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Rexahn Pharmaceuticals Receives U.S. Patent for RX-3117 Anti-Cancer Program

ROCKVILLE, Md., Oct. 26, 2015 (GLOBE NEWSWIRE) -- Rexahn Pharmaceuticals, Inc. (NYSE MKT:RNN) a clinical stage biopharmaceutical company developing best-in-class therapeutics for the treatment of cancer, today announced that it has been issued a U.S. patent from the United States Patent and Trademark Office (USPTO) for claims related to the synthesis of its novel anti-cancer investigational drug candidate, RX-3117. In preclinical studies, RX-3117 has demonstrated broad spectrum anti-tumor activity, notably in human cancer cell lines that have been made resistant to gemcitabine (Gemzar®), a widely-used type of chemotherapy. RX-3117 is currently being evaluated in a Phase Ib clinical trial in cancer patients with solid tumors.

“Rexahn is pleased to expand its intellectual property protection for RX-3117, which we believe holds promise as a next generation, highly-targeted cancer therapeutic designed to enhance treatment efficacy while minimizing the toxic side effects seen with traditional anti-cancer drugs,” said Dr. Peter D. Suzdak, Chief Executive Officer. “This latest patent for RX-3117 is an important addition to our intellectual property estate and further strengthens our global patent position for Rexahn’s innovative oncology pipeline.”

About RX-3117

RX-3117 is a novel, investigational small molecule nucleoside compound. Once intracellularly activated (phosphorylated) by UCK2, it is incorporated into the DNA or RNA of cells and inhibits both DNA and RNA synthesis, which induces apoptotic cell death of tumor cells. UCK2 is overexpressed in various human cancer cells. Preclinical studies have shown that RX-3117 inhibits the growth of various human cancer xenograft models, including pancreatic, lung, bladder, cervical and colon, as well as gemcitabine resistant cancer cells.

RX-3117 has demonstrated broad spectrum anti-tumor activity against over 100 different human cancer cell lines and efficacy in 17 different mouse xenograft models. Notably, the efficacy of RX-3117 in the mouse xenograft models was superior to that of gemcitabine. Further, RX-3117 still retains its full anti-tumor activity in human cancer cell lines made resistant to the anti-tumor effects of gemcitabine. In August 2012, Rexahn reported the completion of an exploratory Phase I clinical trial of RX-3117 in cancer patients conducted in Europe, to investigate the oral bioavailability, safety and tolerability of the compound. In this study, oral administration of a 50 mg dose of RX-3117 demonstrated an oral bioavailability of 56% and a plasma half-life ($T_{1/2}$) of 14 hours. In addition, RX-3117 appeared to be safe and well tolerated in all subjects throughout the dose range tested.

RX-3117 is currently being evaluated in a Phase Ib clinical trial in cancer patients with solid tumors. The Phase Ib clinical trial is a multi-center, dose-escalation study that will evaluate the safety, tolerability, dose-limiting toxicities, and maximum tolerated dose (MTD) of RX-3117 in patients with solid tumors. Secondary endpoints include pharmacokinetic analysis, and an evaluation of the preliminary anti-tumor effects of RX-3117. Patient enrollment has been completed in nine dose groups (30, 60, 100, 150, 200, 500, 1000, 1500 and 2000 mg). The MTD of RX-3117 has not yet been achieved. Given the robust preliminary safety profile observed in the Phase Ib clinical trial to date, it is difficult to predict when the MTD will be achieved and the trial will be completed.

About Rexahn Pharmaceuticals, Inc.

Rexahn Pharmaceuticals Inc. (NYSE MKT:RNN) is a clinical stage biopharmaceutical company dedicated to developing novel, best-in-class therapeutics for the treatment of cancer. The Company's mission is to improve the lives of cancer patients by developing next generation cancer therapies that are designed to maximize efficacy while minimizing the toxicity and side effects traditionally associated with cancer treatment. Rexahn's product candidates work by targeting and neutralizing specific proteins believed to be involved in the complex biological cascade that leads to cancer cell growth. Pre-clinical studies show that certain of Rexahn's product candidates may be effective against multiple types of cancer, drug resistant cancers, and difficult-to-treat cancers, and others may augment the effectiveness of current FDA-approved cancer treatments. The Company has a broad oncology pipeline that includes three anti-cancer compounds currently in clinical development: Supinoxin™, RX-3117, and Archexin®, and a novel nanopolymer-based drug delivery platform technology that may increase the bio-availability of FDA-approved chemotherapies. For more information about the Company and its oncology programs, please visit www.rexahn.com.

Safe Harbor

To the extent any statements made in this press release deal with information that is not historical, these are forward-looking statements under the Private Securities Litigation Reform Act of 1995. Such statements include, but are not limited to, statements about Rexahn's plans, objectives, expectations and intentions with respect to cash flow requirements, future operations and products, enrollments in clinical trials, the path of clinical trials and development activities, and other statements identified by words such as "will," "potential," "could," "can," "believe," "intends," "continue," "plans," "expects," "anticipates," "estimates," "may," other words of similar meaning or the use of future dates. Forward-looking statements by their nature address matters that are, to different degrees, uncertain. Uncertainties and risks may cause Rexahn's actual results to be materially different than those expressed in or implied by Rexahn's forward-looking statements. For Rexahn, particular uncertainties and risks include, among others, the difficulty of developing pharmaceutical products, obtaining regulatory and other approvals and achieving market acceptance; that results of preclinical studies and early clinical trials may not be predictive of the results of later-stage clinical trials; the success and design of clinical testing; and Rexahn's need for and ability to obtain additional financing. More detailed information on these and additional factors that could affect Rexahn's actual results are described in Rexahn's filings with the Securities and Exchange Commission,

including its most recent annual report on Form 10-K and subsequent quarterly reports on Form 10-Q. All forward-looking statements in this news release speak only as of the date of this news release. Rexahn undertakes no obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

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