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Rexahn Pharmaceuticals Announces Positive Top-line Phase IIa Data for Archexin in Patients with Metastatic Pancreatic Cancer

ROCKVILLE, Md.--(BUSINESS WIRE)-- Rexahn Pharmaceuticals, Inc. (NYSE Amex: RNN), a clinical stage biopharmaceutical company focused on developing multi-indication therapeutics in oncology and CNS, today announced top-line results from a Phase II clinical study of Archexin®, its clinical-stage oncology drug candidate. Archexin is being developed as a potential first-in-class inhibitor of the Akt protein kinase (Akt) in cancer cells.

The open label 2-stage study was designed to assess the safety and efficacy of Archexin in combination with gemcitabine. Stage 1 was the dose finding portion and stage 2 was the dose expansion portion using the dose identified in stage 1 to be administered with gemcitabine. The study enrolled 31 subjects aged 18-65 years with metastatic pancreatic cancer at four centers in the United States and five centers in India. The primary endpoint was overall survival following 4 cycles of therapy with a 6-month follow-up.

For those evaluable patients according to the protocol, the study demonstrated that treatment with Archexin in combination with gemcitabine provided a median survival of 9.1 months compared to the historical survival data of 5.65 months (Burris et al., 1997, J. Clin Oncol 15:2403) for standard single agent gemcitabine therapy. The most frequently reported adverse events were constipation, nausea, abdominal pain, and pyrexia, regardless of relatedness.

Dr. Chang Ahn, Chief Executive Officer, Rexahn, said, “We are very pleased with the positive results of this early-stage clinical study to examine Archexin’s profile as a potential Akt inhibitor of solid tumors. With this supportive clinical outcome data, we look forward to progressing the clinical development of this exciting compound.”

Dr. Troy Guthrie, Baptist Medical Center in Jacksonville, FL, who was one of the investigators of the trial commented, “This study suggests that Archexin, in combination with gemcitabine, may be another treatment option for this difficult to treat cancer.”

About Archexin®

Archexin is being developed as an Akt protein kinase inhibitor with potential utility to inhibit cancer cell survival and proliferation, angiogenesis and drug resistance. Phase I clinical trial data also suggest that Archexin was generally well tolerated by the patients in the clinical trial with fatigue being the only observed/reported side effect. Archexin has FDA Orphan drug designation for five different cancer types, including renal cell carcinoma, glioblastoma,

pancreatic, stomach and ovarian cancers. Due to this designation, Archexin is eligible for a 7-year period of market exclusivity upon final FDA approval of the product for the treatment of any of these orphan indications.

About Rexahn Pharmaceuticals, Inc.

Rexahn Pharmaceuticals is a clinical stage pharmaceutical company dedicated to developing and commercializing first in class and market leading therapeutics for cancer, CNS disorders, sexual dysfunction and other unmet medical needs. Rexahn currently has three drug candidates in Phase II clinical trials, Archexin®, Serdaxin®, and Zoraxel™ and a robust pipeline of preclinical compounds to treat multiple cancers and CNS disorders. Rexahn also operates key R&D programs of nano-medicines, 3D-GOLD, and TIMES drug discovery platforms. For more information, 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 future operations and products 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, the difficulty of developing pharmaceutical products, obtaining regulatory and other approvals and achieving market acceptance; the marketing success of Rexahn's licensees or sublicensees; the success of clinical testing; and Rexahn's need for and ability to obtain additional financing. 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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