Idera Pharmaceuticals Announces Top-line Results from a Phase 2 Clinical Trial of IMO-2055 in Treatment of Patients with Advanced Head and Neck Cancer

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CAMBRIDGE, Mass., May 03, 2012 (BUSINESS WIRE) --Idera Pharmaceuticals, Inc. (NASDAQ: IDRA) today announced top-line results of a randomized, controlled Phase 2 clinical trial of IMO-2055, the Company's investigational oncology product candidate targeting Toll-like Receptor 9 in combination with Erbitux(R) (cetuximab) for the treatment of recurrent or metastatic squamous cell carcinoma of the head and neck (SCCHN) in patients who previously progressed on chemotherapy. The study did not meet its primary endpoint of improved progression-free survival following treatment with IMO-2055 in combination with cetuximab compared to treatment with cetuximab alone. The median progression-free survival based on investigator assessments was 2.9 months in both arms; based on independent radiology review, it was 1.9 months in the cetuximab arm and 1.5 months in the combination arm.

The Phase 2 trial was designed and conducted by Merck KGaA of Darmstadt, Germany, under Idera's oncology collaboration with Merck KGaA that was terminated in November 2011. As part of the termination, Idera regained from Merck KGaA all rights for developing TLR9 agonists for the treatment of cancer, including all rights to IMO-2055, and Merck KGaA agreed to conduct the Phase 2 trial through completion.

"We are disappointed with the results of this trial, considering the favorable results reported earlier this year from a single-arm Phase 1b study of IMO-2055 in combination with Tarceva(R) and Avastin(R) in patients with non-small cell lung cancer as well as the safety profile of IMO-2055 in combination with targeted anti-cancer agents that has been observed in multiple clinical trials," said Sudhir Agrawal, D.Phil., Chairman and Chief Executive Officer. "We believe that IMO-2055 may have clinical and commercial potential for certain cancer indications and plan to seek to advance IMO-2055 through collaborations with third parties."

"Idera is focusing its development efforts on the drug candidates in our autoimmune disease program where we recently initiated a Phase 2 clinical trial of IMO-3100 in patients with psoriasis. Further, we are planning to submit an IND for IMO-8400 for the treatment of lupus in 2012. Additionally, we continue to validate our proprietary gene-silencing oligo technology and support our collaborative activities in the area of vaccine adjuvants for cancer, infectious diseases and Alzheimer's disease," Dr. Agrawal concluded.

SCCHN Trial Results

This Phase 2 clinical trial was a randomized, controlled trial of IMO-2055 in combination with cetuximab in second-line cetuximab-naïve patients with recurrent or metastatic SCCHN who have previously progressed on chemotherapy. In this study, 106 patients with SCCHN were randomized into two arms of 53 patients each. In one arm, patients were treated with IMO-2055 at a dose of 0.32 mg/kg given subcutaneously once weekly in combination with weekly cetuximab. In the other arm of the study, patients were treated with cetuximab alone. Crossover of the patients who progressed on cetuximab alone was permitted to the combination arm of IMO-2055 and cetuximab. The trial was conducted at multiple centers in Europe and the United States.

The primary endpoint of the study was progression-free survival. Secondary outcome measures included overall response rate (by RECIST), disease control rate, overall survival, and safety and tolerability in subjects treated with IMO-2055 plus cetuximab compared to cetuximab alone. In the study, the combination of IMO-2055 and cetuximab did not meet the primary endpoint. The median progression-free survival based on investigator assessments was 2.9 months in both arms; based on independent radiology review, it was 1.9 months in the cetuximab arm and 1.5 months in the combination arm. The hazard ratio in both evaluations was 1.1 with no statistical difference between the treatment arms. The relative dose intensity was 96% for IMO-2055 and 99% for cetuximab in the combination arm and was 96% for cetuximab in the cetuximab-alone arm. The detailed data from this trial are expected to be presented at a scientific conference.

