

## New Preclinical Data for Supinoxin™ Show Oral Administration Produces Clinically Meaningful Tumor Growth Inhibition

## Supinoxin<sup>™</sup> Dose Dependently Inhibits Tumor Cell Growth in a Preclinical Model of Human Renal Cell Carcinoma

ROCKVILLE, Md., Jan. 12, 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 it presented new preclinical efficacy data for its novel anti-cancer drug candidate, Supinoxin™ (RX-5902) at the American Society for Clinical Oncology (ASCO) 2016 Genitourinary Cancers Symposium in San Francisco, California.

In a poster presentation entitled "The Anti-Cancer Effects of Supinoxin (RX-5902) in Renal Cell Cancer," Rexahn scientists detailed the results of several preclinical studies showing the antiproliferative effects of Supinoxin in various human renal cancer cell lines and xenograft renal cancer models.

In one study, Supinoxin was administered orally to mice once weekly for four weeks to assess its anti-tumor effects in a xenograft model of renal cell cancer. The results suggested that Supinoxin achieved clinically meaningful tumor growth inhibition of greater than 60%.

In a separate xenograft study, Supinoxin was administered orally to mice five days per week for 21 days (similar to the current dosing paradigm in the ongoing Phase I study). This study suggested that Supinoxin achieved dose-dependent tumor growth inhibition of greater than 60% and a partial clinical response in 60% of the animals and a complete response in 10% of the animals at a dose of 70 mg/kg.

"We are very pleased to see further evidence of the anti-cancer effects of Supinoxin in additional human cancer cell lines," said Dr. Ely Benaim, Chief Medical Officer for Rexahn Pharmaceuticals. "Late last year Rexahn presented data at the San Antonio Breast Cancer Symposium showing potent tumor inhibition effects of Supinoxin in a well validated preclinical model of human triple negative breast cancer (TNBC) – a particularly aggressive form of breast cancer for which there is high unmet medical need. The additional information from the preclinical pharmacokinetic and pharmacodynamic studies, along with data from the ongoing Phase I clinical trial will inform our decision on the recommended dose for a Phase Ib/IIa proof-of-concept clinical study."

About Supinoxin™ (RX-5902)

Supinoxin™ (RX-5902) is an orally administered, potential first-in-class, small molecule inhibitor of phosphorylated-p68 (P-p68). P-p68, which is selectively overexpressed in cancer cells and is absent in normal tissue, increases the activity of multiple cancer related genes including cyclin D1, c-jun and c-myc, and plays a role in tumor progression and metastasis. Over-expression of phosphorylated-p68 has been observed in solid tumors, such as melanoma, colon, ovarian and lung tumors. In preclinical studies, Supinoxin has been shown to inhibit proliferation of cells in over 100 different human cancer cell lines, including breast, colon, pancreas, ovarian, and stomach cancers, and showed potent activity in drugresistant cancer cells. In preclinical animal models, where human cancer cells from breast, ovarian, melanoma, pancreas, or renal tumors were grafted into animals, treatment with Supinoxin resulted in a significant reduction in tumor growth.

Supinoxin is currently being evaluated in a Phase I dose-escalation clinical trial in cancer patients with solid tumors designed to evaluate the safety, tolerability, dose-limiting toxicities and maximum tolerated dose (MTD). Secondary endpoints include pharmacokinetic analysis and an evaluation of the preliminary anti-tumor effects of Supinoxin. This trial is being conducted at three clinical oncology centers in the United States. Each patient has the ability to continue on the drug for up to six cycles of treatment (a dosing cycle is defined as three weeks of drug treatment followed by one week off) if no disease progression is seen. Patients are assessed by CT or MRI prior to the start of therapy and after every two cycles of therapy to assess tumor progression. The decision to escalate dose is made after completion of one cycle of treatment based on safety and tolerability. Patients may receive up to six cycles of treatment if their disease does not progress. Tumor biopsy samples are taken to assess the biomarker phosphorylated-p68. Patients have received doses up to 25, 50, 100, 150, 225, 300, 425, 575, and 775 mg. Based on the favorable safety and pharmacokinetic profile seen at the highest dose levels (575 mg and 775 mg), Rexahn has initiated a dosing schedule modification to increase patients' daily exposure of Supinoxin. All newly enrolled patients are now receiving Supinoxin either three or five times weekly as opposed to once weekly. The new dosing paradigm will increase drug exposure and enable more rapid determination of the MTD for further clinical study.

Interim results from the Phase I study were presented in September 2015 at the European Cancer Congress. The results showed clinical evidence of single-agent activity of Supinoxin, which was observed in 4 patients who showed stable disease persisting from between 255 and 497 days (as of September 14, 2015.) The results also suggested that, at the dose levels tested to date, Supinoxin administered orally appears to be safe and well tolerated with no Grade 3 or Grade 4 adverse events and several unrelated Grade 2 adverse events. The most frequently reported drug related adverse events were mild nausea, vomiting and fatigue. Pharmacokinetic analyses of the current data demonstrate both a predictable and desirable pharmacokinetic profile for an orally-administered route of therapy.

## 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<sup>®</sup> – 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 <a href="https://www.rexahn.com">www.rexahn.com</a>.

## 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. Forwardlooking 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.

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



Source: Rexahn Pharmaceuticals