Idera Pharmaceuticals Presents Final Data from Phase 2 Clinical Trial of IMO-2055 Monotherapy in Renal Cell Carcinoma

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CAMBRIDGE, Mass.--(BUSINESS WIRE)--Sep. 25, 2009-- Idera Pharmaceuticals, Inc. (Nasdaq: IDRA), today announced the presentation of final data from a clinical trial evaluating IMO-2055, an agonist of Toll-like Receptor (TLR) 9, as monotherapy in patients with Renal Cell Carcinoma (RCC). The data are being presented during the Eighth International Kidney Cancer Symposium being held in Chicago, September 25-26, 2009.

In this phase 2 open-label, non-controlled clinical trial, treatment-naïve and second-line patients with RCC were randomly assigned to receive IMO-2055 subcutaneously at 0.16 mg/kg/week or 0.64 mg/kg/week. 89 patients were evaluable for efficacy (intent-to-treat population).

"This clinical trial of IMO-2055 monotherapy in RCC has provided us data that have been helpful in developing the strategy for clinical studies of IMO-2055 in combination with approved anti-cancer agents. Currently IMO-2055 is being evaluated in combination with Tarceva® and Avastin® in non-small cell lung cancer and in combination with Erbitux® and a Camptosar®-containing regimen in colorectal cancer," said Alice Bexon, MBChB, Vice President of Clinical Development. "As previously announced, the primary objective based on RECIST was not achieved in this trial; however, we are encouraged by the progression-free survival compared to published reports with interferon alpha treatment. We have seen prolonged treatment durations in several patients."

Based on the final data analysis:

- Progression-free survival (PFS) medians for treatment-naïve patients were 4.5 months at 0.16 mg/kg/week and 1.9 months at 0.64 mg/kg/week
- PFS medians for second-line patients were 3.4 months at 0.16 mg/kg/week and 4.3 months at 0.64 mg/kg/week
- Median overall survival was 23.5 months overall, although medians were not estimable in 2 of the 4 treatment groups
- 7 patients received weekly IMO-2055 treatment for at least 1 year
- 2 patients (1 second-line and 1 treatment-naïve), each receiving 0.64 mg/kg/week, had confirmed partial responses
- 52 patients (58%) across all groups had stable disease
- IMO-2055 treatment was generally well-tolerated: neither dosage was associated with any dose-limiting toxicity, although the relative dose intensity was higher with the 0.16 mg/kg dosage
- The most common treatment-related adverse events (any grade across groups) were fatigue (51%), nausea (46%), chills (45%), headache (37%), and pyrexia (33%), consistent with IMO-2055-related immune stimulation

The oral and poster presentations, entitled "A phase 2 multicenter, randomized, open-label study of two dose levels of IMO-2055 in patients with metastatic or recurrent renal cell carcinoma", are being made by Timothy Kuzel, M.D. Dr. Kuzel is the Director of the Clinical Research Office for the Robert H. Lurie Comprehensive Cancer Center of Northwestern University and Professor of Medicine within the Division of Hematology/Oncology of the Department of Medicine at Northwestern University's Feinberg School of Medicine in Chicago, IL.

About the Trial

The trial 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 enrollment target was 92, with 23 patients in each of four arms. Treatment-naïve 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 was analyzed, as 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.

Preliminary data from the trial were announced October 1, 2008. The Simon first-stage requirement of greater than 1 response was not met in any group during the trial; therefore, the second stage was not initiated.

About IMO-2055

In December 2007, Idera entered into a worldwide licensing and collaboration agreement with Merck KGaA, Darmstadt, Germany, for the research, development, and commercialization of Idera's TLR9 agonists for the treatment of cancer. IMO-2055 is a novel DNA-based agonist of TLR9 and at present is in a phase 1b clinical study in combination with Tarceva and Avastin in patients with advanced non-small cell lung cancer. IMO-2055 is also being evaluated in a second phase 1b clinical study in combination with Erbitux and a Camptosar-containing regimen in patients with advanced colorectal cancer.

Interim data from the phase 1b trial evaluating IMO-2055 in combination with Tarceva and Avastin in patients with non-small cell lung cancer were presented September 23, 2009, during the joint 15th Congress of the European CanCer Organisation (ECCO) and 34th Congress of the European Society for Medical Oncology (ESMO) in Berlin, Germany (Abstract number 9.148).

About Idera Pharmaceuticals, Inc.

Idera Pharmaceuticals develops drug candidates to treat infectious diseases, autoimmune and inflammatory diseases, cancer, and respiratory diseases, and for use as vaccine adjuvants. Our proprietary drug candidates are designed to modulate specific Toll-like Receptors (TLRs), 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 our internal development programs and our partnered programs, and generates opportunities for additional 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 results obtained in preclinical studies or early-stage clinical trials will be indicative of results obtained in future clinical trials; 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 collaborations with Novartis, Merck & Co., and Merck KGaA will be successful; 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 Idera's Quarterly Report on Form 10-Q for the three months ended June 30, 2009, which important factors are incorporated herein by reference. Idera disclaims any intention or obligation to update any forward-looking statements.

Tarceva is a registered trademark of OSI Pharmaceuticals, Inc. Avastin is a registered trademark of Genentech, Inc. Erbitux is a registered trademark of ImClone Systems Incorporated. Camptosar is a registered trademark of Pfizer.

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