

March 17, 2015



Rexahn Pharmaceuticals Reports Fourth Quarter and Full-Year 2014 Financial Results and Pipeline Update

- Supinoxin™ and RX-3117 Phase I clinical trials expected to be completed in the first half of 2015
- Patient enrollment is ongoing for Phase IIa Archexin® trial in treatment of metastatic renal cell carcinoma

ROCKVILLE, Md., March 17, 2015 (GLOBE NEWSWIRE) -- Rexahn Pharmaceuticals, Inc. (NYSE MKT:RNN), a clinical stage biopharmaceutical company developing best-in-class therapeutics for the treatment of cancer, is providing an update of its three clinical development programs and financial results for the year ending December 31, 2014.

"Rexahn remains very encouraged by the continued progress of the Supinoxin™, RX-3117 and Archexin® clinical development programs. 2015 will be a pivotal year for Rexahn as we determine the maximal tolerated dose (MTD) and preliminary efficacy in cancer patients with solid tumors in the ongoing Phase I clinical studies with Supinoxin™ and RX-3117, and initiate subsequent proof-of-concept studies in the clinic," commented Rexahn's Chief Executive Officer Peter D. Suzdak, PhD.

Pipeline Update:

Supinoxin™ (RX-5902)

An ongoing Phase I dose-escalation clinical trial of Supinoxin is designed to evaluate the safety, tolerability, dose-limiting toxicities and MTD in cancer patients with solid tumors. Secondary endpoints include pharmacokinetic analysis and evaluating the preliminary anti-tumor effects of Supinoxin. Patients in seven dose groups (25, 50, 100, 150, 225, 300 and 425 mg) have been enrolled, and the MTD has not yet been reached. Depending upon the number of dose groups needed to determine the MTD, Rexahn expects to complete this trial in the first half of 2015. Supinoxin continues to be safe and well tolerated, requiring higher dose levels than expected to be tested to achieve the MTD.

RX-3117

An ongoing Phase Ib dose-escalation clinical trial of RX-3117 is designed to evaluate the safety, tolerability, dose-limiting toxicities and MTD in cancer patients with solid tumors. Secondary endpoints include pharmacokinetic analysis and evaluating the preliminary anti-tumor effects of RX-3117. Patient enrollment has been completed in eight dose groups (30, 60, 100, 150, 200, 500, 1000 and 1500 mg). The MTD of RX-3117 has not yet

been achieved. The Company expects to complete this trial in the first half of 2015. RX-3117 continues to be safe and well tolerated, requiring higher dose levels than expected to be tested to achieve the MTD. To date, no dose-limiting toxicities have been associated with RX-3117 treatment.

Archexin®

The Phase IIa proof-of-concept clinical trial of Archexin in metastatic renal cell carcinoma (RCC) patients is ongoing. The first stage of this study is dose ranging, with up to three dose groups with three RCC patients each, to determine the MTD of Archexin in combination with everolimus, an FDA approved drug for the treatment of RCC. Patient enrollment is ongoing. Rexahn has orphan drug designation for this indication.

Additional Highlights from 2014:

- Completed a \$20 million registered direct offering
- Research coverage was initiated by Roth Capital Partners, Brinson Patrick Securities Corporation and Laidlaw & Company
- Appointed Mark Carthy and Richard (Rick) Rodgers to the Board of Directors
- Received five new issued patents from the U.S. Patent and Trademark Office and other international patent authorities
- Received orphan drug designation from the FDA for RX-3117 in pancreatic cancer
- Presented preclinical data on RX-3117 and RX-21101 at the Annual Meeting of the American Association for Cancer Research (AACR)
- Published additional preclinical results for RX-3117 in the peer reviewed journal, Anticancer Research

Financial Update:

Cash Position - Rexahn's cash and investments totaled \$32.7 million as of December 31, 2014, compared to \$19.0 million as of December 31, 2013. The increase of \$13.7 million was primarily due to \$18.6 million in proceeds received from our registered direct public offering, and \$6.2 million received from the exercise of stock options and warrants, offset by \$11.1 million from net cash used in operating activities. Rexahn expects that its cash and cash equivalents as of December 31, 2014 will be sufficient to fund the Company's cash flow requirements for its current activities into the second half of 2016.

R&D Expenses - Research and development expenses were \$7.0 million for the year ended December 31, 2014, compared to \$3.3 million for the year ended December 31, 2013. The increase was primarily attributable to expenses related to the advancement of our drug candidates during the year ended December 31, 2014. Our Phase I trial for Supinoxin initiated in 2013 continued throughout 2014, Archexin entered a Phase IIa clinical trial in January 2014 to study its safety and efficacy in patients with metastatic RCC, and RX-3117 entered a Phase Ib clinical trial in January 2014 to study its safety and efficacy in patients with solid tumors.

G&A Expenses - General and administrative expenses for the year ended December 31, 2014 were approximately \$6.3 million compared to \$4.7 million for the

year ended December 31, 2013. The year over year increase is primarily attributable to an increase in professional fees, personnel and insurance expenses.

Net Loss - Rexahn's loss from operations was \$13.3 million and \$8.0 million for the years ended December 31, 2014 and 2013, respectively. Rexahn's net loss was \$18.5 million, or \$0.11 per share, for the year ended December 31, 2014, compared to a net loss of \$9.5 million, or \$0.07 per share, for the year ended December 31, 2013. Included in net loss for the year ended December 31, 2014 and 2013 is an unrealized loss on the fair value of warrants of \$5.2 million and \$1.4 million, respectively. The fair value adjustments are primarily a result of the changes in the stock price between reporting periods.

