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Rexahn Phase 2a Combination Study of RX-3117 and Abraxane® in First-line Metastatic Pancreatic Cancer Patients Advances to Second Stage

Routine Safety Monitoring Committee Review Confirmed No Dose Reductions Necessary

ROCKVILLE, Md., May 15, 2018 (GLOBE NEWSWIRE) -- Rexahn Pharmaceuticals, Inc. (NYSE American:RNN), a clinical-stage biopharmaceutical company developing innovative, targeted therapeutics for the treatment of cancer, advances its ongoing Phase 2a study of RX-3117 in combination with Abraxane® in first-line patients with metastatic pancreatic cancer following a recently completed routine Safety Monitoring Committee (SMC) review.

The SMC has confirmed that the combination of RX-3117 and Abraxane is safe and well tolerated and that the two drugs can be given in combination at the highest recommended doses for both agents which is once-daily oral administration of 700 mg RX-3117 five times per week plus once-weekly Abraxane® at 125 mg/m^2 IV given on a three weeks on/one week off per four-week cycle schedule.

"This SMC recommendation allows us to enter the second stage of the trial and continue to treat patients with the maximum tolerated doses of both RX-3117 and Abraxane, which we believe may lead to better clinical outcomes," said Ely Benaim, M.D., chief medical officer of Rexahn. "Current standard of care for metastatic pancreatic cancer utilizes gemcitabine and Abraxane in combination; however, not all patients can tolerate this regimen because of unacceptable toxicities. Poor tolerability often results in dose reductions of both agents and a shortening of treatment durations. RX-3117 selectively targets cancer cells providing a potential advantage over gemcitabine."

The Phase 2a is a two-stage, open label clinical proof-of-concept study designed to evaluate the safety and efficacy of RX-3117 in combination with Abraxane in patients with metastatic pancreatic cancer who have had no prior chemotherapies for metastatic disease. The first stage was designed to determine the optimum doses of RX-3117 and Abraxane to be evaluated in the second stage. Up to 40 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 death of tumor cells. Due to the high level of over expression of UCK2 in cancer cells, RX-3117 offers the potential for a targeted anti-cancer therapy with an improved efficacy and safety profile. RX-3117 is currently being studied in a Phase 2a clinical trial in combination with Abraxane® (nab-paclitaxel) in first line metastatic pancreatic cancer patients and a Phase 2a clinical trial in patients with advanced or metastatic bladder cancer. It has received Orphan Drug designation for the treatment of pancreatic cancer. Additional information on RX-3117 can be found at: https://rexahn.com/cms/portfolio/rx-3117/.

Abraxane is a registered trademark of Abraxis Bioscience, LLC, a wholly owned subsidiary of Celgene Corporation.

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. Preclinical studies show that certain of Rexahn's product candidates may be effective against multiple types of cancer, including drug resistant cancers, and difficult-to-treat cancers, and others may augment the effectiveness of current FDA-approved cancer treatments. The company has two oncology product candidates, RX-3117 and RX-5902, in Phase 2 clinical development and additional compounds in preclinical development including RX-0201. 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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