Previously Announced Non-Small Cell Lung Cancer (NSCLC) Trial Results

In January 2012, Idera announced favorable safety and efficacy results from a Phase 1b study of IMO-2055 in combination with Tarceva and Avastin in thirty-six patients with advanced NSCLC who had previously failed one or more prior therapies. In this trial, the combination of IMO-2055 with Tarceva and Avastin was well tolerated. Thirty-three patients were evaluable for efficacy and showed a disease control rate of 79%, a median progression-free survival of 5.6 months and a median overall survival of 16 months. The detailed data from this trial are expected to be presented at a scientific conference.

About TLRs and Idera's Pipeline

Toll-like Receptors (TLRs) represent a class of proteins that play a key role in both inflammation and immunity. Of the 10 human TLRs identified to date, Idera is focusing on compounds targeted to TLRs 3, 7, 8, and 9, which are expressed in different cells and serve unique functions. For example, activation of TLR7 and TLR9 present in certain dendritic cells and lymphocytes may be useful for the treatment of various types of cancer by stimulating immunity. In contrast, inhibition of specific TLRs may be useful in treating autoimmune disorders, such as psoriasis and lupus, by blocking the production of multiple pro-inflammatory mediators. Using its chemistry-based approach, Idera is advancing novel drug candidates to modulate immune response through activation or inhibition of specific TLRs to treat a broad range of diseases, including autoimmune diseases and cancer.

In autoimmune diseases, Idera is developing inhibitors of TLRs 7, 8, and 9 for the potential treatment of psoriasis, lupus, and other diseases. Idera's lead clinical candidate is IMO-3100, an antagonist of TLR7 and TLR9, which is in Phase 2 development for psoriasis. IMO-8400 is an antagonist of TLRs 7, 8, and 9. Idera expects to file an IND application for IMO-8400 during the fourth quarter of 2012. Idera has selected lupus as the initial disease indication for clinical development of IMO-8400.

In oncology, Idera's lead product candidate is IMO-2055, which is designed to activate TLR9. IMO-2055 is the subject of several clinical trials including: the randomized, controlled Phase 2 trial in combination with cetuximab as a second-line therapy for patients with recurrent or metastatic SCCHN that had not been previously treated with cetuximab reported on above; a Phase 1b trial with IMO-2055 in combination with Tarceva and Avastin for the treatment of NSCLC reported on in January 2012; and a Phase 1b trial with IMO-2055 in combination with FOLFIRI and cetuximab in patients with advanced colorectal cancer who have progressed following chemotherapy to be reported on.

About Idera Pharmaceuticals, Inc.

Idera Pharmaceuticals applies its proprietary Toll-like receptor (TLR) drug discovery platform to create immunomodulatory drug candidates and has clinical development programs in autoimmune diseases and cancer. Additionally, Idera has a collaboration with Merck & Co. for the use of TLR-targeted candidates as vaccine adjuvants. The Company is also advancing its gene-silencing oligonucleotide (GSO) technology for the purpose of inhibiting the expression of disease-promoting genes. For more information, visit http://www.iderapharma.com.

Erbitux(R) is a registered trademark of ImClone LLC, a wholly-owned subsidiary of Eli Lilly and Company. Tarceva(R) is a registered trademark of OSI Pharmaceuticals, LLC, an affiliate of Astellas Pharma US, Inc. Avastin(R) is a registered trademark of Genentech, Inc.

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 and clinical trials such as the trials referred to in this release will be indicative of results obtained in future clinical trials, whether for the same or different indications; 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 will be able to license IMO-2055 for further development for oncology on a timely basis or at all; whether the Company's collaboration with Merck & Co, Inc., will be successful; 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 Idera's Annual Report on Form 10-K for the year ended December 31, 2011 which important factors are incorporated herein by reference. Idera disclaims any intention or obligation to update any forward-looking statements.

SOURCE: Idera Pharmaceuticals, Inc.

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