February 8, 2016

Rexahn Pharmaceuticals Completes Stage 1 and Begins Enrollment in Stage 2 of Archexin® Phase IIa Clinical Trial in Metastatic Renal Cell Carcinoma

Evidence of Dose-Dependent Tumor Reduction Presented at Recent Medical Meetings

ROCKVILLE, Md., Feb. 08, 2016 (GLOBE NEWSWIRE) -- Rexahn Pharmaceuticals, Inc. (NYSE:RNN), a clinical stage biopharmaceutical company developing next generation therapeutics for the treatment of cancer, announced today that it has identified a maximum tolerated dose and completed Stage 1 of a dose-escalation Phase IIa clinical trial of Archexin in combination with everolimus, a widely used chemotherapy drug, in patients with metastatic renal cell carcinoma (RCC). In addition, Rexahn also announced that it has commenced enrollment in Stage 2 of the Phase IIa Archexin clinical trial to evaluate safety and efficacy of the combination.

“Data from the first phase (Stage 1) of the Archexin clinical trial have yielded exciting preliminary clinical findings suggesting that Archexin, in combination with everolimus, showed evidence of a potential dose and time-dependent clinical benefit in patients with advanced, metastatic kidney cancer,” said Dr. Ely Benaim, Chief Medical Officer for Rexahn. “The data from Stage 1, which were recently presented at the American Society for Clinical Oncology (ASCO) Genitourinary Cancers Symposium, show three patients who have experienced stable disease for 383, 191, and 122 days, respectively, and two patients who experienced a tumor burden reduction of 16% and 36%, respectively as of January 6, 2016.”

The results indicated that at the dose levels tested to date, Archexin appeared to be safe and well tolerated. The most commonly reported adverse event in patients taking both Archexin and everolimus is thrombocytopenia. To date, no adverse events have been dose limiting.

Dr. Benaim continued, “While preliminary, we are particularly excited about the results from this study as these are heavily pre-treated patients who have not previously responded to other cancer therapies. Consequently, we are pleased to begin enrollment in Stage 2 of the Phase IIa clinical trial to further evaluate the potential anti-cancer effects of Archexin in patients with advanced, metastatic kidney cancer.”

Stage 2 of the Phase IIa clinical study – which has commenced enrolling patients, is a randomized, open-label, two-arm dose expansion study of Archexin in combination with everolimus, versus everolimus alone to determine safety and efficacy of the combination. The trial is anticipated to enroll up to 30 RCC patients who will be randomized to receive

either Archexin in combination with everolimus, or everolimus alone, in a ratio of 2:1. The maximum tolerated dose of 250 mg/m^2/day of Archexin – identified in Stage 1, will be administered along with 10 mg of everolimus versus 10 mg everolimus alone.

The primary endpoint of Stage 2 is the percentage of progression free patients following eight cycles of therapy. Patients are scanned (CT or MRI) for the assessment of tumor progression after every 2 cycles of therapy. Secondary endpoints include pharmacokinetic profile, incidence of adverse events, changes in clinical laboratory tests and vital signs over time, tumor response, duration of response, time to response, and response rate. Exploratory endpoints include blood levels of AKT pathway biomarkers, tumor apoptosis biomarkers, or other relevant biomarkers.

In preclinical studies, Archexin has been shown to inhibit the growth of human renal cell carcinoma cells in tissue culture. Also in preclinical studies, Archexin has also been shown to exhibit an additive anti-tumor effect when combined with other cancer drugs in inhibiting the growth of human RCC cells in tissue culture.

About Archexin®

Archexin is a unique anti-sense drug candidate that specifically inhibits the cancer cell signaling protein Akt-1. Archexin is the only specific inhibitor of Akt-1 in clinical development. The activated form of Akt-1, which is involved in cancer cell growth, survival, angiogenesis, and drug resistance, has been shown to be present or elevated in more than 12 different human cancer cell lines, including pancreatic and renal cell carcinoma. By inhibiting Akt-1, Archexin has been shown to both inhibit the growth of renal cell carcinoma cell lines and exhibit a longer survival benefit in the human renal cell carcinoma animal xenograft model. Thus, while Akt-1 is a very specific anti-cancer target, it may have broad therapeutic potential across multiple types of cancer.

Archexin has completed a Phase I clinical trial in cancer patients with solid tumors and was shown to be safe and well tolerated. The dose-limiting toxicity was Grade 3 fatigue. In a small Phase IIa trial in advanced pancreatic cancer patients, Archexin in combination with gemcitabine was shown to be safe and well tolerated and showed a preliminary efficacy signal with a median survival of 9.1 months in evaluable patients.

Metastatic RCC represents an attractive market opportunity with an estimated annual incidence of 90,000 patients worldwide. Metastatic RCC patients receiving standard of care treatment have a poor prognosis with an overall survival of less than two years. Rexahn has received U.S. Food and Drug Administration (FDA) Orphan Drug Designation for Archexin for metastatic RCC as well as four other cancers.

About Rexahn Pharmaceuticals, Inc.

Rexahn Pharmaceuticals Inc. (NYSE: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 indicate 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, anticipated market sizes, 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, understandings and beliefs regarding the role of certain biological mechanisms and processes in cancer; drug candidates being in early stages of development, including in pre-clinical development; the ability to initially develop drug candidates for orphan indications to reduce the time-to-market and take advantage of certain incentives provided by the U.S. Food and Drug Administration; and the ability to transition from our initial focus on developing drug candidates for orphan indications to candidates for more highly prevalent indications. 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.

Contact:
Stacey Jurchison
Rexahn Investor Relations
240-268-5300 x 324
Jurchisons@rexahn.com

rexahn
PHARMACEUTICALS

Source: Rexahn Pharmaceuticals