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Rexahn Pharmaceuticals Presents Preliminary Safety and Efficacy Data from Ongoing Phase 2a Clinical Trial of RX-3117 in Combination with Abraxane® in Patients Newly Diagnosed with Metastatic Pancreatic Cancer

Combination of RX-3117 and Abraxane Appears Safe and Well-Tolerated When Administered at the Recommended Phase 2 Dose of RX-3117 and the Maximal Labeled Dose of Abraxane

Preliminary Efficacy was Observed With One Complete Response, Three Partial Responses and Eight Patients With Stable Disease in the First 14 Evaluable Patients

ROCKVILLE, Md., Oct. 02, 2018 (GLOBE NEWSWIRE) -- Rexahn Pharmaceuticals, Inc. (NYSE American: RNN), a clinical stage biopharmaceutical company developing innovative, targeted therapeutics for the treatment of cancer, today announced preliminary safety and efficacy data from the ongoing Phase 2a clinical trial of RX-3117 in combination with Abraxane® (nab-paclitaxel) in patients newly diagnosed with metastatic pancreatic cancer. The data are being presented in a poster presentation titled “RX-3117, A Novel, Oral Nucleoside Analog, in Combination with Nab-Paclitaxel (nab-pac) in First-line Metastatic Pancreatic Cancer (met-PC): Safety, Tolerability and Preliminary Responses” at the 5th NCI Pancreatic Cancer Symposium held October 2-3, 2018 at the National Institutes of Health in Bethesda, Maryland.

Highlights from the poster reflecting data as of September 19, 2018:

- Combined administration of RX-3117 and Abraxane in newly diagnosed pancreatic cancer patients appeared to be safe and well-tolerated
  - The most common (≥20%) adverse events were diarrhea, nausea, fatigue, alopecia, anorexia and rash
  - There were no dose-limiting toxicities
- Combined administration of RX-3117 and Abraxane showed preliminary signs of efficacy in newly diagnosed metastatic pancreatic cancer patients. Of the 14 subjects that had at least one on-study scan (after 2 cycles of therapy):
  - One patient experienced a complete response (CR) after 6 cycles of therapy
  - Three patients exhibited a partial response (PR): two after 2 cycles (39-47% tumor reductions) and one after 4 cycles of therapy (36% tumor reduction)
  - An additional eight patients experienced stable disease (SD) for at least 2 cycles

with tumor marker (CA19-9) reductions ranging between 43-69%
- The disease control rate (CR+PR+SD) for evaluable patients was 86%
- Overall response rate (CR+PR) was 29%

“These preliminary data are encouraging, showing that the combined administration of RX-3117 and Abraxane in newly diagnosed metastatic pancreatic cancer patients appears to be safe and well tolerated and showing evidence of clinical activity,” said Dr. Ely Benaim, M.D., chief medical officer of Rexahn. “As of September 19, 2018, there was one complete response and three partial responses from the first 14 evaluable patients. In addition, there were eight patients with stable disease who had tumor reductions of up to 16% and who are still being actively dosed. We are encouraged by this preliminary data reflecting a disease control rate of 86% and an overall response rate of 29%. We look forward to completing the study enrollment and plan to report the final data in 2019.”

“The safety profile of RX-3117 continues to be encouraging as it can be administered at its recommended Phase 2 dose together with the maximal labeled dose of Abraxane without producing an increase in severe adverse events,” said Peter D. Suzdak, Ph.D., chief executive officer of Rexahn. “This differs from current standard of care where the doses of both gemcitabine and Abraxane, when given in combination, may have to be reduced to avoid grade 3 and 4 dose limiting toxicities.”

The current trial, which is a multicenter, open-label, 2 stage Phase 1b/2a study, is designed to assess the safety, tolerability and efficacy of the combined administration of the maximal labeled dose of Abraxane and the full Phase 2 dose of RX-3117 in newly diagnosed metastatic pancreatic cancer patients. Phase 1 was a dose-finding, open-label study of oral RX-3117 administered in combination with nab-pac to subjects with newly diagnosed met-PC. RX-3117 was administered at a dose of 700 mg orally once-daily for 5 consecutive days with 2 days off per week and Abraxane (nab-pac) was administered at a dose of 125 mg/m^2 once weekly for 3 weeks with 1 week off per 4-week cycle. In stage 1 of the trial, the combination of RX-3117 and nab-pac appeared to be safe and well-tolerated and not associated with dose-limiting toxicities following one cycle of treatment. In stage 2, a total of 40 subjects will be recruited into the study for up to 8 cycles of combined therapy. Currently there are 14 patients that had at least one on-study scan (after 2 cycles of therapy) 11 of who are still receiving treatment in the study. The complete data from these, and all patients, are expected to be available in the first half of 2019.

A copy of the poster is available 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 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 the ongoing Phase 2a clinical trial of RX-3117 in combination with Abraxane®, future operations and products, 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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