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Rexahn Pharmaceuticals' Archexin® Shows Dose-Dependent Tumor Reduction in a Phase IIa Clinical Study

Phase IIa Clinical Data Presented at the ASCO 2016 Genitourinary Cancers Symposium

ROCKVILLE, Md., Jan. 11, 2016 (GLOBE NEWSWIRE) -- Rexahn Pharmaceuticals, Inc. (NYSE MKT:RNN), a clinical stage biopharmaceutical company developing next generation therapeutics for the treatment of cancer, announced today that additional interim clinical data from an ongoing Phase IIa study of its novel anti-cancer drug candidate, Archexin® were recently presented at the 2016 American Society for Clinical Oncology (ASCO) Genitourinary Cancers Symposium.

"We are excited about the results from our ongoing Phase IIa study of Archexin in renal cell carcinoma, which continue to look promising," said Dr. Ely Benaim, Chief Medical Officer for Rexahn. "Interim data presented in November 2015 showed that at the lowest dose of Archexin tested (125 mg/m^2/day), one patient had stable disease for over a year and a 16% reduction in the size of the patient's primary tumor following four cycles of treatment. The latest data show a reduction in tumor size of 36% in a second patient receiving 200 mg/m^2/day of Archexin following 2 treatment cycles, suggestive of a dose and time-dependent clinical benefit."

Stage 2 of the clinical trial – a randomized, open-label, two-arm dose expansion study of Archexin in combination with everolimus, versus everolimus alone, is expected to start in early 2016 and will further evaluate the efficacy of Archexin in metastatic renal cell carcinoma (RCC). Rexahn has received U.S. Food and Drug (FDA) Orphan Drug Designation for Archexin for metastatic RCC as well as four other cancers.

Archexin Clinical Data

New interim data from the Phase IIa Archexin clinical trial were presented on Saturday, January 9, 2016 by study investigators, Drs. S. Tagawa, G. Chatta, N. Agarwal, and Rexahn scientists in a poster presentation entitled *"Archexin, A Novel AKT-1 Specific Inhibitor for the Treatment of Metastatic Renal Cancer."*

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.

Early evidence of the potential clinical activity of Archexin in combination with everolimus

has been observed. Among the patients enrolled in the study, three patients have experienced stable disease, which has persisted for 383, 170 and 115 days (as of January 6, 2016). In addition, two patients have experienced a reduction from baseline in their tumor size of 16% (125 mg/m^2/day) and 36% (200 mg/m^2/day) following four and two treatment cycles, respectively.

Scott Tagawa, MD, MS, Medical Director, Genitourinary Oncology Research Program, Richard A. Stratton Associate Professor in Hematology & Oncology, Weill Cornell Medicine, commented, "We continue to be encouraged by the data from the Phase IIa clinical study, suggesting a potential clinical benefit of Archexin in combination with everolimus. Its novel mechanism of action and potential synergistic benefit, when used in combination with everolimus, make Archexin a promising new anti-cancer drug candidate. By suppressing AKT-1 – an increasingly well understood cancer pathway – it is possible that Archexin could both inhibit the growth of cancer cells and also play a role in overcoming resistance to mTor inhibitors, which would be an important breakthrough in cancer therapy if confirmed in future clinical study. I look forward to completing Stage 1 of the current clinical trial and commencing the randomized phase of the study."

The Phase IIa clinical study is designed to evaluate the efficacy of Archexin in combination with everolimus (Afinitor®) to treat metastatic RCC patients and is being conducted in two stages. Stage 1 is an open-label, dose-escalation study designed to identify a safe and tolerable dose of Archexin when given in combination with everolimus. Stage 2 is a randomized, open-label, 2-arm dose expansion study of Archexin in combination with everolimus versus everolimus alone to determine safety and efficacy of the combination.

In Stage 1, escalating doses of Archexin of 125, 200 and 250 mg/m^2/day are administered by continuous IV infusion for 14 days followed by 1 week of rest. Based on previous clinical data, the target dose of Archexin is anticipated to be no more than 250 mg/m^2 per day. Patient assessments include safety, pharmacokinetics, laboratory and physical exams. Once the maximum tolerated dose of Archexin in combination with everolimus has been determined, thirty RCC patients will be randomized to receive either Archexin in combination with everolimus, or everolimus alone, in a ratio of 2:1.

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. 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 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 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.

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