Idera Pharmaceuticals Announces Preliminary Data from Phase 2a Clinical Study of IMO-2055 Monotherapy in Renal Cell Carcinoma

October 1, 2008 11:01 AM EDT

CAMBRIDGE, Mass.--(BUSINESS WIRE)--

Idera Pharmaceuticals, Inc. (Nasdaq: IDRA), today announced preliminary data from the first part of a Phase 2 clinical study conducted by the Company of IMO-2055 monotherapy in patients with metastatic or recurrent clear cell renal carcinoma (RCC). The primary objective was not achieved in the study. The primary objective was tumor response based on RECIST (Response Evaluation Criteria In Solid Tumors). Secondary objectives included time to progression, survival and safety. Progression-free survival also has been analyzed. Treatment-naive and second-line patients were randomly assigned to receive IMO-2055 subcutaneously at either 0.16 mg/kg/week or 0.64 mg/kg/week. 89 patients were evaluable for efficacy endpoints. Median progression-free survival among the four arms ranged from 2 to 4 months. IMO-2055 treatment was generally well-tolerated with good dose intensity in all arms of the study.

"We are encouraged that IMO-2055 was well-tolerated for prolonged treatment durations in many patients in this study. The progression-free survival data are comparable with other studies of immunotherapies used for this hard-to-treat RCC patient population," said Alice Bexon, MBChB, Vice President of Clinical Development. "This study has provided us with valuable experience with IMO-2055 and will help guide the clinical development of IMO-2055."

"We entered into a collaboration with Merck KGaA in December 2007 for the development of IMO-2055 and other TLR9 agonists for the treatment of cancer," said Sudhir Agrawal, D. Phil., Chief Executive Officer and Chief Scientific Officer. "Merck KGaA's current clinical development plan for IMO-2055 in cancer treatment is focused on combination therapies with selected targeted agents in solid tumors."

About the Study

The study was conducted at centers in the U.S. and followed a Simon two-stage statistical design based on historical performance of interferon-alpha and IL-2 in this patient population. The first part of the study (also referred to as Stage A) has been completed, for which the enrollment target was 92, with 23 patients in each of four arms. Treatment-naive and second-line patients were randomly assigned to receive IMO-2055 subcutaneously at either 0.16 mg/kg/week or 0.64 mg/kg/week. 89 patients were evaluable for efficacy endpoints. Patients continued to receive treatment until disease progression or another protocol-specified stopping criterion was met. The primary objective was tumor response according to RECIST (Response Evaluation Criteria In Solid Tumors). Secondary objectives included time to progression, survival and safety. Progression-free survival also has been analyzed. The Company believes progression-free survival is a more rigorous measure than time to progression because it accounts for any patients who died prior to disease progression.

The primary objective was not achieved in the study. Median progression-free survival for each of the four arms was 2 months, 3 months, 4 months, and 4 months. IMO-2055 treatment was generally well-tolerated with good dose intensity in all arms of the trial. The most common adverse events were mild to moderate and included chills, fatigue, nausea, pyrexia, headache, myalgia, and vomiting. These flu-like symptoms were expected based on the immune stimulatory mechanism of action of IMO-2055. The Company expects to present detailed study results at a future scientific conference.

About IMO-2055

IMO-2055 is a novel DNA-based agonist of TLR9 that Idera has licensed to Merck KGaA for the treatment of cancer, excluding cancer vaccines. Under the collaboration with Merck KGaA, IMO-2055 is currently in a Phase 1b clinical study in combination with Tarceva(R) and Avastin(R) in patients with advanced non-small cell lung cancer. A second Phase 1b clinical study of IMO-2055 in combination with Erbitux(R) and Camptosar(R) in patients with advanced colorectal cancer is planned.

About Idera Pharmaceuticals, Inc.

Idera Pharmaceuticals develops drug candidates to treat infectious diseases, autoimmune diseases, cancer, and respiratory diseases, and for use as vaccine adjuvants. Our proprietary drug candidates are designed to modulate specific Toll-like Receptors, which are a family of immune system receptors that direct immune system responses. Our pioneering DNA and RNA chemistry expertise enables us to create drug candidates for internal development and generates opportunities for multiple collaborative alliances. For more information, visit www.iderapharma.com.

Idera Forward Looking Statements

This press release contains forward-looking statements concerning Idera Pharmaceuticals, Inc. that involve a number of risks and uncertainties. For this purpose, any statements contained herein that are not statements of historical fact may be deemed to be forward-looking statements. Without limiting the foregoing, the words "believes," "anticipates," "plans," "expects," "estimates," "intends," "should," "could," "will," "may," and similar expressions are intended to identify forward-looking statements. There are a number of important factors that could cause Idera's actual results to differ materially from those indicated by such forward-looking statements, including whether the Company's continuing evaluation of the data from the study will result in different or conflicting interpretations; whether results obtained in early clinical studies or in preclinical studies such as the study referred to above will be indicative of results obtained in future clinical trials or warrant additional trials or further development; whether products based on Idera's technology will advance into or through the clinical trial process on a timely basis or at all and receive approval from the United States Food and Drug Administration or equivalent foreign regulatory agencies; whether, if the Company's products receive approval, they will be successfully distributed and marketed; whether the Company's collaborators will support the development and commercialization of products under their collaborations with the Company; whether the patents and patent applications owned or licensed by the Company will protect the Company's technology and prevent others from infringing it; whether Idera's cash resources will be sufficient to fund the Company's operations; and such other important factors as are set forth under the caption "Risk Factors" in the Company's Quarterly Report on Form 10-Q filed on August 1, 2008, which important factors are incorporated herein by reference. The Company disclaims any intention or obligation to update any forward-looking statements.

Source: Idera Pharmaceuticals, Inc.