RXi Pharmaceuticals Licenses Novel, Targeted Cancer Vaccine for Gynecological Cancers

- Vaccine targets Folate Binding Protein (FBP) which is over-expressed in more than 90% of ovarian cancers and in the majority of other adenocarcinomas.
- RXi plans to initiate Phase 1 clinical trials of the FBP vaccine by year-end 2011.
- License doubles RXi's oncology pipeline which includes NeuVax™(E75), scheduled to commence its Phase 3 PRESENT study in breast cancer in 1H 2012.

WORCESTER, Mass., Sept. 21, 2011 (GLOBE NEWSWIRE) -- RXi Pharmaceuticals Corporation (Nasdaq:RXII), a biotechnology company focused on discovering, developing and commercializing innovative therapies addressing major unmet medical needs using targeted biotherapeutics, announced today that it licensed worldwide rights to develop and commercialize a Folate Binding Protein-E39 (FBP) targeted vaccine to prevent recurrence in gynecological cancers such as ovarian and endometrial adenocarcinomas. The FBP vaccine was licensed from The University of Texas M D Anderson Cancer Center (MD Anderson) and Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc. (HJF). FBP has been granted Investigational New Drug (IND) approval by the U.S. Food and Drug Administration (FDA) to enter clinical trials. Institutional Review Board (IRB) approval has also been received allowing RXi to initiate Phase 1 trials by the end of 2011.

"Licensing FBP which is already IND- and IRB- approved, and ready to commence two Phase 1 clinical trials in ovarian/endometrial and breast cancers, doubles our pipeline and further advances RXi's leadership in cancer immunotherapy," said Mark J. Ahn, PhD, CEO and President of RXi Pharmaceuticals. "We anticipate initiation of clinical trials this year and are excited about exploring the promising potential of the FBP vaccine in critical areas of unmet medical need."

The FBP vaccine consists of the E39 peptide combined with the immune adjuvant granulocyte macrophage colony stimulating factor (GM-CSF). FBP is over-expressed (20-80 fold) in more than 90% of ovarian and aggressive endometrial cancers, as well as 20—50% of breast, lung, colorectal, and renal cell carcinomas. FBP has very limited tissue distribution and expression in non-malignant tissue and has many years of validation as an ideal immunotherapy target.

"The broad overexpression of FBP in such a wide variety of cancers suggests the exciting potential of a widely applicable FBP-based vaccine in epithelial cancers," said COL George E Peoples, MD, FACS, one of the inventors of the FBP patents and Director, Cancer Vaccine Development Program; Deputy Director, United States Military Cancer Institute (USMCI); Professor, Surgery, Uniformed Services University of the Health and Sciences; Chief Surgical Oncology, Brooke Army Medical Center (BAMC). USMCI is a component of the Uniformed Services University of the Health Sciences, an institution of higher learning within the Department of Defense, an agency of the U.S. Government, located in Bethesda, MD.

About Ovarian/Endometrial Cancers

Ovarian cancer occurs in over 22,000 patients per year in the U.S. and is the most lethal gynecologic cancer. Despite the incidence of ovarian cancer being only a small fraction of breast cancer, the number of patients that die from ovarian cancer is nearly 50% that of breast cancer. Due to the lack of specific symptoms, the majority of ovarian cancer patients are still diagnosed at later stages of the disease. These patients are routinely surgically debulked to minimal residual disease, and then treated with platinum- and/or taxane-based chemotherapy. While most patients respond to this treatment regime and become clinically free of disease, the majority of these patients will relapse, and once the disease recurs, the treatment options and successes drop dramatically.

Endometrial cancer is the most common gynecologic cancer and occurs in over 43,000 women in the US annually. There are two basic types of endometrial cancer: endometriod and papillary serous. The latter has a much more aggressive clinical course similar to ovarian cancer and the majority of these patients will die of this form of the disease.

About NeuVax™ (E75)

RXi is also pursuing development of a cancer vaccine for breast cancer. NeuVax consists of the E75 peptide derived from HER2 combined with the immune adjuvant granulocyte macrophage-colony stimulating factor (GM-CSF). Treatment with NeuVax stimulates cytotoxic (CD8+) T cells in a highly specific manner to target cells expressing any level of HER2. NeuVax is given as an intradermal injection once a month for six months, followed by a booster injection once every six months. Based on a successful Phase 2 trial, which achieved its primary endpoint of disease free survival (DFS), the FDA granted NeuVax a Special Protocol Assessment (SPA) for its Phase 3 PRESENT (Prevention of Recurrence in Early-Stage, Node-Positive Breast Cancer with Low to Intermediate HER2 Expression with NeuVax™ Treatment) study. The Phase 3 trial is expected to commence in the first half of 2012.
According to the National Cancer Institute, over 200,000 women in the U.S. are diagnosed with breast cancer annually. Of these women, about 75% test positive for HER2 (IHC 1+, 2+ or 3+). Only 25% of all breast cancer patients, those with HER2 3+ disease are eligible for Herceptin® (trastuzumab; Roche-Genentech) which had revenues of over $5 billion in 2010. NeuVax targets the remaining 50% of HER2 positive patients (HER2 1+ and 2+) who achieve remission with current standard of care, but have no available HER2 targeted adjuvant treatment options to maintain their disease free status.

About Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc. (HJF)

HJF, located in Rockville, Maryland, is a private, not-for-profit organization authorized by Congress to support medical education and research at the Uniformed Services University of the Health Sciences and throughout the military medical community.

About RXi Pharmaceuticals Corporation

RXi Pharmaceuticals Corporation (Nasdaq:RXII) is a biotechnology company focused on discovering, developing and commercializing innovative therapies addressing major unmet medical needs using targeted biotherapeutics. For more information, visit www.rxipharma.com.

The RXi Pharmaceuticals Corporation logo is available at http://www.globenewswire.com/newsroom/prs/?pkgid=10128

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Such statements include, but are not limited to, statements about the future expectations, plans and prospects of the development of RXi Pharmaceuticals Corporation's products. These forward-looking statements about future expectations, plans and prospects of the development of the Company's products are subject to a number of risks, uncertainties and assumptions, including those identified under "Risk Factors" in the Company's most recently filed Annual Report on Form 10-K, Quarterly Report on Form 10-Q and in other filings the Company periodically makes with the SEC. Actual results may differ materially from those contemplated by these forward-looking statements to reflect a change in its views or events or circumstances that occur after the date of this presentation.

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