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# Rexahn Pharmaceuticals Reports Third Quarter 2014 Financial Results and Pipeline Update

## Encouraging Data From Dose-Escalation Studies, Plus FDA Orphan Drug Designation in Pancreatic Cancer

ROCKVILLE, Md., Nov. 13, 2014 (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 overview of its three clinical development programs and financial results for the quarter ended September 30, 2014.

"Data from the ongoing clinical trials with Supinoxin™, RX-3117 and Archexin® continue to look encouraging and we are pleased with the continued progress of our clinical development programs. Significant Supinoxin™ and RX-3117 exposure is being achieved in cancer patients without signs of dose-limiting side effects. As one of the primary outcome measures from these trials is the determination of the maximal tolerated dose (MTD) these positive safety results require that we continue testing additional higher doses of Supinoxin™ and RX-3117," stated Rexahn's Chief Executive Officer Peter D. Suzdak, PhD.

Rexahn is continuing its discussions with multiple pharmaceutical companies to explore collaborative business structures in an effort to maximize the potential upside value of the Supinoxin and RX-3117 clinical development programs.

### Pipeline Update:

#### ***Supinoxin™ (RX-5902)***

In August 2013, Rexahn initiated a Phase I dose-escalation study of Supinoxin designed to evaluate the safety, tolerability, dose-limiting toxicities and MTD in cancer patients with solid tumors that have previously failed treatment with approved therapies. Secondary endpoints include pharmacokinetic analysis and evaluating the preliminary anti-tumor effects of Supinoxin. Patients in five dose groups (25, 50, 100, 150 and 225 mg) have been enrolled. The Company is currently enrolling patients for the sixth dose group (300 mg), 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 quarter of 2015.

#### ***RX-3117***

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 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 five dose groups (30, 60, 100, 150 and 200 mg) and patients are now enrolling for the sixth dose group (500 mg). The MTD of RX-3117 has not yet been achieved. The Company expects to complete patient enrollment of the RX-3117 Phase Ib clinical trial late in the first quarter of 2015.

### **Archexin<sup>®</sup>**

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 its MTD of Archexin in combination with everolimus, an FDA approved drug for the treatment of RCC. Once the MTD has been determined, thirty RCC patients will be randomized to either Archexin in combination with everolimus or everolimus alone, in a ratio of 2:1. Rexahn expects to complete the initial safety component of this study in early 2015.

### **Additional Highlights from Third Quarter 2014:**

- Received orphan drug designation from the FDA for RX-3117 in the treatment of pancreatic cancer
- Received a notice of allowance from the U.S. Patent and Trademark Office for a novel targeted cancer drug delivery platform
- Presented company updates at three (Rodman and Renshaw Global Investment Conference, BioPharm America, and Biotech in Europe Forum for Global Partnering & Investment) financial and/or business development conferences

### **Financial Update:**

**Cash Position** - Rexahn's cash and investments totaled \$35.6 million as of September 30, 2014, compared to \$38.3 million as of June 30, 2014. The decrease of \$2.7 million was primarily due to net cash used in operating activities. Rexahn expects that its cash and cash equivalents as of September 30, 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 approximately \$1.8 million for the third quarter of 2014, compared to approximately \$0.8 million for the third quarter of 2013. Research and development expenses were \$4.8 million for the nine months ended September 30, 2014, compared to \$2.3 million for the nine months ended September 30, 2013. The increase was primarily attributable to expenses related to the advancement of our drug candidates. During the nine months ended September 30, 2014, one of our drug candidates, Archexin, entered a Phase IIa clinical trial to study its safety and efficacy in patients with metastatic RCC, and another drug candidate, RX-3117, entered a Phase Ib clinical trial to study its safety and efficacy in patients with solid tumors.

**G&A Expenses** - General and administrative expenses were approximately \$1.2 million

for the third quarter of 2014, compared to approximately \$0.9 million for the third quarter of 2013. General and administrative expenses for the nine months ended September 30, 2014 were approximately \$4.3 million compared to \$3.0 million in the nine months ended September 30, 2013. The year over year increases for both the three month and nine month period ended September 30, 2014 is primarily attributable to an increase in professional fees and personnel expenses.

**Net Loss** - Rexahn's net loss was \$1.9 million, or \$0.01 per share, for the three months ended September 30, 2014, compared to a net loss of \$2.1 million, or \$0.02 per share, for the three months ended September 30, 2013. Included in net loss for the three months ended September 30, 2014 and 2013 is an unrealized gain (loss) on the fair value of warrants of \$1.2 million and (\$0.2 million), respectively. The fair value adjustments are primarily a result of the changes in the stock price between reporting periods. Rexahn's loss from operations was \$3.1 million and \$1.8 million for the three months ended September 30, 2014 and 2013, respectively.

### **About Supinoxin™ (RX-5902)**

Supinoxin is an orally administered, first-in-class, small molecule inhibitor of phosphorylated-p68 RNA helicase (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 P-p68 has been observed in solid tumors such as melanoma, colon, ovarian and lung.

### **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 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. These findings have either been previously presented at the American Association of Cancer Research Meeting in 2012 or will be the subject of a peer reviewed publication to be published in early 2014. 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.

### **About Archexin®**

Archexin® is a unique anti-cancer drug candidate that inhibits the cancer cell signaling protein Akt-1, which is involved in cancer cell growth, survival, angiogenesis, and drug resistance. 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 a 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 demonstrated a preliminary efficacy signal with a median survival of 9.1 months in evaluable patients.

### **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, Archexin®, RX-3117 and Supinoxin™ (RX-5902) 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](http://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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