January 22, 2019

Rexahn Presents Updated Preliminary Data on RX-3117 in Pancreatic Cancer at the 2019 ASCO GI Symposium

Overall Response Rate of 38% Observed in the First 24 Patients Who Had At Least One Scan on Treatment

ROCKVILLE, Md., Jan. 22, 2019 (GLOBE NEWSWIRE) -- Rexahn Pharmaceuticals, Inc. (NYSE American: RNN), a clinical-stage biopharmaceutical company developing innovative therapies to improve patient outcomes in cancers that are difficult to treat, presented updated, preliminary data from the ongoing Phase 2a clinical trial of RX-3117 in combination with ABRAXANE® (paclitaxel protein-bound particles for injectable suspension) in first-line metastatic pancreatic cancer patients at the 2019 ASCO Gastrointestinal Cancers (ASCO GI) Symposium on January 18, 2019.

The multicenter, single-arm, open-label study is designed to evaluate RX-3117 in combination with ABRAXANE in first-line metastatic pancreatic cancer patients. The Phase 2a trial is expected to enroll 40 evaluable patients. As of January 9, 2019, 36 patients were enrolled into the study, and 24 patients had at least one scan on treatment and were included in the evaluation of overall response. One patient (1/24, 4.2%) had a complete response (CR) after 6 cycles of treatment and eight patients (8/24, 33.3%) had a partial response (PR). A further 13 patients had stable disease (13/24, 54.2%). The overall response rate (ORR) was 38%, and the disease stabilization rate at eight weeks was 92%. The combination of RX-3117 and ABRAXANE appears to be safe and well-tolerated. The most common related adverse events were nausea, diarrhea, fatigue, alopecia, decreased appetite, rash, vomiting, and anemia.

While no head-to-head studies have been conducted between RX-3117 and gemcitabine in metastatic pancreatic cancer, for background purposes, the registration trial for the combination of gemcitabine and ABRAXANE demonstrated an ORR of 23%.

“We continue to be encouraged by the preliminary data from this study,” said Ely Benaim, M.D., chief medical officer of Rexahn. “Because most patients are still being treated in the study, it is too early to estimate progression free survival, but we expect to complete enrollment and report additional efficacy data later this year.”

A copy of the poster is available on the Company’s website at https://www.rexahn.com/news-media/posters.

About RX-3117

RX-3117 is a novel, investigational, oral, small molecule nucleoside compound. As observed

in preclinical studies, once intracellularly activated (phosphorylated) by uridine cytidine kinase 2 (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 overexpression 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® (paclitaxel protein-bound particles for injectable suspension) 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 Celgene Corporation.

About Rexahn Pharmaceuticals, Inc.

Rexahn Pharmaceuticals Inc. (NYSE American: RNN) is a clinical stage biopharmaceutical company developing innovative therapies to improve patient outcomes in cancers that are difficult to treat. 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 several 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-0301. 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 the timing, progress, results and other matters regarding our ongoing clinical trial of RX-3117 in combination with ABRAXANE®; expectations regarding the potential effectiveness and safety of Rexahn's product candidates, including RX-3117 in combination with Abraxane; future operations; 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 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 press 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.

Media Contact:
DGI Comm
Susan Forman or Laura Radocaj
+1-212-825-3210
sforman@dgicomm.com
lradocaj@dgicomm.com

Investor Contact:
ir@rexahn.com

rexahn
PHARMACEUTICALS

Source: Rexahn Pharmaceuticals