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Rexahn Pharmaceuticals Announces Collaboration with Zhejiang Haichang Biotechnology Co., Ltd. for the Development of RX-0201 (Archexin®) for the treatment of Hepatocellular Carcinoma

Haichang to fund development through completion of Phase IIa Proof-of-Concept Clinical Trial

Clinical trials will be designed to meet both the US and China FDA requirements

ROCKVILLE, Md., Feb. 08, 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 it has entered into a collaboration and license agreement with Zhejiang Haichang Biotechnology Co., Ltd. (Haichang), to develop RX-0201 (Archexin®) for the treatment of hepatocellular carcinoma (HCC), the most common form of liver cancer.

Under the terms of the agreement, Haichang will develop a nano-liposomal formulation of RX-0201 using its proprietary QTsome™ technology and conduct certain pre-clinical and clinical activities through completion of a Phase IIa proof-of-concept clinical trial for the treatment of HCC. Any clinical trials conducted by Haichang will be designed to meet both U.S. and Chinese regulatory requirements. Haichang will fund all research and development activities through completion of the Phase IIa clinical trial.

The parties will share in an agreed ratio downstream licensing fees and royalties paid by third parties in connection with the further development and commercialization of the nano-liposomal formulation of RX-0201 for the treatment of HCC.

“We are delighted to enter into this collaboration to take RX-0201 forward in hepatocellular carcinoma,” said Peter D. Suzdak, Ph.D., Chief Executive Officer of Rexahn. “We are impressed with Haichang’s QTsome™ technology. It has the potential to target RX-0201 to the liver and to promote uptake into cancer cells to enhance efficacy. We are also very pleased to have non-dilutive funding to take the program through Phase IIa proof-of-concept studies.”

“The incidence of liver cancer is growing worldwide, and especially in Asia,” said Dr. Ben

Zhao, Chief Executive Officer of Haichang. “There are very few treatment options for patients and unfortunately, the prognosis for patients with advanced disease is very poor. Akt-1 is an important signaling protein in liver cancer and we are excited about the potential for RX-0201. It is an ideal candidate for our liposomal technology and we look forward to advancing the development of RX-0201 in collaboration with Rexahn.”

”While we continue to be encouraged by the safety and efficacy of RX-0201, the treatment landscape for metastatic renal cell carcinoma (mRCC) has significantly changed over the past two years with the approval of three new therapies by the FDA. This will limit the commercial viability of RX-0201 in mRCC. For this reason, Rexahn has decided to stop the development of RX-0201 for mRCC,” said Lisa Nolan, Ph.D., Chief Business Officer for Rexahn. “The Haichang collaboration allows Rexahn to capitalize on the clinical data already generated in Phase I and Phase II clinical studies and change the focus of the RX-0201 program to hepatocellular carcinoma using non-dilutive funding to take the program through Phase IIa proof-of-concept studies while retaining the potential for future milestones/royalties for the product. This will also allow Rexahn to focus its own resources on progressing RX-3117 and Supinoxin™ (RX-5902) through Phase II clinical development.”

In connection with the agreement with Haichang, Rexahn plans to discontinue the internally funded programs of Archexin and will cease enrollment in the current Phase IIa clinical study of Archexin in metastatic renal cell carcinoma (mRCC). Patients currently enrolled in the trial will continue to be followed.

About Hepatocellular Carcinoma

Hepatocellular carcinoma (liver cancer) is the sixth most common type of cancer worldwide and the second-leading cause of cancer-related deaths. Each year approximately 780,000 new cases of liver cancer are diagnosed worldwide and over 740,000 people will die of the disease.[1] The incidence of liver cancer in the U.S. has more than tripled since 1980.[2] It is estimated that there will be approximately 41,000 new cases of liver and intrahepatic bile duct cancer and 29,000 deaths from these diseases in the U.S. in 2017.[3] The majority of these cases are caused by Hepatitis B virus (HBV) or Hepatitis C virus (HCV) infections. The increasing prevalence of metabolic syndrome and nonalcoholic steatohepatitis (NASH) is expected to contribute to increased rates of liver cancer in the U.S. in the foreseeable future.[4] Outside the U.S., the incidence of liver cancer is approximately 40,000 in Europe and 36,000 in Japan. Incidence is particularly high in China due to the prevalence of HBV and HCV infections and the incidence is estimated at 260,000 in 2017.

Treatment options are limited for patients with advanced liver cancer, which account for approximately 30% of newly diagnosed patients. Nexavar® (sorafenib) is approved for first line treatment. Supportive care is the standard of care for second line treatment. Opdivo® (nivolumab) has recently been approved for patients who have disease progression after treatment with Nexavar, but only 14% of patients respond to treatment. Overall, the prognosis for patients with advanced liver cancer is typically very poor.

About Zhejiang Haichang Biotechnology Co., Ltd

Zhejiang Haichang Biotechnology Co., Ltd. is a privately owned specialized biotechnology company headquartered in Hangzhou, China. The company is focused on the development and manufacture of complex intravenous pharmaceutical products including liposome and microsphere products, primarily for cancer treatment. The company has strategic collaborations with Sinopharm and its liposomal doxorubicin product (Libaoduo®) is marketed by Shanghai Fudan-Zhangjiang Bio-pharm Co., Ltd in China.

Haichang's QTsome™ technology is a patented gene delivery technology that was co-developed with Professor Robert Lee at the Ohio State University. The technology is designed to enhance cellular uptake of large molecules such as oligonucleotides (antisense, siRNA and miRNA) and to target certain organs such as the liver where nanoparticles accumulate.

About RX-0201 (Archexin®)

RX-0201 is an antisense oligonucleotide compound that is complementary to Akt-1 mRNA and highly selective for inhibiting its mRNA expression, which leads to reduced production of Akt-1. Akt-1 is a protein that is associated with cancer cell growth and proliferation and the development of resistance to certain anticancer agents. Akt-1 is over-expressed in multiple forms of cancer including hepatic, renal, breast, colorectal, gastric, pancreatic, prostate and melanoma. In a Phase I clinical trial in patients with advanced cancers, RX-0201 appears to be safe and well tolerated with minimal side effects. The dose-limiting adverse event in such clinical trial was Grade 3 fatigue with no significant hematological abnormalities observed.

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. Pre-clinical 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 a broad oncology pipeline that includes three anti-cancer compounds currently in clinical development: RX-3117, RX-5902 (Supinoxin™) and RX-0201 (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, relationships with collaborators, the path of preclinical and 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; the ability to maintain relationships and enter new markets with our collaborators; 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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Source: Rexahn Pharmaceuticals