Idera Pharmaceuticals Presents Interim Data from Phase 1b Clinical Trial of IMO-2055 in Combination with Tarceva(R) and Avastin(R) in Non-Small Cell Lung Cancer

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CAMBRIDGE, Mass.--(BUSINESS WIRE)--Sep. 23, 2009-- Idera Pharmaceuticals (Nasdaq: IDRA) today presented interim data from a phase 1b, single arm clinical trial evaluating IMO-2055, an agonist of Toll-like Receptor (TLR) 9, in combination with Tarceva® and Avastin® in patients with non-small cell lung cancer (NSCLC). The data were presented 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).

“Interim data in this trial show that the triple combination of IMO-2055, Tarceva, and Avastin has demonstrated some anti-tumor activity in NSCLC patients who had progressed during or after one or more prior therapy regimens. These data are encouraging in light of the recent results reported for the Tarceva-Avastin combination in a similar patient population,” said Dr. Alice Bexon, MBChB, Vice President of Clinical Development. “A dose level was selected for further study.”

The trial is designed to determine the tolerability and safety of IMO-2055 in combination with Tarceva and Avastin. Interim data presented at the meeting show:

- IMO-2055 was tolerated at dosages up to 0.48 mg/kg/week in combination with Tarceva plus Avastin
- The most common possibly-related adverse events were injection site reactions, fatigue and fever
- Six grade 3 adverse events were reported: injection site reactions (2), diarrhea (2), fatigue (1) and low potassium (1)
- 8 of 16 patients remained on treatment at least 18 weeks
- Of the 13 evaluable patients, 3 had a partial response and 8 experienced stable disease

Recruitment of additional patients is continuing at the anticipated recommended phase 2 dose level for IMO-2055 in this combination.

The presentation was made by David Smith, M.D., of US Oncology in Vancouver, WA.

About the Trial

The phase 1b trial evaluating IMO-2055 is being conducted in patients with advanced or metastatic NSCLC who have progressed on previous therapy. The trial is designed to assess safety of the IMO-2055, Tarceva, and Avastin combination and to determine the recommended dosage of IMO-2055 for use in a subsequent phase 2 trial. IMO-2055 is administered subcutaneously on days 1, 8, and 15 of a 3-week cycle. Avastin and Tarceva are used in the care of NSCLC. A standard dosage of Tarceva is given daily and a standard dosage of Avastin is given on day 1 of each cycle. The target enrollment for the trial is up to 40 patients. Patients will continue therapy until disease progression as determined by standard guidelines to evaluate the response to treatment in solid tumors (RECIST).

IMO-2055 dosages of 0.08, 0.16, 0.32, and 0.48 mg/kg/week were evaluated in the dose escalation portion of the trial.

Preclinical studies have shown increased anti-tumor activity when a TLR9 agonist similar to IMO-2055 is combined with targeted agents such as Tarceva and Avastin. TLR9 agonists, in addition to being immune modifiers, affect epidermal growth factor receptor (EGFR) and vascular endothelial growth factor (VEGF) pathways. Tarceva is an inhibitor of EGFR, and Avastin is an inhibitor of VEGF.

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, in addition to the trial presented at the Congress, is also being evaluated in a second phase 1b clinical study in combination with an Erbitux® and Camptosar® containing regimen in patients with advanced colorectal cancer.

Final data from a phase 2 trial evaluating IMO-2055 monotherapy in patients with renal cell carcinoma will be presented during the Eighth International Kidney Cancer Symposium taking place September 25-26, 2009, in Chicago.

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 interim clinical data from a clinical trial will be indicative of the final results of the trial; 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.

Source: Idera Pharmaceuticals

Idera Pharmaceuticals, Inc.
Kelly Luethje, 617-679-5519
kluethje@iderapharma.com
or
MacDougall Biomedical Communications
Chris Erdman, 508-647-0209
cerdman@macbiocom.com