Idera Pharmaceuticals Provides Update on IMO-2055 Clinical Development Program

July 7, 2011 11:46 AM EDT

CAMBRIDGE, Mass., Jul 07, 2011 (BUSINESS WIRE) -- Idera Pharmaceuticals (NASDAQ: IDRA) today provides an update on the clinical development of IMO-2055 (EMD 1201081), a TLR9 agonist for cancer treatment being developed by Merck KGaA, Darmstadt, Germany, under its collaboration with Idera. Merck KGaA has informed Idera that, based on increased incidence of neutropenia and electrolyte imbalances reported in its Phase 1 trial of IMO-2055 in combination with cisplatin/5-FU and cetuximab (Erbitux(R)) in patients with first-line squamous cell carcinoma of the head and neck (SCCHN) and subsequent re-evaluation of its clinical development program, Merck KGaA has determined that it will not conduct further clinical development of IMO-2055 at this stage.

Merck KGaA also has informed Idera that it plans to complete its ongoing Phase 2 trial of IMO-2055 in combination with Erbitux(R) in second-line patients with recurrent or metastatic SCCHN and to continue evaluating follow-on TLR9 agonists created by Idera under the collaboration.

"Although we are disappointed that Merck has decided not to advance the development of IMO-2055, we are pleased that Merck KGaA plans to complete the ongoing Phase 2 study of IMO-2055 in combination with Erbitux(R) and to evaluate follow-on TLR9 agonist compounds," commented Sudhir Agrawal, D. Phil., Chairman and Chief Executive Officer of Idera. "It is important to note that IMO-2055 has been well tolerated in multiple trials both as monotherapy and in combination with targeted anti-cancer agents and, based on the intended mechanism of action of TLR9 agonists and the clinical data generated thus far, we believe a potential use of IMO-2055 is in combination with targeted anti-cancer agents."

The IMO-2055 clinical development program in collaboration with Merck KGaA includes the following studies:

- A Phase 1b clinical trial to investigate multiple ascending dosages of IMO-2055 in combination with cisplatin/5-FU and Erbitux(R) in patients with first-line SCCHN. In this trial, treatment with IMO-2055 plus cisplatin/5-FU and Erbitux(R) was associated with increased neutropenia and electrolyte imbalances as compared to a clinical trial of cisplatin/5-FU and Erbitux(R) (Vermorken J, et al. N Engl J Med 2008; 359:1116). This study has been terminated by Merck KGaA.
- A Phase 2 clinical trial of Erbitux(R) with or without IMO-2055 as a second-line treatment in patients with recurrent and/or metastatic SCCHN. This study is ongoing and no serious safety concerns have been observed to date.
- A Phase 1b clinical trial of IMO-2055 in combination with Erbitux(R) and FOLFIRI (5-FU/leucovorin/irinotecan) in patients with metastatic colorectal cancer. The trial consisted of two steps, a dose escalation component and a dose expansion component. Merck KGaA has decided not to initiate the dose expansion component. Final analysis of data from the dose escalation part of this study is ongoing.
- A Phase 1b clinical trial of IMO-2055 in combination with erlotinib (Tarceva(R)) and bevacizumab (Avastin(R)) in patients with advanced non-small cell lung cancer. The study has been completed without safety concerns.

About the Collaboration

Idera Pharmaceuticals entered into a worldwide licensing and collaboration agreement with Merck KGaA, Darmstadt, Germany in December 2007 for the research, development and commercialization of Idera's Toll-like Receptor 9 (TLR9) agonists, including IMO-2055 (EMD 1201081), for the potential treatment of certain cancers, excluding cancer vaccines.

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, 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 http://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 collaborations will be successful, including the Company's collaboration with Merck KGaA; whether results obtained in early clinical trials of a compound such as the safety results from the clinical trials of IMO-2055 referred to in this release will be indicative of results obtained in later clinical trials of the compound or follow-on compounds; 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 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 Quarterly Report on Form 10-Q for the three months ended March 31, 2011, which important factors are incorporated herein by reference. Idera disclaims any intention or obligation to update any forward-looking statements.

Erbitux is a registered trademark of ImClone LLC, a wholly-owned subsidiary of Eli Lilly and Company. Tarceva is a registered trademark of OSI Pharmaceuticals, Inc. Avastin is a registered trademark of Genentech, Inc.

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