June 6, 2016

Rexahn Pharmaceuticals Presents Clinical Data for Three Novel Targeted Oncology Programs at the 2016 American Society of Clinical Oncology Annual Meeting

Data Show RX-3117, Archexin® and Supinoxin™ Appear to be Safe and Well Tolerated in Cancer Patients with Advanced and Metastatic Solid Tumors and Show Early Evidence of Clinical Activity

ROCKVILLE, Md., June 06, 2016 (GLOBE NEWSWIRE) -- Rexahn Pharmaceuticals, Inc. (NYSE MKT:RNN), a clinical stage biopharmaceutical company developing next generation therapeutics for the treatment of cancer, announced today that Phase I and/or Phase II clinical data from each of its novel oncology programs were presented at the 2016 American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago, Illinois, June 3-7, 2016.

“The accumulating clinical data for RX-3117, Supinoxin™, and Archexin®, which were presented at ASCO, highlight the unique mechanism of action of these investigational compounds and continue to support their safety, tolerability and potential clinical activity in the treatment of solid tumors,” said Peter D. Suzdak, Ph.D., Chief Executive Officer.

“The latest clinical data from our three studies is consistent with the preliminary findings announced last fall, showing single agent activity of both RX-3117 and Supinoxin, and clinical activity of Archexin in combination with everolimus, as demonstrated by both tumor reduction and stable disease. Based on these findings, we recently commenced a Phase Ib/IIa proof-of-concept clinical trial of RX-3117 in advanced pancreatic and muscle-invasive bladder cancer, and have advanced Archexin into Stage 2 of an ongoing Phase II study in metastatic renal cell carcinoma (RCC). In addition, we anticipate commencing a Phase Ib/IIa proof-of-concept clinical trial of Supinoxin in triple negative breast cancer and advanced ovarian cancer shortly,” said Dr. Suzdak.

RX-3117 Phase Ib Clinical Data

The final results from a Phase Ib clinical trial of RX-3117 were presented on Sunday, June 5, 2016 in a poster presentation entitled *“Phase I Data of Single Agent RX-3117, an Oral Antimetabolite Nucleoside,”* authored by Drs. Drew W. Rasco, Jaime R. Merchan, and Rexahn collaborators.

The final data show promising evidence of the potential clinical activity of RX-3117. In the Phase Ib study, 12 patients had stable disease persisting for up to 276 days. Patients participating in the Phase Ib program had advanced metastatic disease and were heavily pre-treated. Notably, approximately 44% of patients had received four or more therapies

prior to their enrollment in the clinical trial.

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. The most frequently reported treatment emergent adverse events were moderate to severe anemia, mild to moderate fatigue and nausea, mild diarrhea, vomiting, and anorexia.

Supinoxin™ (RX-5902) Phase I Clinical Data

Updated clinical data from an ongoing Phase I study of Supinoxin™ (RX-5902) were presented on Sunday, June 5, 2016 in a poster presentation entitled "*Results of a Phase I Study of RX-5902, an Orally Bioavailable Inhibitor of Phosphorylated p68, Targeted Solid Tumors,"* authored by Drs. S. Gail Eckhardt, W. Larry Gluck, Martin Gutierrez, and Rexahn collaborators.

The updated results from the ongoing Phase I clinical trial continue to show intriguing evidence of single-agent, clinical activity of Supinoxin. In this study, stable disease was observed in five patients, persisting up to 732 days. As of May 25, 2016, three patients have had stable disease for more than a year, or 504 days, 514 days, and 746 days, respectively, and each of these patients continues to remain on active treatment in the study. Notably, approximately 56% of the patients in the study had received four or more therapies prior to their enrollment in the Phase I clinical study.

At the dose levels tested to date, Supinoxin, administered orally, appeared to be safe and well tolerated with no dose limiting toxicities or treatment-related serious adverse events. The most frequently reported drug related adverse events were mild nausea, vomiting and fatigue. Pharmacokinetic analyses of the current data show a predictable pharmacokinetic profile for an orally-administered route of therapy.

Archexin® Phase Ib/II Clinical Data

Phase Ib/II clinical trial results for Archexin were presented on Sunday, June 5, 2016, in a poster presentation entitled, "*Results from a Phase Ib/II Study of RX-0201 (Archexin®), A Novel Akt-1 Antisense Combined with Everolimus to Treat Metastatic Clear Cell Renal Carcinoma."*

The results from Stage 1 of the Phase Ib/II study presented at ASCO showed that in metastatic RCC patients that have previously received multiple anti-cancer therapies, Archexin treatment produced both stable disease, which persisted for up to 383 days or a median of 165.5 days, and a reduction in tumor burden.

Compared to baseline CT scans, three patients experienced reductions in the size of their tumors of up to 36%. At the lowest dose level of Archexin administered (125 mg/m^2/day), one patient had stable disease for over one year and a 16% tumor reduction after four cycles of treatment. At the second dose level (200 mg/m^2/day), one patient experienced a 36% tumor reduction after two cycles of treatment. At the highest dose level (250 mg/m^2/day), which has been determined to be the maximum tolerated dose, one patient had a 17% overall reduction in lesions (RECIST v 1.1) with a range of 6% to 37.5% following two cycles

of treatment.

Archexin, administered in combination with everolimus, appeared to be safe and well tolerated at each of the dose levels tested with no dose limiting adverse events. The most commonly reported adverse event in patients taking the combination of Archexin and everolimus was thrombocytopenia.

