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Rexahn Pharmaceuticals Presents Preliminary Efficacy Data from the Ongoing Phase IIa Clinical Trial of RX-3117 in Metastatic Bladder Cancer at the American Society of Clinical Oncology (ASCO) 2017 Annual Meeting

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

Stage 2 of the Study has Begun, Based on Positive Preliminary Efficacy Results from Stage 1

ROCKVILLE, Md., June 04, 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 interim update on the safety and efficacy of RX-3117 in an ongoing Phase IIa clinical trial in metastatic bladder cancer at the American Society for Clinical Oncology (ASCO) 2017 Annual Meeting.

“The study achieved our predefined criteria for efficacy in metastatic bladder cancer,” said Ely Benaim, M.D., Chief Medical Officer, Rexahn. “Twenty percent of patients showed progression free survival of greater than 6 months and there was tumor reduction in some patients. This is not expected in patients with metastatic bladder cancer who have already failed 3 or more prior cancer therapies and have developed resistance to most anticancer agents including gemcitabine. Current options for these patients are usually limited to palliative or best supportive care. So we are very pleased with the outcome in this first stage of the study and we will continue to enroll additional patients into the second stage of this Phase IIa study.”

“Patients with metastatic bladder cancer, who have already developed resistance to gemcitabine and other anticancer treatments, are very difficult to treat,” said Dr. Sumanta Pal, Associate Professor at City of Hope Comprehensive Cancer Center, Duarte, California. “It was very unexpected to see prolonged stable disease in patients in this study who had failed multiple prior treatments that included gemcitabine/cisplatin and immunotherapy, so these preliminary data are very encouraging. RX-3117 also appears to be remarkably safe and well-tolerated with no dose limiting side-effects.”

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 4, 2017 in a poster presentation entitled *Activity of RX-3117, an oral antimetabolite nucleoside, in subjects with metastatic bladder cancer resistant to gemcitabine: Preliminary results of a phase Ib/IIa study* authored by Drs. 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. S 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 reported data on the first ten patients enrolled into stage 1 of a two stage Phase IIa study in metastatic bladder cancer. Patients enrolled into stage 1 of the clinical trial had actively progressing bladder cancer with distant metastases to multiple sites including the liver, lung, lymph nodes and pelvis. Seven of the ten patients had three or more prior treatments for metastatic cancer and nine had failed on gemcitabine given in combination with cisplatin or carboplatin. These patients would usually be offered palliative or supportive care and expected progression-free survival is two to three months. Currently, 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, two of ten patients treated with RX-3117 exhibited progression free survival of greater than 6 months and one of these patients is continuing in the study with stable disease at 175 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 at least 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. To date a total of 12 patients have been enrolled. Fifty-percent (50%), or six, of the patients have stable disease for greater than 56 days and three of the twelve remain in the study with prolonged stable disease, with all patients remaining in the study having stable disease for at least 56 days. RX-3117 appears to be 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.

A copy of the ASCO poster can be viewed on the company's website at <https://rexahn.com/cms/media-center/publication/posters/>

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. Preclinical studies have shown that RX-3117 has a broad spectrum anti-tumor activity against over 100 different human cancer cell lines and efficacy in 17 different mouse xenograft models including

pancreatic, bladder, lung, cervical and colon cancers, as well as gemcitabine resistant cancer cells. Importantly, RX-3117 still retains its full anti-tumor activity in human cancer cell lines made resistant to the anti-tumor effects of gemcitabine. Rexahn is developing RX-3117 for metastatic pancreatic cancer and for advanced or metastatic bladder cancer.

Rexahn has previously reported the completion of a Phase Ib clinical trial of RX-3117 at the American Society of Clinical Oncology Annual Meeting 2016 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.

Based on these data, Rexahn initiated a two-stage Phase IIa clinical trial of RX-3117 in patients with relapsed or refractory pancreatic cancer to further evaluate the safety and anti-cancer properties of this compound. Preliminary data were presented at the European Society of Medical Oncology Congress in October 2016. This Phase IIa clinical trial is a multi-center study that will evaluate the safety and efficacy of RX-3117 in this target patient population. Patients in this 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 ≥ 4 months) which triggered the enrollment of an additional 40 pancreatic cancer patients (stage 2).

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 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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