

# Rexahn Pharmaceuticals Announces Presentations at the American Society of Clinical Oncology (ASCO) 2018 Annual Meeting

Phase 2a Trial of RX-5902 Advances to Stage 2 Based on Encouraging Progression Free Survival and Evidence of Tumor Shrinkage Observed in Heavily Pre-treated Metastatic Triple Negative Breast Cancer Patients

Phase 2a Trial of RX-3117 Demonstrates Encouraging Efficacy, Including a Complete Response, in Patients with Advanced Bladder Cancer Who Had Failed on Multiple Prior Treatments Including Immunotherapy and Gemcitabine

ROCKVILLE, Md., June 04, 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 that preliminary data from a Phase 2a clinical trial of RX-5902 in metastatic triple negative breast cancer (TNBC) and updated data from the Phase 2a trial of RX-3117 in advanced bladder cancer were presented at the American Society of Clinical Oncology (ASCO) 2018 annual meeting on June 2, 2018.

"We are encouraged by the data presented at ASCO including a complete response in advanced bladder cancer in a patient being treated with RX-3117. Emerging clinical data continue to suggest that Rexahn's pipeline of novel targeted cancer therapeutics are safe and well tolerated and have significant potential in hard-to-treat cancers," said Peter D. Suzdak, Ph.D., chief executive officer of Rexahn. "We look forward to presenting additional interim data from our programs later this year including from the ongoing Phase 2a trial of RX-3117 in combination with Abraxane® in newly diagnosed metastatic pancreatic cancer patients."

# **RX-5902** in Triple Negative Breast Cancer

An interim analysis of the first 10 evaluable patients in a Phase 2a trial of RX-5902 in TNBC showed five patients exhibited a clinical response including one patient who had an 18% reduction in tumor size and two patients experiencing progression free survival (PFS) greater than 200 days. The patients detailed were heavily pre-treated and had at least two prior treatments for refractory TNBC (range 2-9). RX-5902 was safe and well tolerated in this study and the study met the predefined criteria for advancement to the second stage. Enrollment of additional patients is ongoing.

"Metastatic TNBC is a notoriously difficult-to-treat cancer and there are currently no FDA-approved drug therapies designed specifically for this indication," said Ely Benaim, M.D.,

chief medical officer of Rexahn. "It is very encouraging to see some good clinical responses in patients who have progressed after multiple prior therapies and we look forward to providing further updates later this year."

### **RX-3117 in Advanced Bladder Cancer**

Updated interim data from a Phase 2a clinical trial of RX-3117 monotherapy for the treatment of advanced bladder cancer showed that, of the 24 evaluable patients enrolled into the study, one patient had a complete response (100% tumor reduction) and an additional four patients had tumor reductions of greater than 15%. In addition, six patients (25%) showed disease stabilization for greater than four months (range 133-315 days). Ninety percent (90%) of the patients had received two or more prior therapies including gemcitabine (83% of patients) and immunotherapy (69% of patients). RX-3117 was also safe and well tolerated in these patients.

"Patients with advanced bladder cancer who have already developed resistance to gemcitabine and whose cancer has progressed on immunotherapy are very difficult to treat," said Dr. Sumati Gupta, a medical oncologist at Huntsman Cancer Institute at the University of Utah in Salt Lake City, UT. "It is very promising to see evidence of tumor reduction in some patients including a complete response in one patient whose tumor had progressed after chemotherapy and immunotherapy. RX-3117 also appears to be safe and well tolerated with no dose-limiting side effects under the parameters of this study."

Copies of the ASCO posters can be viewed on the company's website at <a href="https://rexahn.com/cms/media-center/publication/posters/">https://rexahn.com/cms/media-center/publication/posters/</a>

### About RX-5902

RX-5902 (Supinoxin) 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  $\beta$ -catenin/Wnt pathway and plays a role in tumor progression, metastasis and tumor immunogenicity.

In preclinical studies, RX-5902 has been shown to inhibit the growth and proliferation of multiple human cancer cell lines (including triple negative breast cancer), decrease tumor growth in patient derived xenograft models and potentiate the activity immune checkpoint inhibitors and other anti-tumor agents. Additional information on RX-5902 can be found at: <a href="https://rexahn.com/cms/portfolio/rx-5902/">https://rexahn.com/cms/portfolio/rx-5902/</a>.

### 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: <a href="https://rexahn.com/cms/portfolio/rx-3117/">https://rexahn.com/cms/portfolio/rx-3117/</a>.

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 <a href="https://www.rexahn.com">www.rexahn.com</a>.

### 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. Forwardlooking 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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