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# Rexahn Pharmaceuticals Reports First Quarter 2016 Financial Results and Provides Corporate Update

*Progresses Novel Targeted Anti-Cancer Therapies in Clinical Development*

*Initiates Phase Ib/IIa Clinical Trial of RX-3117 and Begins Enrollment in Phase IIa Randomized Clinical Trial of Archexin®*

ROCKVILLE, Md., May 09, 2016 (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 first quarter ended March 31, 2016 and provided an update on the Company's clinical development programs.

"Rexahn achieved important milestones in the first quarter marked by advances in each of our clinical oncology programs," said Peter D. Suzdak, Ph.D., Chief Executive Officer. "First, we completed Stage 1 of a Phase IIa clinical trial evaluating Archexin®, in a combination with everolimus, in patients with metastatic renal cell carcinoma. Data from the clinical trial were recently presented at the 2016 American Association for Cancer Research annual meeting and showed promising early evidence of the potential clinical activity of Archexin, evidenced by both stable disease and a reduction in tumor burden in several patients. We are very encouraged by these data and look forward to potentially confirming these results in the randomized part of the Phase IIa study which is now enrolling patients."

"We were also pleased to commence the next stage of RX-3117 clinical development. During the quarter we completed a Phase Ib clinical trial of RX-3117 and identified a maximum tolerated dose which we are now evaluating in a Phase Ib/IIa clinical proof-of-concept study in patients with relapsed and refractory pancreatic cancer and advanced bladder cancer. RX-3117, which has a novel mechanism of action, holds promise as a targeted therapy for cancers with high unmet medical need. We are committed to advancing each of our targeted oncology programs with the goal of finding better ways to treat cancer patients," continued Dr. Suzdak.

## **First Quarter 2016 Corporate Highlights:**

- ***Phase Ib/IIa Clinical Proof-of-Concept Study of RX-3117 Commences***

During the first quarter Rexahn completed an ongoing Phase Ib clinical trial of RX-3117 and commenced enrollment in a Phase Ib/IIa proof-of-concept clinical study in patients

with relapsed and refractory pancreatic cancer and advanced bladder cancer. The Phase Ib/IIa clinical trial is a multicenter, open-label, single-agent study of RX-3117 being conducted at 10 clinical centers in the United States. RX-3117 is being administered orally five times weekly on a three weeks on, one week off dosing schedule. The primary endpoint for the trial is an assessment of the progression free survival rate or an objective clinical response rate and reduction in tumor size. Secondary endpoints include time to disease progression, overall response rate and duration of response, as well as pharmacokinetic assessments and safety parameters.

- ***Stage 1 of the Phase IIa Archexin Clinical Trial Completed and MTD Confirmed; Stage 2 Begins Enrollment***

Rexahn recently completed Stage 1 of a Phase IIa clinical trial of Archexin in combination with everolimus, a widely used chemotherapy drug, in patients with metastatic renal cell carcinoma (RCC). A maximum tolerated dose of Archexin of 250 mg/m<sup>2</sup>/day was identified and will be used in Stage 2 of the clinical trial. Data from the dose escalation stage of the Archexin clinical trial yielded encouraging preliminary clinical findings suggesting that Archexin, in combination with everolimus, showed evidence of a potential dose- and time-dependent clinical benefit in patients with advanced metastatic kidney cancer. Based on these results, Rexahn has commenced enrolling patients in a randomized, open-label, two-arm dose expansion study of Archexin in combination with everolimus, versus everolimus alone. The trial is anticipated to enroll up to 30 RCC patients who will be randomized to receive either Archexin in combination with everolimus, or everolimus alone, in a ratio of 2:1. The maximum tolerated dose of 250 mg/m<sup>2</sup>/day of Archexin — identified in Stage 1, is being administered along with 10 mg of everolimus versus 10 mg everolimus alone.

