuse potential as documented in the literature, its safety record in clinical practice outside the U.S. and discusses how IV tramadol may become a useful option for patients with acute pain in the U.S. The review includes the following:

- The PK profile of the IV tramadol dosing regimen, which results in similar overall steady-state C_{max} (peak serum concentration) and AUC (Area Under the Curve) for tramadol, and a lower C_{max}, AUC, as well as slower onset of M1 (tramadol's primary metabolite and a more potent μ agonist than the parent compound), as compared to oral tramadol 100 mg administered once every 6 hours.
- A focused and targeted review of the literature regarding tramadol abuse in the U.S. where oral tramadol is available and in countries where oral and IV tramadol are approved. It found that the abuse potential for IV tramadol is highly likely to be even lower than that of oral tramadol and much lower than other opioids, and that the abuse potential for oral tramadol is low in comparison to more potent opioids such as morphine, oxycodone, and hydrocodone.
- An examination of the most frequently reported adverse events ("AEs") associated with IV tramadol use in the Vigibase, the WHO global database of Individual Case Safety Reports. Despite the potential limitations of this spontaneous reporting database, IV tramadol in general appears to be comparable to oral tramadol with respect to AE reports in all regions.

The paper concluded that the availability of IV tramadol as an alternative to pure μ opioid analgesics should be a valuable option for U.S. clinicians who treat acute pain in the hospital setting.

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 and was founded by Fortress Biotech, Inc. (NASDAQ: FBIO). 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; the early stage of products under development; 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.

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