“We continue to be very encouraged by the clinical data emerging from each of the ongoing studies of RX-3117, Supinoxin and Archexin,” said Ely Benaim, M.D., Chief Medical Officer for Rexahn. “These data suggest that our compounds appear to be safe and well tolerated and offer an early efficacy signal suggesting their potential utility in the treatment of solid tumors. We are especially encouraged given that these patients have very advanced disease, and have stopped responding to other therapies, yet we are seeing evidence of stable disease – in certain cases persisting for over a year – in these early clinical trials.”

“Given the ability to specifically target cancer cells and spare normal, healthy cells, each of these programs, if successful, has the potential to meaningfully change the oncology treatment paradigm and improve the quality of life of cancer patients. Together with the support and encouragement of our clinical investigators, we are moving RX-3117, Supinoxin and Archexin into advanced clinical development to more fully understand their clinical activity. We look forward to the results of these studies,” said Dr. Benaim.

About RX-3117

RX-3117 is a novel, investigational 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 inhibits the growth of various human cancer xenograft models, including pancreatic, bladder, lung, cervical and colon cancers, as well as gemcitabine resistant cancer cells.

RX-3117 has shown broad spectrum anti-tumor activity against over 100 different human cancer cell lines and efficacy in 17 different mouse xenograft models. Notably, the efficacy of RX-3117 in the mouse xenograft models was superior to that of gemcitabine. Importantly, RX-3117 still retains its full anti-tumor activity in human cancer cell lines made resistant to the anti-tumor effects of gemcitabine. In August 2012, Rexahn reported the completion of an exploratory Phase I clinical trial of RX-3117 in cancer patients conducted in Europe, to investigate the oral bioavailability, safety and tolerability of the compound. In this study, oral administration of a 50 mg dose of RX-3117 showed an oral bioavailability of 56% and a plasma half-life ($T_{1/2}$) of 14 hours. In addition, RX-3117 appeared to be safe and well tolerated in all subjects throughout the dose range tested.

RX-3117 is currently being evaluated in a Phase Ib/IIa clinical trial in cancer patients with relapsed or refractory pancreatic cancer or advanced bladder cancer. The Phase Ib/IIa clinical trial is a multi-center study that will evaluate the safety and efficacy of RX-3117 in these target patient populations. Secondary endpoints include safety and pharmacokinetic analyses. Patient enrollment has been initiated. Patients in the trial will be receiving a daily oral dose of RX-3117 of 700 mg, five times weekly for three weeks in a 28 day cycle for up to eight treatment cycles, or until their disease progresses. Rexahn has received U.S. Food

and Drug Administration (FDA) Orphan Drug Designation for RX-3117 for pancreatic cancer.

About Supinoxin™ (RX-5902)

Supinoxin™ (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, increases the activity of multiple cancer related genes including cyclin D1, c-jun and c-myc, and plays a role in tumor progression and metastasis. Overexpression of phosphorylated-p68 has been observed in solid tumors, such as melanoma, colon, breast, ovarian and lung tumors. In preclinical studies, Supinoxin has been shown to inhibit proliferation of cells in over 100 different human cancer cell lines, including breast, colon, pancreas, ovarian, and stomach cancers, and showed potent activity in drug-resistant cancer cells. In preclinical animal models, where human cancer cells from breast, ovarian, melanoma, pancreas, or renal tumors were grafted into animals, treatment with Supinoxin resulted in a significant reduction in tumor growth.

Supinoxin is currently being evaluated in a Phase I dose-escalation clinical trial in cancer patients with solid tumors designed to evaluate the safety, tolerability, dose-limiting toxicities and maximum tolerated dose (MTD). Secondary endpoints include pharmacokinetic analysis and an evaluation of the preliminary anti-tumor effects of Supinoxin. This trial is being conducted at three clinical oncology centers in the United States. Each patient has the ability to continue on the drug for up to six cycles of treatment (a dosing cycle is defined as three weeks of drug treatment followed by one week off) if no disease progression is seen. Patients are assessed by CT or MRI prior to the start of therapy and after every two cycles of therapy to assess tumor progression.

About Archexin®

Archexin is a unique antisense drug candidate that specifically inhibits the cancer cell signaling protein Akt-1. Archexin is the only specific inhibitor of Akt-1 in clinical development. The activated form of Akt-1, which is involved in cancer cell growth, survival, angiogenesis, and drug resistance, has been shown to be present or elevated in more than 12 different human cancer cell lines, including pancreatic and renal cell carcinoma. By inhibiting Akt-1, Archexin has been shown to both inhibit the growth of RCC cell lines and exhibit a longer survival benefit in the human RCC animal xenograft model. Thus, while Akt-1 is a very specific anti-cancer target, it may have broad therapeutic potential across multiple types of cancer.

Archexin has completed a Phase I clinical trial in cancer patients with solid tumors and was shown to be safe and well tolerated. The dose-limiting toxicity was Grade 3 fatigue. In a small Phase IIa trial in advanced pancreatic cancer patients, Archexin in combination with gemcitabine was shown to be safe and well tolerated and showed a preliminary efficacy signal with a median survival of 9.1 months in evaluable patients.

Metastatic RCC represents an attractive market opportunity with an estimated annual incidence of 90,000 patients worldwide. Metastatic RCC patients receiving standard of care treatment have a poor prognosis with an overall survival of less than two years. Rexahn has received FDA Orphan Drug Designation for Archexin for metastatic RCC as well as four other cancers.

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. 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, anticipated market sizes 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, the difficulty of developing pharmaceutical products, obtaining regulatory and other approvals and achieving market acceptance; that results of preclinical studies and early clinical trials may not be predictive of the results of later-stage clinical trials; the success and design of clinical testing; and Rexahn's need for and ability to obtain additional financing. 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:
Stacey Jurchison
Rexahn Investor Relations
240-268-5300 x 324
Jurchisons@rexahn.com

Source: Rexahn Pharmaceuticals