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Avenue Therapeutics Announces Publication of Real-World Data on Nonmedical Use of Tramadol in ASI-MV Network

NEW YORK, Dec. 18, 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 titled "Real-World Data on Nonmedical Use of Tramadol from Patients Evaluated for Substance Abuse Treatment in the NAVIPPRO Addiction Severity Index–Multimedia Version (ASI-MV®) Network" has been published in *Drug Safety*, a peer-reviewed international journal covering pharmacoepidemiology and pharmacovigilance. The publication can be accessed here.

"Utilization of real-world data adds significant value to the post market benefit-risk evaluation of prescription opioid medications, because comparative rates of nonmedical use (NMU) between prescription opioid compounds can help providers and patients with pain management decision making, balancing the need for pain therapy with potential risk of NMU," commented Jody L. Green, Ph.D., the paper's lead author and Chief Scientific Officer for Inflexxion, a division of Integrated Behavioral Health. "Compared to other common opioid compounds, tramadol had significantly lower rates of NMU, non-oral routes of administration such as snorting or injecting, and diversion, suggesting a lower abuse potential."

The objective of the study was to evaluate nonmedical use (NMU) and diversion of tramadol and comparator opioids (morphine, oxycodone, and hydrocodone) using real-world data from the Addiction Severity Index–Multimedia Version (ASI-MV®). A cross-sectional study design was used to evaluate past 30-day tramadol and comparator opioid NMU among adults assessed for substance abuse treatment using the ASI-MV from 2010-2018. The paper concluded that tramadol had a significantly lower rate of NMU than comparator opioids and was less likely to be diverted or used via higher-risk non-oral routes, and that these findings support previous evaluations by WHO and the United States Drug Enforcement Agency that concluded that tramadol has a low potential for abuse.

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.

About Inflexxion and Integrated Behavioral Health
Inflexxion joined the Integrated Behavioral Health (IBH) family of companies in July 2018.

Inflexxion is a healthcare data and analytics company that specializes in the collection, surveillance, monitoring and analysis of critical public health issues including prescription drug abuse, substance use, behavioral health, and pain management. With over 30 years in the industry, Inflexxion works with healthcare organizations, medical professionals, pharmaceutical companies, and regulatory authorities to assess, track and improve patient care and inform public policy. Inflexxion collects, analyzes and disseminates extensive behavior and health-related data for pharmaceutical post-market surveillance, risk management, epidemiological studies, product improvements, abuse prevention and outcome measurement.

About Addiction Severity Index–Multimedia Version (ASI-MV)
The ASI-MV is a comprehensive, evidence-based, patient self-administered assessment tool. Based on the widely used Addiction Severity Index (ASI), the ASI-MV provides clinical information, severity ratings and composite scores in seven life domains: medical; employment; alcohol; drug; legal; family/social; and psychological. Behavioral health professionals use the ASI-MV to conduct standardized, thorough, and efficient substance-use assessments and to gather real-time data on client outcomes.

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, 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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