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Rexahn Pharmaceuticals Presents Clinical Trial Results for Archexin® at the 2016 American Association for Cancer Research Annual Meeting

Data Featured at Late Breaking and Clinical Trials Session Suggest Potential Dose and Time Dependent Clinical Benefit of Archexin® in Combination with Everolimus

Additional Poster Presentations on RX-3117 and Archexin®-Nano Also Showcased

ROCKVILLE, Md., April 20, 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 final data from the dose-escalation segment (Stage 1) of a Phase Ib/IIa clinical trial of Archexin® were presented at the 2016 American Association for Cancer Research Annual Meeting (AACR) in New Orleans, Louisiana.

The Phase Ib/IIa clinical trial is evaluating Archexin, in combination with everolimus (a widely used chemotherapy drug) in patients with metastatic renal cell carcinoma (mRCC). The results were presented during the Late Breaking and Clinical Trials Session at AACR by Drs. S. Tagawa, G. Chatta, N. Agarwal and Rexahn scientists in a poster presentation entitled *"Phase Ib/IIa Study of RX-0201 (Archexin®), A Novel Akt-1 Antisense Combined with Everolimus to Treat Metastatic Clear Cell Renal Carcinoma."*

"The results from the Archexin dose escalation clinical study are promising and offer an early signal of the potential safety and clinical activity of Archexin in combination with everolimus," commented Scott Tagawa, MD, MS, Medical Director of the Genitourinary Oncology Research Program at Weill Cornell Medicine. "The combination of Archexin and everolimus is rational based upon potential complementary mechanisms of action. While the primary objective of the initial dose escalation phase of the study was not intended to provide an efficacy evaluation, we nevertheless observed evidence of stable disease and tumor burden reduction in a significant number of patients in the study. When you consider that these are patients with very advanced disease, who have stopped responding to other therapies, we believe these data are especially encouraging."

Archexin Phase Ib/IIa Clinical Data

The results from Stage 1 of the Phase Ib/IIa study presented at AACR showed that in mRCC patients that have previously received multiple anti-cancer therapies, Archexin treatment produced both stable disease (which persisted for up to 383 days) and a reduction in tumor burden. Compared to baseline CT scans, three patients experienced reductions in the size

of their tumors of up to 36%. At the lowest dose level of Archexin administered (125 mg/m^2/day) one patient had a 16% tumor reduction after four cycles of treatment. At the second dose level (200 mg/m^2/day) one patient experienced a 36% tumor reduction after two cycles of treatment. At the highest dose level (250 mg/m^2/day), which has been determined to be the maximum tolerated dose, one patient had a 32% tumor reduction following six cycles of treatment.

In the present study Archexin appeared to be safe and well tolerated at each of the dose levels tested with no dose limiting adverse events. The most commonly reported adverse event in patients taking the combination of Archexin and everolimus was thrombocytopenia.

"The emerging clinical data from our Archexin program suggest a potentially unique profile in metastatic renal cell carcinoma with both a dose and time dependent clinical benefit," said Dr. Ely Benaim, Chief Medical Officer for Rexahn. "Based on these encouraging results, and our identification of a maximum tolerated dose, Rexahn has commenced enrollment in the second part of the study, which is a randomized, open-label, two-arm dose expansion study to further evaluate the safety and efficacy of Archexin in combination with everolimus, versus everolimus alone. We look forward to the possibility of confirming these results in the randomized part of the study."

The second part (Stage 2) of the Phase Ib/IIa study will enroll up to 30 patients with mRCC 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 in Stage 2 of the Phase Ib/IIa clinical trial 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 two 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.

Additional Poster Presentations at AACR

Rexahn scientists and their collaborators also presented two additional posters detailing advancements in the Company's RX-3117 and Archexin-Nano programs.

In a poster presentation entitled *"Inhibition of DNA Methyltransferase by RX-3117 Leads to Upregulation of Hypomethylated Targets,"* Rexahn scientists presented new preclinical data further describing the novel mechanism of action of RX-3117, an orally bioavailable, small molecule, investigational anti-cancer therapy that targets a unique biological pathway implicated in the development and metastasis of numerous cancers.

In a separate poster presentation entitled *"Folate Receptor-Targeted Lipid Coated Albumin Nanoparticles (F-LCAN) for Therapeutic Delivery of RX-0201 (Archexin), An Antisense Oligonucleotide against Akt-1,"* preclinical study results of a nanoparticle-Archexin combination under development by Rexahn (Archexin-Nano) were presented. Preclinical

results from in vitro cell studies, pharmacokinetic and biodistribution studies and in vivo xenograft efficacy studies showed increased potency and a prolonged duration of action for Archexin-nano, suggesting that the F-LCAN formulation could be an effective formulation for therapeutic delivery of antisense agents such as Archexin.

About Archexin®

Archexin is a unique antisense 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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