- ***New Preclinical Data for Supinoxin™ Presented at ASCO Symposia Show Dose Dependent Tumor Cell Growth Inhibition in Pancreatic and Renal Cancer Cell Lines***

During the first quarter Rexahn scientists and their collaborators presented new preclinical data for Supinoxin at the American Society for Clinical Oncology (ASCO) 2016 Genitourinary Cancers Symposium and the 2016 Gastrointestinal Cancers Symposium showing the anti-proliferative effects of Supinoxin in various human pancreatic and renal cancer cell lines and xenograft cancer models.

In these studies, Rexahn scientists showed that oral administration of Supinoxin in mice at various doses up to 70 mg/kg for 21 days achieved a dose-dependent, clinically meaningful tumor response. In addition, at the dose of 70 mg/kg daily, 70% of the animals treated with Supinoxin showed a complete regression of their tumor and experienced tumor free survival.

- ***New Preclinical Data for Supinoxin in Triple Negative Breast Cancer Presented at the 2016 Targeted Anti-Cancer Therapeutics (TAT) Congress***

Rexahn has previously reported data showing the ability of Supinoxin to dose-dependently decrease the migration of human triple negative breast cancer (TNBC) cells in a preclinical

model of cancer cell metastasis, suggesting a potential role for Supinoxin in the prevention of cancer metastasis.

New data presented during the first quarter at the 2016 TAT Congress, demonstrated the anti-proliferative effects of Supinoxin in multiple TNBC cell lines in which a high level of sensitivity to Supinoxin was observed in the majority of these cell lines, suggesting broad activity of Supinoxin across various molecular subtypes of TNBC. These data are supported by in vivo studies in TNBC demonstrating that oral administration of Supinoxin inhibits tumor growth in a dose-dependent manner, with meaningful tumor growth inhibition of greater than 60% at higher doses and the achievement of complete responses and tumor free survival in mice.

- ***Rexahn Completes \$5 Million Registered Direct Offering***

In March, Rexahn strengthened its financial position and completed a registered direct offering with a single dedicated institutional healthcare investor to purchase approximately 15.6 million shares of its common stock and warrants exercisable for up to approximately 11.7 million shares of its common stock for gross proceeds to the Company of \$5 million.

### **Upcoming 2016 Milestones**

- Initiate Supinoxin Phase Ib/IIa proof-of-concept clinical trial in triple negative breast cancer and platinum resistant ovarian cancer
- Report interim data for Supinoxin and RX-3117 Phase Ib/IIa clinical trials
- Complete enrollment in Archexin Phase IIa randomized clinical trial

### **First Quarter 2016 Financial Results:**

#### **Cash and Investments**

Rexahn's cash and investments totaled approximately \$24.5 million as of March 31, 2016, compared to approximately \$23.4 million as of December 31, 2015. The increase in cash and investments during the three months ended March 31, 2016 was due to \$4.6 million of net proceeds received from the registered direct offering in March 2016, offset by approximately \$3.5 million of cash used in operating activities. Rexahn expects that its cash and investments as of March 31, 2016 will be sufficient to fund the Company's cash flow requirements for its current activities into the second half of 2017.

#### **Research and Development Expenses**

Research and development expenses were \$3.5 million for the three months ended March 31, 2016, compared to \$2.9 million for the three months ended March 31, 2015. The increase in research and development expenses in 2016 is primarily attributable to additional clinical trial and drug manufacturing costs related to ongoing Archexin and Supinoxin clinical trials and partially attributable to an increase in personnel expenses.

#### **General and Administrative Expenses**

General and administrative expenses for the three months ended March 31, 2016 were

approximately \$1.4 million, compared to \$1.5 million for the three months ended March 31, 2015. The year over year decrease is primarily attributable to higher personnel and recruiting costs in the prior year period. 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 \$4.9 million and \$4.4 million for the three months ended March 31, 2016 and 2015, respectively. Net loss was \$4.1 million, or \$0.02 per share, for the three months ended March 31, 2016, compared to a net loss of \$4.3 million, or \$0.02 per share, for the three months ended March 31, 2015. Included in the net loss for the three months ended March 31, 2016 and 2015 are unrealized gains on the fair value of warrants of \$0.9 million and \$0.1 million, respectively. The fair value adjustments are primarily a result of the changes in the Company's stock price between reporting periods.

## **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](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, 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.

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