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Rexahn Pharmaceuticals Doses First Patient in a Phase IIa Clinical Trial of RX-3117 in Combination with Abraxane® in Patients Newly Diagnosed with Metastatic Pancreatic Cancer

ROCKVILLE, Md., Nov. 08, 2017 (GLOBE NEWSWIRE) -- Rexahn Pharmaceuticals, Inc. (NYSE AMERICAN:RNN), today announced that it has dosed the first patient in a Phase IIa clinical study of RX-3117 in combination with Abraxane® in patients newly diagnosed with metastatic pancreatic cancer who have had no prior chemotherapy. Abraxane® (albumin-bound paclitaxel) is commonly used in the treatment of pancreatic cancer in combination with other chemotherapies.

“With the initiation of this study, we are exploring the potential of RX-3117 in patients newly diagnosed with metastatic pancreatic cancer, who have not been treated previously with chemotherapy. This is the largest patient segment, accounting for 60% of all pancreatic cancer patients, and this patient population potentially may benefit most from treatment with RX-3117,” commented Peter D. Suzdak, Ph.D., Chief Executive Officer of Rexahn. “RX-3117 has already shown both safety and preliminary efficacy in a Phase IIa study in pancreatic cancer in patients who had progressing disease after multiple prior cancer treatments.“

“There is a strong clinical rationale for combining RX-3117 with Abraxane,” said Ely Benaim, M.D., Chief Medical Officer of Rexahn. “We know that drugs with a mechanism of action similar to RX-3117 work well in combination with Abraxane. However, not all patients can tolerate combinations with Abraxane due to the emergence of grade 3/4 toxicities. A major advantage of RX-3117 is that it selectively targets cancer cells and has been shown to be safe and well tolerated in Phase I and IIa clinical trials. Our goal is to be able to treat patients with higher doses of both Abraxane and RX-3117, allowing them to stay on treatment for longer periods of time, leading to a better clinical outcome.”

The Phase IIa clinical proof-of-concept study is an open-label evaluation of the safety and efficacy of RX-3117 in combination with Abraxane (albumin-bound paclitaxel) in patients with metastatic pancreatic cancer who have had no prior chemotherapies. The study is a two stage study. The first stage is designed to determine the optimum dose of RX-3117 and Abraxane to be evaluated in the second stage. Up to 50 patients will be enrolled into the second stage of the study and the primary endpoint is progression free survival.

About RX-3117

RX-3117 is a novel, investigational, oral, 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 highly overexpressed in various human cancer cells. RX-3117 has recently announced that the European Medicines Agency's (EMA) Committee for Orphan Medicinal Products (COMP) has issued a positive opinion recommending orphan medicinal product (orphan drug) designation for RX-3117 for the treatment of pancreatic cancer. The U.S. Food and Drug Administration (FDA) previously granted orphan drug designation for RX-3117 in pancreatic cancer in 2014.

Rexahn has previously completed a Phase Ib clinical trial of RX-3117 showing encouraging evidence of the single agent activity. Patients in the study were heavily pre-treated, and had generally received four or more cancer therapies prior to enrollment. In this study, 12 patients experienced stable disease persisting for up to 276 days and three patients showed evidence of tumor burden reduction. A maximum tolerated dose of 700 mg was identified in the study and will be administered for five consecutive days, with two days off, for three treatment weeks, followed by a week of rest. At the doses tested to date, RX-3117, administered orally, appeared to be safe and well tolerated with a predictable pharmacokinetic profile for an orally-administered route of therapy.

Pancreatic Cancer: Rexahn initiated a two stage Phase IIa clinical trial of RX-3117 in patients with relapsed or refractory pancreatic cancer. Preliminary data were presented at the European Society of Medical Oncology (ESMO) Congress in October 2016. Patients in the trial are receiving a 700 mg daily oral dose of RX-3117, five times weekly for three weeks 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, 10 patients with relapsed or refractory metastatic pancreatic cancer were enrolled and 20% of the patients achieved the predefined criteria (progression free survival of > 4 months) which triggered the enrollment of an additional 40 pancreatic cancer patients (stage 2).

Patients enrolled into stage 1 of the clinical trial had actively progressing disease with 88% of them having received 4 or more prior cancer therapies (including 5-FU and gemcitabine-based therapies). These patients would usually be offered palliative or best supportive care. 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. In the current 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. RX-3117 was shown to be safe and well tolerated in this patient group. The most frequently reported drug related adverse events were mild to moderate fatigue, diarrhea and decreased white blood cell counts. Stage 2 of the study has been initiated and an initial data readout is expected in 4Q 2017.

Advanced and metastatic bladder cancer: In 2016, Rexahn initiated a two stage Phase IIa clinical trial in advanced and metastatic bladder cancer. The 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 study is following a two-stage design. In the initial stage, 10 patients with advanced and metastatic bladder cancer will be enrolled. If there is an increase in progression free survival of greater than 4 months in 20% of the patients or a reduction in tumor size, then an additional cohort of patients will be enrolled. At the 2017

European Society for Medical Oncology (ESMO) congress Rexahn presented the initial data from this trial. Four of ten patients treated with RX-3117 exhibited progression free survival of greater than 5 months and one of these patients is continuing in the study with stable disease at 259 days. Two patients had reductions of 19% and 15% in tumor size. As a result, the study began enrolling an additional 10 patients in this second stage. There were no dose-limiting toxicities.

About Rexahn Pharmaceuticals, Inc.

Rexahn Pharmaceuticals Inc. (NYSE American:RNN) is a clinical stage biopharmaceutical company dedicated to developing novel, targeted 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, 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; the ability to transition from our initial focus on developing drug candidates for orphan indications to candidates for more highly prevalent indications; and the expecting timing of results from our clinical trials. 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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