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Rexahn Pharmaceuticals Reports Third Quarter 2015 Financial Results and Provides Corporate Update

Interim Data Suggest Potential Clinical Activity of Supinoxin™ and RX-3117 Anti-Cancer Therapies

ROCKVILLE, Md., Nov. 03, 2015 (GLOBE NEWSWIRE) -- Rexahn Pharmaceuticals, Inc. (NYSE MKT:RNN), a clinical stage biopharmaceutical company developing best-in-class therapeutics for the treatment of cancer, today announced financial results for the third quarter ended September 30, 2015 and provided an update on recent corporate and oncology pipeline developments.

“Rexahn made important progress during the third quarter presenting new interim clinical data for Supinoxin and RX-3117 at an international medical conference,” said Peter D. Suzdak, Ph.D., Chief Executive Officer. “We were particularly excited to see that these compounds appear to be safe and well tolerated in ongoing clinical studies and show encouraging early signs of clinical efficacy exhibited as stable disease or in some cases, tumor regression. Given that these are very sick patients with advanced disease that have been heavily pre-treated and have previously failed other forms of therapy, we are especially pleased to observe potential efficacy signals at this stage. Rexahn is committed to developing novel, highly targeted cancer treatments that may bring meaningful quality of life improvements for patients and their families and we look forward to continuing to advance our next generation cancer programs through clinical development.”

Third Quarter 2015 Corporate Highlights:

Promising Interim Clinical Data for Supinoxin and RX-3117 Presented at the18th ECCO – 40th ESMO European Cancer Congress 2015

During the quarter, Rexahn scientists and their scientific collaborators presented new interim clinical data for both Supinoxin and RX-3117 at the European Cancer Congress.

The interim clinical results demonstrated that both Supinoxin and RX-3117 appeared to be safe and well tolerated and also showed preliminary evidence of clinical activity, which Rexahn believes underscores the unique mechanism of action of these compounds and their ability to selectively target key molecular pathways involved in cancer biology, while potentially sparing non-cancerous, healthy cells from the side effects normally associated with the use of existing chemotherapeutic agents.

Notably, clinical evidence of single-agent activity of Supinoxin was observed in 4 patients enrolled in the ongoing trial who showed stable disease persisting from between 255 and 497 days (as of September 14, 2015.) At present, 3 of those patients with stable disease continue to remain in the study on active treatment.

For RX-3117, potential anti-tumor activity was also reported, with evidence of tumor reduction of approximately 9% observed in 1 patient and stable disease observed in approximately 5 patients persisting from between 112 and 276 days before disease progression occurred.

Based on the favorable safety and pharmacokinetic profile seen at the highest dose levels tested for both Supinoxin and RX-3117, Rexahn has initiated a dosing schedule modification in the ongoing clinical studies to increase drug exposure and maximize the potential therapeutic activity to enable more rapid determination of either a maximum tolerated dose or best tolerated dose for further clinical study.

“We are very encouraged by the accumulating interim clinical data which suggest that Supinoxin and RX-3117 appear to be well tolerated in patients with serious and advanced forms of cancer, and – despite not yet having reached the maximum tolerated dose, are showing intriguing initial signs of efficacy,” said Dr. Suzdak. “Research suggests that our anti-cancer compounds are targeting specific proteins or enzymes that are highly expressed or exclusively expressed in cancer cells, giving us confidence in their ability to target cancerous tissue without the harmful side effects associated with traditional chemotherapy.”

Third Quarter 2015 Financial Results:

Cash and Investments - Rexahn's cash and investments totaled approximately $21.5 million as of September 30, 2015, compared to approximately $26.0 million and $32.7 million as of June 30, 2015 and December 31, 2014, respectively. The decrease in cash and investments during the three months ended September 30, 2015 is primarily due to $4.5 million in cash used in operating activities, as financing activities were minimal. The decrease in cash and investments during the first nine months of 2015 was primarily due to $12.9 million of cash used in operating activities, offset by approximately $1.7 million in proceeds received from the exercise of stock options and the sale of common stock. Rexahn expects that its cash and investments as of September 30, 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 $3.1 million for the three months ended September 30, 2015, compared to $1.8 million for the three months ended September 30, 2014. Research and development expenses for the nine month period ended September 30, 2015 were $9.2 million compared to $4.8 million for the same period in 2014. The increase in research and development expenses during both the three and nine month periods of 2015 is primarily attributable to additional clinical trial and drug manufacturing costs related to ongoing Archexin, Supinoxin and RX-3117 clinical studies, and partially attributable to an increase in personnel expenses.

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

September 30, 2015 were approximately $1.6 million, compared to $1.3 million for the three months ended September 30, 2014. General and administrative expenses for the nine month period ended September 30, 2015 were $4.7 million compared to $4.6 million for the same period in 2014. The year over year increase is primarily attributable to an increase in professional fees, insurance, and personnel expenses. 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 $4.7 million and $3.1 million for the three months ended September 30, 2015 and 2014, respectively. Rexahn's net loss was $4.0 million, or $0.02 per share, for the three months ended September 30, 2015, compared to a net loss of $1.9 million, or $0.01 per share, for the three months ended September 30, 2014. For the nine month period ending September 30, 2015, Rexahn's net loss was $11.5 million, or $0.06 per share compared to $16.3 million or $0.09 per share for the same period in 2014. Included in the net loss for the three months ended September 30, 2015 and 2014 is an unrealized gain on the fair value of warrants of $0.6 million and $1.2 million, respectively. For the nine month period ended September 30, 2015 and 2014, Rexahn recorded an unrealized gain (loss) on the fair value of warrants of $2.3 million and $(6.8) 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 over 100 different 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 melanoma, pancreas, renal or ovarian 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 in nine dose groups (25, 50, 100, 150, 225, 300, 425, 575, and 775 mg) have been enrolled to date, and at this time, the MTD has not yet been reached. Given the robust preliminary safety profile observed in the Phase I clinical trial to date, it is difficult to predict when the MTD will be achieved and the trial will be completed.

About RX-3117

RX-3117 is a novel, investigational small molecule nucleoside compound. Once intracellularly activated (phosphorylated) by UCK2, it is incorporated into the 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. Preclinical studies have shown that RX-3117 inhibits the growth of various human cancer xenograft models, including pancreatic, lung, bladder, cervical and colon, as well as gemcitabine resistant cancer cells.

RX-3117 has demonstrated broad spectrum anti-tumor activity against over 100 different human cancer cell lines and efficacy in 17 different mouse xenograft models. Notably, the efficacy of RX-3117 in the mouse xenograft models was superior to that of gemcitabine. Further, 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 a 50 mg dose of RX-3117 demonstrated an oral bioavailability of 56% and a plasma half-life ($T_{1/2}$) of 14 hours. In addition, RX-3117 appeared to be safe and well tolerated in all subjects throughout the dose range tested.

RX-3117 is currently being evaluated in 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 maximum tolerated dose (MTD) of RX-3117 in patients with solid tumors. Secondary endpoints include pharmacokinetic analysis, and an evaluation of the preliminary anti-tumor effects of RX-3117. Patient enrollment has been completed in nine dose groups (30, 60, 100, 150, 200, 500, 1000, 1500 and 2000 mg). The MTD of RX-3117 has not yet been achieved. Given the robust preliminary safety profile observed in the Phase Ib clinical trial to date, it is difficult to predict when the MTD will be achieved and the trial will be completed.

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®, 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, 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; that results of preclinical studies and early clinical trials may not be predictive of the results of later-stage clinical trials; 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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