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 expressed 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 breast, melanoma, colon, ovarian and lung tumors. In preclinical studies, Supinoxin has been shown to inhibit proliferation of cells in 18 human cancer cell lines including breast, colon, pancreas, ovarian, and stomach cancers, and showed potent activity in drug-resistant cancer cells. In preclinical animal models, where human cancer cells from triple negative breast, K-ras mutation colon, melanoma, pancreas, renal or platinum-resistant ovarian tumors were grafted into animals, treatment with Supinoxin resulted in a significant reduction in tumor growth.

The Phase I trial of Supinoxin is a dose-escalation study designed to evaluate the safety, tolerability, dose-limiting toxicities and maximal tolerated dose (MTD) in patients with solid cancer tumors. Secondary endpoints include pharmacokinetic analysis and evaluating 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 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 have the possibility to receive up to six cycles of treatment if there is no disease progression. Tumor biopsy samples are taken to assess the biomarker phosphorylated-p68. Patient enrollment has been completed in seven dose groups (25, 50, 100, 150, 225, 300 and 425 mg). The MTD of Supinoxin has not yet been achieved. In preliminary pharmacokinetic data, Supinoxin has approximately 51% oral bioavailability. The ongoing Phase I clinical trial is expected to be completed in the first half of 2015.

About RX-3117

RX-3117 is a novel small molecule anti-metabolite that is incorporated into DNA or RNA of cells and inhibits both DNA and RNA synthesis which induces apoptotic cell death of tumor cells. RX-3117 also mediates the downregulation of DNA methyltransferase 1 (DNMT1),

an enzyme responsible for the methylation of cytosine residues on newly synthesized DNA and also a target for anticancer therapies. Preclinical studies have shown RX-3117 to be effective in both inhibiting the growth of various human cancer xenograft models, including colon, lung, renal and pancreas, as well as overcoming chemotherapeutic drug resistance.

RX-3117 has demonstrated a broad spectrum anti-tumor activity against 80 different human cancer cell lines and efficacy in 12 different mouse xenograft models. The efficacy in the mouse xenograft models was superior to that of gemcitabine. In addition, 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 RX-3117 demonstrated an oral bioavailability of 56% and a plasma half-life ($T_{1/2}$) of 14 hours. In addition, RX-3117 was safe and well tolerated in all subjects throughout the dose range tested.

Rexahn initiated a Phase Ib clinical trial of RX-3117 in cancer patients with solid tumors in January 2014. 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 will include characterizing the pharmacokinetic profile of RX-3117 and evaluating the preliminary anti-tumor effects of RX-3117. Patient enrollment has been completed in eight dose groups (30, 60, 100, 150, 200, 500, 1000 and 1500 mg). The MTD of RX-3117 has not yet been achieved. The Company expects to complete this trial in the first half of 2015.

About Archexin®

Archexin® is a specific inhibitor of the cancer cell signaling protein Akt-1. The activated form of Akt-1 (phospho-Akt-1) has been shown to be involved in cancer cell growth, survival, angiogenesis, and drug resistance. Phospho-Akt-1 has been shown to be significantly increased in more than 12 different human cancer cell lines including human renal cell carcinoma (RCC) cells. Archexin has shown to inhibit the growth of human RCC cells in tissue culture and produce a substantial survival benefit in animal xenograft models of RCC. Archexin also exhibits additive anti-tumor effect when combined with other cancer drugs in inhibiting the growth of human RCC cells in tissue culture. In addition, resistance to the anti-cancer effects of clinically used mTOR inhibitors such as everolimus (Afinitor®), which is used as second line therapy in RCC patients, has been attributed to an increase in Akt-1 activity. Thus, treatment with Archexin may both inhibit the growth/proliferation of RCC and overcome the resistance to mTOR inhibitors such as everolimus, resulting in an increase in efficacy. Rexahn has initiated a Phase IIa proof-of-concept clinical trial designed to evaluate the efficacy of Archexin in combination with everolimus (Afinitor®) to treat metastatic RCC patients that will be conducted in two stages. Stage 1 will be dose ranging with up to 3 cohorts of 3 RCC patients to determine its maximum tolerated dose in combination with everolimus. Based on previous clinical data the target dose of Archexin is anticipated to be no more than 250 mg/m² per day. The decision to enroll the next group of patients and escalate the dose will be made after completion of the first 21 day cycle of treatment. Patient assessments will include safety, pharmacokinetics, laboratory and physical exams. Once the maximum tolerated dose of

Archexin in combination with everolimus has been determined, stage 2 will be initiated with thirty RCC patients being randomized to either Archexin in combination with everolimus or everolimus alone, in a ratio of 2:1.

About Rexahn Pharmaceuticals, Inc.

Rexahn Pharmaceuticals is a clinical stage biopharmaceutical company dedicated to developing best-in-class therapeutics for the treatment of cancer. Rexahn currently has three clinical stage oncology candidates, Supinoxin™ (RX-5902), RX-3117 and Archexin® and a robust pipeline of preclinical compounds to treat multiple types of cancer. Rexahn has also developed proprietary drug discovery platform technologies in the areas of Nano-Polymer-Drug Conjugate Systems (NPDCS), nano-medicines, 3D-GOLD, and TIMES. For more information, 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; 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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Source: Rexahn Pharmaceuticals