

November 7, 2016



Rexahn Pharmaceuticals Reports Third Quarter 2016 Financial Results and Provides Corporate Update

Preliminary Efficacy Data from Phase Ib/IIa Clinical Trial of RX-3117 in Metastatic Pancreatic Cancer presented at European Society for Medical Oncology (ESMO) Congress

Initiates Stage 2 of the Phase IIa clinical trial of RX-3117 in Relapsed and Refractory Metastatic Pancreatic Cancer

Begins Enrollment in Phase Ib/IIa trial of RX-3117 in Advanced Bladder Cancer

ROCKVILLE, Md., Nov. 07, 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 third quarter ended September 30, 2016 and provided an update on the Company's clinical development programs.

"Rexahn achieved a major milestone in the third quarter with the progression of RX-3117 to stage 2 of a Phase Ib/IIa clinical trial evaluating RX-3117 in relapsed and refractory pancreatic cancer," said Peter D. Suzdak, Ph.D., Chief Executive Officer. "We are very encouraged by the stage 1 data which shows preliminary evidence of efficacy with the most difficult to treat patients who have not been responsive to multiple prior rounds of chemotherapy. Data from stage 1 of this clinical trial were recently presented at the European Society of Medical Oncology (ESMO) annual congress."

"RX-3117 is also being evaluated in bladder cancer, another difficult to treat patient group. We commenced enrollment in a Phase Ib/IIa clinical trial of RX-3117 in patients with advanced bladder cancer, where there is a high unmet need for better medications and no major advance in treatments in the last twenty years," continued Dr. Suzdak.

"During the third quarter, Rexahn continued to advance the Phase IIa clinical trial of Archexin[®] in combination with everolimus in metastatic renal cell carcinoma. The study continues to show promising signs of clinical efficacy evidenced by both stable disease and a reduction in tumor burden in several patients," Dr. Suzdak added.

"We are nearing completion of our Phase I dose escalating study with Supinoxin[™] and anticipate beginning a Phase Ib/IIa study of Supinoxin in patients with triple negative breast cancer in the near future. Data from the Supinoxin Phase I study were recently presented at ESMO. The updated results show that Supinoxin is safe and well tolerated at the doses and dosing schedules tested with no dose limiting toxicities or treatment-related serious adverse events. Initial signs of clinical activity have been observed in patients with breast,

neuroendocrine, paraganglioma, head and neck and colorectal cancers, demonstrating stable disease for up to 880 days. Of these patients approximately 55% had received four or more therapies prior to their enrollment in the Phase I clinical study and we are encouraged to see signs of clinical activity in this study,” concluded Dr. Suzdak.

Third Quarter 2016 Corporate Highlights:

- ***Stage 2 of the Phase Ib/IIa Clinical Trial of RX-3117 in Relapsed and Refractory Pancreatic Cancer Commences***

During the third quarter Rexahn completed the first stage of a Phase Ib/IIa clinical trial of RX-3117 in patients with relapsed refractory pancreatic cancer and commenced enrollment in the second stage. The decision to proceed was based on satisfying the predefined criteria for preliminary efficacy for stage 1 of the trial. RX-3117 was safe and well tolerated with preliminary efficacy seen in pancreatic cancer patients for whom three prior therapies had been ineffective.

The ongoing 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. Patients receive a 700 mg daily oral dose of RX-3117, five times weekly on a three weeks on, one week off dosing schedule in a 28 day cycle for up to eight treatment cycles, or until their disease progresses. The study follows a two-stage design. In stage 1 of the trial, up to 10 patients with relapsed or refractory metastatic pancreatic cancer were enrolled. Based on predefined criteria, if 20% or more of the patients had progression free survival of 4 months or more, or an objective clinical response rate and reduction in tumor size, then an additional 40 pancreatic cancer patients would be enrolled into stage 2. The clinical study is still on-going. However since the predefined efficacy criteria have been achieved, stage 2 of the study has been initiated. Data from stage 1 of the clinical trial was recently presented at ESMO. Patients with relapsed or refractory metastatic pancreatic cancer, 88% of whom had received 4 or more prior cancer therapies, were treated with RX-3117. There are no approved treatments for pancreatic cancer patients who have failed three or more prior therapies and their survival is usually less than 2 months. These patients would usually be offered palliative or best supportive care. In this study more than 20% of patients treated with RX-3117 exhibited progression free survival of greater than 4 months. An additional 20%, for a total of 40%, of the patients exhibited progression free survival of 2.5 months. Based on positive results, stage 2 of the study has been initiated and an additional 40 pancreatic cancer patients are currently being enrolled.

