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Avenue Therapeutics Receives Notices of Allowance for Patent Applications Covering Methods of Administration for Intravenous Tramadol

NEW YORK, Jan. 03, 2017 (GLOBE NEWSWIRE) -- Avenue Therapeutics, Inc. ("Avenue"), a Fortress Biotech (NASDAQ:FBIO) Company, today announced that Notices of Allowance have now been received from the U.S. Patent and Trademark Office (USPTO) for two patent applications that cover methods of administration for its lead product candidate intravenous (IV) tramadol. These patent applications are continuation patent applications of issued U.S. patent 8,895,622, titled "Intravenous Administration of Tramadol." The patents to be issued from these allowed applications (U.S. Application Nos. 14/550,279 and 14/713,775), which carry a patent term to at least 2032, contain claims directed to Avenue's proposed administration of IV tramadol for Phase III development. Issuance of both of these patents is expected early in the first quarter of 2017.

"These patents will significantly strengthen the protection of the methods of administration for our IV tramadol in acute pain and are important additions to our intellectual property portfolio," said Lucy Lu, MD, Avenue's Interim Chief Executive Officer. "The timing of the allowance is ideal as we prepare to begin our Phase III clinical program in 2017."

These patent applications fall under Avenue's licensing agreement with Revogenex Ireland Ltd.

About Avenue Therapeutics

Avenue Therapeutics, Inc. ("Avenue"), a Fortress Biotech Company, is a specialty pharmaceutical company that acquires or in-licenses, develops and commercializes products for use in acute healthcare or hospital settings. Avenue's lead product candidate is intravenous (IV) Tramadol for the management of post-operative pain. The company plans to initiate a Phase III development program of IV Tramadol in 2017. 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. Additionally, Fortress recently

acquired a controlling interest in National Holdings Corporation (NASDAQ:NHLD), a diversified independent brokerage company (together with its subsidiaries, "NHLD"). 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, 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 price. Factors that could cause actual results to differ materially from those currently anticipated are: risks related to our growth strategy; risks relating to the results of research and development activities; 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; as well as competition. 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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