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Rexahn Pharmaceuticals Reports First Quarter 2015 Financial Results and Pipeline Update

New Data on RX-3117 and Supinoxin(TM) Substantially Increase Excitement Around These Programs in Scientific and Clinical Oncology Communities

ROCKVILLE, Md., May 11, 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 quarter ending March 31, 2015.

"Rexahn remains very encouraged by the continued progress of the Supinoxin™, RX-3117 and Archexin® clinical development programs. The additional data recently published with RX-3117 and Supinoxin has substantially increased the excitement around both of these programs by the scientific and clinical oncology communities. In these new studies RX-3117 demonstrated its ability to inhibit the growth of gemcitabine-resistant human pancreatic cancer cells in a cancer patient derived xenograft model; while Supinoxin was shown to decrease the expression of a number of related oncogenes and to decrease the migration of human triple negative breast cancer cells in a metastatic cancer model. With the addition of Ely Benaim, M.D., as Chief Medical Officer, Rexahn is planning clinical proof-of-concept studies for both RX-3117 and Supinoxin, which we hope to initiate by the end of 2015," commented Rexahn's CEO Peter D. Suzdak, Ph.D.

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 maximum tolerated dose (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 preliminary demonstrate safety and tolerability, requiring higher dose levels than expected 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. Rexahn expects to complete this trial in the first half of 2015. RX-3117 continues to preliminary demonstrate safety and tolerability, 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 the First Quarter of 2015:

- Appointed Ely Benaim, M.D. as Chief Medical Officer
- Presented at the Roth Capital Conference, Bio Europe Conference, Bio Asia Conference, Sachs Bio Cancer Forum, BIO CEO & Investor Conference,and Biotech Showcase Conference
- Published additional preclinical results for RX-3117 and Supinoxin™ in the peer reviewed journals Anticancer Research and Journal of Cellular Biochemistry, respectively
- Research coverage was initiated by MLV & Co.

Financial Update:

Cash Position - Rexahn's cash and investments totaled $29.4 million as of March 31, 2015, compared to $32.7 million as of December 31, 2014. The decrease of $3.3 million was primarily due to $4.0 million of cash used in operating activities, offset by $0.7 million in proceeds received from the exercise of stock options. Rexahn expects that its cash and investments as of March 31, 2015 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 $2.9 million for the three months ended March 31, 2015, compared to $1.3 million for the three months ended March 31, 2014. The increase was primarily attributable to expenses related to the advancement of our drug candidates. During the three months ended March 31, 2015, we incurred additional clinical trial and drug manufacturing costs as we have advanced our Phase IIa clinical trial for Archexin, and Phase I clinical trials for RX-3117 and Supinoxin. The increase is also partially attributable to an increase in personnel expenses.

G&A Expenses - General and administrative expenses for the three months ended

March 31, 2015 were approximately $1.5 million, roughly the same G&A expenses from the three months ended March 31, 2014. General and administrative expenses consist primarily of salaries and related expenses for executive, finance and other administrative personnel, recruitment expenses, professional fees and other corporate expenses, including business development, investor relations, and general legal activities.

Net Loss - Rexahn's loss from operations was $4.4 million and $2.8 million for the three months ended March 31, 2015 and 2014, respectively. Rexahn's net loss was $4.3 million, or $0.02 per share, for the three months ended March 31, 2015, compared to a net loss of $14.6 million, or $0.09 per share, for the three months ended March 31, 2014. Included in the net loss for the three months ended March 31, 2015 and 2014 is an unrealized gain (loss) on the fair value of warrants of $0.1 million and $11.7 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 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 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 model, where human cancer cells from melanoma, pancreas, renal or ovarian tumors were grafted into animals, treatment with Supinoxin resulted in a significant reduction in tumor growth.

Supinoxin is undergoing a Phase I dose-escalation clinical trial in cancer patients with solid tumors designed to evaluate the safety, tolerability, dose-limiting toxicities and maximal tolerated dose (MTD). Secondary endpoints include pharmacokinetic analysis and evaluating the preliminary anti-tumor effects of Supinoxin. This trial is being conducted at 3 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 3 weeks of drug treatment followed by 1 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 6 cycles of treatment if the disease does not progress. Tumor biopsy samples are taken to assess the biomarker phosphorylated-p68. 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. 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 once the MTD has been achieved.

About RX-3117

RX-3117 is a novel small molecule nucleoside compound that once activated (phosphorylated) by UCK2 is incorporated into DNA or RNA of cells and inhibits both DNA and RNA synthesis which induces apoptotic cell death of tumor cells. UCK2 is overexpressed in various human cancer 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 gemcitabine resistant cancer cells.

RX-3117 has demonstrated a broad spectrum anti-tumor activity against 50 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.

RX-3117 is undergoing a Phase Ib clinical trial in cancer patients with solid tumors. The Phase Ib clinical trial is a multi-center dose-escalation study that will evaluate the safety, tolerability, dose-limiting toxicities and maximal 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 ongoing Phase I clinical trial is expected to be completed in the first half of 2015 once the MTD has been achieved.

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/m^2 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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