- ***Stage 1 of the Phase Ib/IIa Clinical Trial of RX-3117 in Bladder Cancer Begins Enrollment***

During the third quarter Rexahn commenced enrollment in a Phase Ib/IIa trial of RX-3117 in patients with 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.

- ***Rexahn Completes \$6 Million Registered Direct Offering***

In September, Rexahn strengthened its financial position and completed a registered direct offering of 24 million shares of common stock and warrants to purchase 18 million shares of common stock for gross proceeds of \$6 million. The shares and warrants were sold in units, each consisting of one share of common stock and a warrant to purchase 0.75 shares of common stock, at an offering price of \$0.25 per unit. The warrants will become exercisable six months following the issuance date, will remain exercisable until the fifth anniversary of the initial exercise date and have an exercise price of \$0.30 per share. The net proceeds of the offering will be used for further development of Rexahn's lead clinical programs, including the funding of clinical development programs for RX-3117, Supinixin and Archexin and for working capital and general corporate purposes.

Upcoming Milestones

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

Third Quarter 2016 Financial Results:

Cash Position - Rexahn's cash and investments totaled approximately \$21.8 million as of September 30, 2016, compared to approximately \$23.4 million as of December 31, 2015. The decrease in cash and investments during the nine months ended September 30, 2016 was due to approximately \$11.7 million of cash used in operating activities, offset by an aggregate \$10.1 million of proceeds received from registered direct offerings in March and September 2016. Rexahn expects that its cash and investments as of September 30, 2016 will be sufficient to fund the company's cash flow requirements for its current activities into the first half of 2018.

R&D Expenses - Research and development expenses were \$2.3 million for the three months ended September 30, 2016, compared to \$3.1 million for the three months ended September 30, 2015. Research and development expenses for the nine month period ended September 30, 2016 were \$8.0 million, compared to \$9.2 million for the same period in 2015. Decreased research and development costs for the three and nine months ended September 30, 2016 is primarily attributable to lower drug manufacturing costs due to a significant supply of our drug candidates already being available from earlier manufacturing campaigns.

G&A Expenses - General and administrative expenses for the three months ended September 30, 2016 were approximately \$1.4 million, compared to \$1.6 million for the three months ended September 30, 2015. General and administrative expenses for the nine month periods ended September 30, 2016 and 2015 were \$4.5 million and \$4.7 million, respectively. The year over year decrease for the three and nine months ended September 30, 2016 is primarily attributable to lower personnel costs and professional fees. 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 \$3.7 million and \$4.7 million for the three months ended September 30, 2016 and 2015, respectively. Rexahn's net loss was \$2.9 million, or \$0.01 per share, for the three months ended September 30, 2016, compared to a net loss of \$4.0 million, or \$0.02 per share, for the three months ended September 30, 2015. For the nine month period ended September 30, 2016, Rexahn's net loss was \$8.8 million, or \$0.04 per share compared to \$11.5 million, or \$0.06 per share for the same period in 2015. Included in the net loss for the three months ended September 30, 2016 and 2015 is an unrealized gain on the fair value of warrants of \$1.0 million and \$0.6 million, respectively. For the nine month period ended September 30, 2016 and 2015, Rexahn recorded an unrealized gain on the fair value of warrants of \$3.9 million and \$2.3 million. The fair value adjustments are primarily a result of the changes in the 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. Preclinical 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, 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.

CONTACT:

LifeSci Advisors, LLC
Matthew P. Duffy
(212) 915-0685
matthew@lifesciadvisors.com



Source: Rexahn Pharmaceuticals