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Rexahn Pharmaceuticals Presents Final Data from the Supinoxin™ Phase I Clinical study and New Preclinical Data on RX-3117 at the 2017 European Society for Medical Oncology (ESMO) Congress

Supinoxin™ is well tolerated and shows preliminary evidence of clinical activity in difficult to treat tumors

Preclinical studies on RX-3117 demonstrate additive and synergistic effects with Abraxane® and immunotherapy

ROCKVILLE, Md., Sept. 11, 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 that final data on the Supinoxin™ Phase I clinical study in solid tumors were presented at the 2017 European Society for Medical Oncology (ESMO) Congress. Rexahn also presented data from preclinical studies evaluating RX-3117 in combination with Abraxane® and immunotherapy.

"Orally administered Supinoxin™ was well tolerated in Phase I clinical testing," commented Ely Benaim, M.D. Chief Medical Officer of Rexahn. "Despite the fact that a majority of the cancer patients enrolled in the study had received 4 or more prior cancer therapies, there were preliminary indications of single agent activity against several hard to treat cancers including triple negative breast cancer and neuroendocrine cancer."

"In preclinical studies, the combination of RX-3117 and Abraxane® was very effective at inhibiting tumor growth in a patient-derived pancreatic xenograft model in the absence of dose-limiting adverse events. These data provide the scientific basis for a Phase IIa trial looking at the combination of RX-3117 and Abraxane®, which has recently begun enrolling patients," commented Peter D. Suzdak, Ph.D., CEO of Rexahn. "In addition, the synergistic efficacy between RX-3117 and anti-PD-1 immuno-oncology agents opens the possibility for combination trials in a number of different types of cancers."

Supinoxin™ Phase I clinical data

Clinical data from the completed Phase I clinical trial with Supinoxin are being presented on Monday September 11, 2017 in a poster presentation entitled *Phase 1 study of RX-5902, a novel Orally Bioavailable Inhibitor of Phosphorylated P68, which prevents β -catenin Translocation in Advanced Solid Tumors* authored by Drs. J Diamond and SG Eckhardt (University of Colorado Cancer Center), WL Gluck (Translational Oncology Research, Greenville, SC), M Gutierrez (John Theurer Cancer Center, Hackensack University Medical Center, NJ) and Rexahn Pharmaceuticals.

The completed results from the Phase I clinical trial with Supinoxin™ showed evidence of single-agent, clinical activity with Supinoxin in patients with solid tumors who had failed multiple prior therapies. Supinoxin was safe and well tolerated at the selected Phase IIa dose, which was identified as 250mg once daily for five days on, two days off for three consecutive weeks in a four week cycle. The most frequently reported drug related adverse events were mild nausea, vomiting and fatigue. Initial signs of clinical activity have been observed in patients with breast (including triple negative), neuroendocrine, paraganglioma, head and neck and colorectal cancers, demonstrating stable disease for up to 1,170 days. Of these patients, approximately 64% had received four or more therapies prior to their enrollment in the Phase I clinical study.

RX-3117 Preclinical Data

Preclinical studies on the use of RX-3117 in combination with Abraxane® (nab-paclitaxel) and with immunotherapy (checkpoint inhibitor) are being presented on Monday, September 11, 2017 in a poster presentation entitled *A Novel Small Molecule Nucleoside Analog, RX-3117, Shows Potent Therapeutic Activity in Combination with Nab-paclitaxel and Checkpoint Inhibitors in Xenograft Models* authored by Drs. J Frank, D.J. Kim, E Benaim, Rexahn Pharmaceuticals. The poster reported on three preclinical studies; two studies evaluating RX-3117 in combination with a checkpoint inhibitor (immunotherapy) in animal models of colon and pancreatic cancer and a third study evaluating RX-3117 in combination with Abraxane® (nab-paclitaxel) in a pancreatic cancer model. RX-3117 was shown to be effective in pancreatic cancer models and had an additive effect with Abraxane®, providing preclinical support for the planned Phase II clinical study of RX-3117 in combination with Abraxane® in patients newly diagnosed with metastatic pancreatic cancer. RX-3117 was also shown to have additive or synergistic effects with a checkpoint inhibitor that may support a future clinical trial with RX-3117 in combination with immunotherapy in various cancers.

About Supinixin™

Supinixin™ (RX-5902) is an orally administered, potential first-in-class, small molecule inhibitor of phosphorylated-p68 (P-p68). P-p68, which is selectively overexpressed in cancer cells and is absent in normal tissue, modulates the activity of the β -catenin/wnt pathway and plays a role in tumor progression and metastasis. In preclinical studies, Supinixin has been shown to inhibit the growth and proliferation of multiple human cancer cell lines (including triple negative breast cancer) and decrease tumor growth in patient derived xenograft models.

Supinixin has completed a Phase I dose-escalation clinical trial in cancer patients was shown to be safe and well tolerated at the selected Phase IIa dose (250mg once daily for five days on, two days off for four consecutive weeks in a four week cycle). The most frequently reported drug related adverse events were mild nausea, vomiting and fatigue. Initial signs of clinical activity have been observed in patients with breast (including triple negative), neuroendocrine, paraganglioma, head and neck and colorectal cancers, demonstrating stable disease for up to 1,170 days. Of these patients, approximately 64% had received four or more therapies prior to their enrollment in the Phase I clinical study. In February 2017, Rexahn initiated a Phase IIa clinical proof-of-concept study to evaluate the safety and efficacy of Supinixin™ monotherapy in patients with metastatic triple negative breast cancer who have failed multiple prior chemotherapeutic regimens.

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 is developing RX-3117 for metastatic pancreatic cancer and for advanced or metastatic bladder cancer.

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 ≥ 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, 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. The Company has a broad oncology pipeline that includes three anti-cancer compounds currently in Phase II 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 clinical development; the timing of completion of clinical trials; 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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