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Rexahn Pharmaceuticals Doses First Patient in a Phase IIa Trial of Supinoxin™ in Patients with Metastatic Triple Negative Breast Cancer

ROCKVILLE, Md., Feb. 23, 2017 (GLOBE NEWSWIRE) -- Rexahn Pharmaceuticals, Inc. (NYSE MKT:RNN), today announced that is has begun enrolling patients into a Phase IIa clinical study of Supinoxin™ in metastatic triple negative breast cancer (TNBC). The study will evaluate the safety and efficacy of Supinoxin™ in patients with metastatic TNBC who have failed prior treatments.

"The dosing of the first patient in the Phase IIa clinical trial with Supinoxin™ is a major milestone for the program," said Peter D. Suzdak, Ph.D., Chief Executive Officer of Rexahn. "Our decision to focus initially on triple negative breast cancer underscores our commitment to developing our targeted treatments for cancers that are difficult to treat and for which there are limited treatment options. There is currently no approved drug treatment for TNBC, and no established standard of care, so there is a tremendous unmet medical need."

"Supinoxin™ has a unique mechanism of action," said Ely Benaim, M.D., Chief Medical Officer. "It targets a key biological pathway implicated in cancer cell proliferation. We have seen very promising activity in our preclinical models of triple negative breast cancer so we look forward to the preliminary readout from this first clinical study, which we anticipate later this year."

"This is the first Phase IIa study with Supinoxin™ and our initial proof of concept study in triple negative breast cancer," continued Dr. Benaim. "We plan also to evaluate Supinoxin™ in combination with other cancer treatments in triple negative breast cancer and in other solid tumors."

The Phase IIa clinical proof-of-concept study is an open-label evaluation of the safety and efficacy of Supinoxin™ monotherapy in patients with metastatic triple negative breast cancer who have failed multiple prior chemotherapeutic regimens. The study will recruit an initial 10 patients and can be extended up to 50 patients, if warranted, based on the data readout from the initial cohort of patients. The primary endpoint is progression free survival. Patients will be enrolled at seven study sites in the United States. Based on the initial clinical data, we may conduct additional clinical studies looking at the combination of Supinoxin together with other anti-cancer agents in TNBC.

Supinoxin™ (RX-5902) is an orally administered, potential first-in-class, small molecule modulator of the β-catenin pathway — a key biological pathway that is activated in tumor cells leading to production of multiple cancer oncogenes and tumor proliferation and metastasis. Supinoxin™ modulates the pathway through inhibition of the interaction of phosphorylated p68 (a regulatory protein) with β-catenin.

Supinoxin™ has been shown to significantly inhibit tumor growth in a preclinical xenograft model of triple negative breast cancer. In addition, it was shown to have markedly synergistic effects when used in combination with a range of commonly used cytotoxics including paclitaxel, cisplatin and doxorubicin against triple negative breast cancer cell lines in *in vitro* studies.

Supinoxin™ has been evaluated in a Phase I dose-escalation study in patients with a diverse range of metastatic, treatment-refractory tumors including breast, ovarian, colorectal and neuroendocrine tumors. Supinoxin™ was safe and well tolerated at the doses tested 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. The study showed preliminary evidence of clinical activity with seven patients experiencing disease stabilization and three patients continuing treatment beyond one year.

About Triple Negative Breast Cancer

Triple negative breast cancer (TNBC) refers to any breast cancer that does not express the genes for estrogen receptor (ER), progesterone receptor (PR) or Her2/neu. The most effective breast cancer treatments target those three receptors, which are lacking in TNBC, and therefore, the available targeted therapies such as Herceptin (trastuzumab) or hormonal therapies are usually ineffective in this sub-group of breast cancer patients. TNBC is also more aggressive than other types of breast cancer and is more likely to recur. There are currently no FDA-approved treatments for TNBC and there is no standard chemotherapy treatment for patients. TNBC accounts for approximately 15-20% of all breast cancer cases with an

annual incidence of 30,000 patients in the US and over 150,000 worldwide (GlobalData).

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, 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 in pre-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; and the ability to transition from our initial focus on developing drug candidates for orphan indications to candidates for more highly prevalent indications. 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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