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Rexahn Pharmaceuticals Receives FDA Approval to Initiate a Phase II Trial for Archexin in Patients with Renal Cell Carcinoma

ROCKVILLE, Md.--(BUSINESS WIRE)--

Rexahn Pharmaceuticals, Inc. (OTC BB:RXHN), a biopharmaceutical company dedicated to the discovery, development, and commercialization of innovative treatments for cancer, central nervous system disorders, sexual dysfunction and other unmet medical needs, today announced that it has received approval from the U.S. Food & Drug Administration (FDA) to initiate a Phase II clinical trial for its lead oncology compound, Archexin (formerly known as RX-0201), in patients with renal cell carcinoma (RCC). Enrollment is expected to begin in Q3 2007.

Commenting on today's news, Chang Ahn, Ph.D., Chairman and Chief Executive Officer of Rexahn Pharmaceuticals, said, "We are very pleased to have received FDA approval to move this important compound into a Phase II trial for renal cell carcinoma patients, most of whom have limited treatment options. Archexin is designed to disrupt the signals responsible for cancer progression, and as such, may someday offer patients a more targeted, less toxic therapeutic approach to cancer treatment. We look forward to moving this compound ahead in its clinical development."

The Phase II trial, a non-blind, multi-center study, is designed to assess the efficacy of Archexin in patients with advanced RCC who have failed previous treatment or are unwilling or unable to be treated with standard systematic line therapy.

About Archexin

Archexin is a first-in-class signal inhibitor that directly blocks the production of AKT, a protein kinase that plays a key role in cancer progression by stimulating cell proliferation and cell survival, and promoting angiogenesis. In both preclinical and Phase I clinical trials, Archexin has demonstrated effectiveness at inhibiting the proliferation of various cancer cells at nanomolar concentrations and regulating the growth of tumors, with its only dose limiting toxicity being fatigue at a dosage of 315mg/m2.

In December 2004, the FDA granted Rexahn "orphan drug designation" for Archexin, for kidney, stomach, ovarian, pancreas and brain cancers. The orphan drug program is intended to provide patients with faster access to drug therapies for diseases and conditions that affect fewer than 200,000 people, annually.

About Renal Cell Carcinoma (RCC)

RCC is the most common form of kidney cancer; occurring more often in men than in women and usually affecting men older than 55. In total, the disease affects about three in 10,000 people, resulting in about 31,000 new cases in the United States, and approximately 12,000 deaths per year. RCC is one of the most difficult cancers to treat, often proving resistant to both radiation therapy and chemotherapy, although some cases respond to immunotherapy. Only 20% of metastatic RCC tumors respond to standard therapy, leaving 80% of advanced RCC patients with no effective treatment options. The five year survival rate with existing therapies is currently less than 20%.

About Rexahn Pharmaceuticals, Inc.

Rexahn Pharmaceuticals is a biopharmaceutical company leveraging its unique technology platform to discover, develop and commercialize innovative treatments for cancer, central nervous system disorders, sexual dysfunction and other unmet medical needs. Rexahn's compounds are designed to uniquely treat various disease states while significantly minimizing side effects in order to allow patients to regain quality of life through therapy. For Additional information about Rexahn visit www.rexahn.com.

Safe Harbor

This press release contains statements (including projections and business trends) that are forward-looking statements. Rexahn's actual results may differ materially from the anticipated results and expectations expressed in these forward-looking statements as a result of certain risks and uncertainties, including, Rexahn's lack of profitability, its auditor's going concern qualification and the need for additional capital to operate its business to develop its product candidates; the risk that Rexahn's development efforts relating to its product candidates may not be successful; the possibility of being unable to obtain regulatory approval of Rexahn's product candidates; the risk that the results of clinical trials may not be completed on time or support Rexahn's claims; demand for and market acceptance of Rexahn's drug candidates; Rexahn's reliance on third party researchers and manufacturers to develop its product candidates; Rexahn's ability to develop and obtain protection of its intellectual property; and other risk factors set forth from time to time in our filings with the Securities and Exchange Commission. These forward-looking statements are made as of the date hereof, Rexahn assumes no obligation to update these forward-looking statements.

Source: Rexahn Pharmaceuticals, Inc.