

June 6, 2018



Avenue Therapeutics to Host Key Opinion Leader Call on Intravenous (IV) Tramadol for the Management of Postoperative Pain

Neil Singla, M.D., Lotus Clinical Research, and Harold Minkowitz, M.D., HD Research Corporation, to participate in call on Monday, June 11, 2018, at 11 a.m. EDT

NEW YORK, June 06, 2018 (GLOBE NEWSWIRE) -- Avenue Therapeutics, Inc. (Nasdaq:ATXI) ("Avenue"), a company focused on the development and commercialization of intravenous (IV) tramadol, today announced that it will host a Key Opinion Leader (KOL) call on intravenous (IV) tramadol for the management of postoperative pain on Monday, June 11, 2018, at 11 a.m. EDT.

The call will feature a moderated discussion with key opinion leaders Neil Singla, M.D., Lotus Clinical Research, and Harold Minkowitz, M.D., HD Research Corporation, who will discuss the unmet medical need and potential role of IV tramadol in the management of postoperative pain. Drs. Singla and Minkowitz will be available to answer questions following the conclusion of the discussion.

Avenue Therapeutics' management team will also be available to answer questions on the company's ongoing development and commercialization of IV tramadol. Avenue recently announced positive topline results from its Phase 3 trial of IV tramadol in patients undergoing bunionectomy surgery. A second pivotal Phase 3 trial in patients following abdominoplasty surgery is expected to initiate in the third quarter of 2018.

Dr. Neil Singla is the founder and Chief Scientific Officer of Lotus Clinical Research, a contract research organization, research site and regulatory consulting firm in Pasadena, Calif., specializing in pain management research. In the company's 17-year history, Dr. Singla and Lotus have played a significant role in bringing numerous analgesic molecules to market. Dr. Singla has published extensively and is a frequent lecturer for physicians, pharmaceutical companies and research institutes worldwide. He currently chairs the Analgesic Clinical Trials Special Interest Group at both the American Pain Society (APS) and the International Association for the Study of Pain (IASP). He also chairs the annual APS Conference on Analgesic Clinical Trials (APS-CAT), which aims to help experts advance best practices in analgesic drug development. Dr. Singla's academic research focuses on minimizing the inherent variability in subjective endpoint analgesic clinical trials.

As a result, Dr. Singla and Lotus have developed novel techniques for patient education designed to minimize variability, reduce placebo response and increase effect size.

Dr. Harold Minkowitz is an anesthesiologist and clinical researcher with a special interest in the study of acute pain therapy. He currently serves as the Director of Clinical Investigation at HD Research Corp. Dr. Minkowitz has more than 20 years of experience as a clinical researcher and has played a role in nearly 300 clinical trials, including being involved in the clinical development of several novel therapies. In addition, Dr. Minkowitz is widely published and enjoys discussing his findings with colleagues as a lecturer both nationally and internationally and presenting his work at society meetings around the world. In order to rapidly enroll patients into clinical trials while maintaining data integrity at HD Research Corp., Dr. Minkowitz is proud to work with a large team of research professionals who share his passion in the highly specialized area of acute pain research.

Conference Call and Webcast

Avenue will host the KOL conference call and webcast on IV tramadol for the management of postoperative pain at 11 a.m. EDT / 8 a.m. PDT on Monday, June 11, 2018. To participate in the conference call, please dial (866) 548-4713 (domestic) or (323) 794-2093 (international) and enter the conference code: 9864657. A live audio webcast will be available on the Events page of the Investors section of Avenue's website at www.avenuetx.com. A replay of the audio webcast will be available approximately two hours after the call on the Events page of the Investors section of Avenue's website for a period of 30 days following the call.

About IV Tramadol

Tramadol is a synthetic, dual-acting opioid with a unique mechanism of action that delivers opioid efficacy with less potential for abuse and a lower risk of dependence than conventional narcotics. Oral tramadol has a well-established efficacy and safety profile, and is currently approved and marketed in the U.S. for moderate to moderately severe pain in adults. There is currently no approved IV formulation in the U.S.

Avenue is evaluating IV tramadol in a pivotal Phase 3 clinical program: a trial in patients following bunionectomy surgery ([NCT03290378](https://clinicaltrials.gov/ct2/show/study/NCT03290378)) has been completed and a safety study ([NCT03395808](https://clinicaltrials.gov/ct2/show/study/NCT03395808)) is ongoing. A pivotal Phase 3 trial in patients following abdominoplasty surgery is expected to initiate in the third quarter of 2018.

About Avenue Therapeutics

Avenue Therapeutics, Inc. ("Avenue"), a Fortress Biotech (NASDAQ:FBIO) Company, is a specialty pharmaceutical company focused on the development and commercialization of intravenous (IV) tramadol for the management of moderate to moderately severe postoperative pain. IV tramadol may fill a gap in the acute pain market between IV acetaminophen/NSAIDs and IV conventional narcotics. Avenue is currently evaluating IV tramadol in a pivotal Phase 3 program for the management of postoperative pain. Avenue is headquartered in New York City. For more information, visit www.avenuetx.com.

About Fortress Biotech

Fortress Biotech, Inc. ("Fortress") is a biopharmaceutical company dedicated to acquiring, developing and commercializing novel pharmaceutical and biotechnology products. Fortress develops and commercializes products both within Fortress and through certain of its subsidiary companies, also known as Fortress Companies. In addition to its internal

development programs, Fortress leverages its biopharmaceutical business expertise and drug development capabilities and provides funding and management services to help the Fortress Companies achieve their goals. Fortress and the Fortress Companies may seek licensings, acquisitions, partnerships, joint ventures and/or public and private financings to accelerate and provide additional funding to support their research and development programs. For more information, visit www.fortressbiotech.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 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.

Investor Relations Contact:

Jeremy Feffer
Managing Director, LifeSci Advisors, LLC
(212) 915-2568
jeremy@lifesciadvisors.com

Company Contact:

Jaclyn Jaffe
Avenue Therapeutics, Inc.
(781) 652-4500
ir@avenuetx.com

Media Relations Contact:

Sarah Hall
Phase IV Communications
(215) 313-5638
sarah@phaseivcommunications.com



Source: Avenue Therapeutics