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Rexahn Pharmaceuticals Presents Preliminary Efficacy Data from the Ongoing Phase IIa Clinical Trial of RX-3117 in Advanced Bladder Cancer at the 2017 European Society for Medical Oncology (ESMO) Congress

RX-3117 Monotherapy Increased Progression Free Survival and Showed Evidence of Tumor Shrinkage in Patients with Advanced Bladder Cancer Resistant to Gemcitabine who had failed on Multiple Prior Treatments

ROCKVILLE, Md., Sept. 10, 2017 (GLOBE NEWSWIRE) -- Rexahn Pharmaceuticals, Inc. (NYSE MKT:RNN), a clinical stage biopharmaceutical company developing innovative, targeted therapeutics for the treatment of cancer, today announced an update on the safety and efficacy of RX-3117 in an ongoing Phase IIa clinical trial in advanced bladder cancer at the 2017 European Society for Medical Oncology (ESMO) Congress in Madrid, Spain.

"The presentation at ESMO, is an update on the first ten patients enrolled into stage 1 of the study, that we reported on earlier in the year," said Peter D. Suzdak, Ph.D., Chief Executive Officer for Rexahn. "Forty percent of patients are now showing an increase in progression free survival (PFS) of greater than 5 months — with one patient at 9 months without disease progression. This increase in progression free survival exceeds the pre-set criteria for success. We are very impressed with these preliminary data and we will continue to enroll additional patients into the second stage of the study as we progress RX-3117 through clinical development."

"It was very unusual to see prolonged stable disease in patients in this study who had failed on multiple prior treatments that included immunotherapy," said Ely Benaim, M.D., Chief Medical Officer for Rexahn. "Ninety percent of the patients had already developed resistance to gemcitabine so these preliminary data are very encouraging. We look forward to completion of the study and to reporting additional data over the coming months."

RX-3117 Phase IIa Clinical Data

The updated efficacy data for RX-3117 from an ongoing Phase IIa clinical trial in metastatic bladder cancer are being presented on Sunday June 10, 2017 in a poster presentation entitled *RX-3117, An Oral Hypomethylating Agent to Treat Advanced Solid Tumors (ST): Interim results from an Ongoing Phase 2a Study in Advanced Urothelial Cancer* authored by Drs. MC Maia, S Pal, J Gong and V Chung (City of Hope Comprehensive Cancer Center, CA); Dr. J Picus (Division of Oncology, Dept. of Medicine, Washington University School of Medicine, MO); Dr. ST Tagawa (Sandra and Edward Meyer Cancer Center, Weill Cornell Medicine, NY); Dr. S Gupta (Huntsman Cancer Institute at the University of Utah, UT) and Rexahn Pharmaceuticals.

The poster presentation is an update on the progression free survival (PFS) of patients enrolled in stage 1 of the Phase IIa study in advanced and metastatic bladder cancer. The initial data from these patients was reported in June at the American Society of Clinical Oncology (ASCO) 2017 Annual Meeting. Patients had actively progressing bladder cancer with distant metastases to multiple sites including the liver, lung, lymph nodes and pelvis. Six of the ten patients had three or more prior treatments for metastatic cancer and nine had failed on gemcitabine. These patients would usually be offered palliative or supportive care and expected progression free survival is two or three months. There are no approved treatments for metastatic bladder cancer patients who have failed two or more prior therapies.

In stage 1 of the current study, 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 a reduction of 19% and 15% in tumor size. The predefined efficacy criteria for continuing the study to enroll additional patients was two of ten patients achieving a progression free survival of 4 months or a partial or complete tumor response. These criteria have been met and the study is enrolling an additional 10 patients in this second stage. RX-3117 was very well tolerated. The most common side effects were mild nausea, vomiting diarrhea and fatigue and only two subjects had thrombocytopenia. There were no dose-limiting toxicities.

The ongoing Phase IIa clinical trial is a multicenter, open-label single-agent study of RX-3117 being conducted at 6 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.

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.

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.

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 will be administered orally five times weekly on a three weeks on, one week off dosing schedule. The study will follow 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 American Society for Clinical Oncology (ASCO) meeting Rexahn presented the initial data from this trial. 20% of the patients treated with RX-3117 exhibited progression free survival of greater than 6 months. Two patients also had a reduction 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.

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 will receive 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 $\geq$ 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.

Rexahn has received U.S. Food and Drug Administration (FDA) Orphan Drug Designation for RX-3117 for pancreatic cancer.

About Rexahn Pharmaceuticals, Inc.

Rexahn Pharmaceuticals Inc. (NYSE MKT: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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