

## Idera Pharmaceuticals Regains Global Rights to IMO-2055 in Oncology from Merck KGaA

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## Phase 2 Data Anticipated in Second Quarter of 2012

CAMBRIDGE, Mass., Nov 30, 2011 (BUSINESS WIRE) --

Idera Pharmaceuticals, Inc. (NASDAQ: IDRA) today announced that it has regained global rights to IMO-2055, an agonist of Toll-like Receptor (TLR) 9, as part of an agreed-upon termination of its oncology collaboration with Merck KGaA, Darmstadt, Germany. During the collaboration, Merck KGaA conducted Phase 1 trials of IMO-2055 in several cancer indications and has an ongoing randomized Phase 2 trial of IMO-2055 in combination with Erbitux<sup>(R)</sup> in patients with squamous cell cancer of the head and neck (SCCHN). As previously announced in July 2011, Merck had informed Idera that it would not continue clinical development of IMO-2055 beyond completing the ongoing Phase 2 trial in SCCHN.

"We believe the potential of IMO-2055 immunotherapy is in combination with targeted anti-cancer agents. Under our termination agreement with Merck KGaA, Merck KGaA will continue to conduct the ongoing Phase 2 trial in patients with SCCHN and Idera will have rights to the data, as well as to the data from Phase 1 trials conducted in other cancer indications. We believe that regaining our rights to IMO-2055, as well as the rights to the clinical data, will provide us greater flexibility and control in the clinical development of IMO-2055 and the opportunity to pursue new business collaborations," commented Sudhir Agrawal, D Phil, Chairman and Chief Executive Officer of Idera. "We appreciate the efforts made by the Merck KGaA team members in significantly advancing this program."

Idera expects data from the following clinical trials with IMO-2055 to be available in the near-term:

- A Phase 1b clinical trial of IMO-2055 in combination with Tarceva<sup>(R)</sup> and Avastin<sup>(R)</sup> in patients with advanced non-small cell lung cancer (NSCLC).
  - The NSCLC Phase 1b clinical trial evaluated four dose levels of IMO-2055 in combination with Tarceva<sup>(R)</sup> and Avastin<sup>(R)</sup>. Thirty-six patients have been recruited in this trial and data analysis is ongoing.
- A Phase 1b clinical trial of IMO-2055 in combination with Erbitux<sup>(R)</sup> and FOLFIRI (5-fluorouracil/leucovorin/irinotecan) in patients with metastatic colorectal cancer (CRC).
  - The CRC Phase 1b clinical trial evaluated three dose levels of IMO-2055 in combination with Erbitux<sup>(R)</sup> and FOLFIRI. Twenty-two patients have been recruited and data analysis is ongoing.
- A randomized Phase 2 clinical trial of IMO-2055 in combination with Erbitux<sup>(R)</sup> versus Erbitux alone as a second-line treatment in patients with recurrent and/or metastatic SCCHN.
  - The design of the Phase 2 study provides for the enrollment of 104 patients, 52 in each
    of the two arms. Crossover of patients from Erbitux alone to IMO-2055 in combination
    with Erbitux is permitted under specified circumstances. The primary endpoint of the trial
    is progression-free survival. This study is fully enrolled and patient treatment and
    follow-up are ongoing.

Merck KGaA has conducted additional clinical trials of IMO-2055 including:

- A Phase 1 trial of IMO-2055 in combination with Erbitux, cisplatin, and 5-fluorouracil for the
  first-line treatment of SCCHN. In this trial, treatment with IMO-2055 plus cisplatin/5-fluorouracil
  and Erbitux was associated with increased neutropenia and electrolyte imbalances as
  compared to a clinical trial of cisplatin/5-fluorouracil and Erbitux (Vermorken J, et al. NEJM
  2008; 359:1116). This study was terminated by Merck KGaA.
- A Phase 1 trial in healthy subjects to evaluate safety and dose-dependent pharmacokinetics and pharmacodynamics of IMO-2055 after three weekly doses by subcutaneous or intravenous administration.

Idera Pharmaceuticals entered into its 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, for the potential treatment of certain cancers, excluding cancer vaccines. As part of the agreement between Idera and Merck KGaA as to the termination of the collaboration, Idera has regained all rights for developing TLR9 agonists for the treatment of cancer, including all rights to IMO-2055 and any follow-on TLR9 agonists, and rights to data created under and during the collaboration. Merck KGaA has decided to complete the ongoing Phase 2 trial of IMO-2055 in SCCHN. Idera has agreed to reimburse approximately EUR 1.8 million of Merck KGaA's expenses during the course of the ongoing Phase 2 trial, which the Company expects to pay over the course of approximately twelve months starting in March 2012. Idera has also agreed to pay to Merck KGaA milestone payments of EUR 1 million each upon entering into any future partnership for IMO-2055, upon initiating the next clinical trial of IMO-2055 that is a Phase 2 or Phase 3 clinical trial, and upon the regulatory submission of IMO-2055 in any country.

## About Idera Pharmaceuticals, Inc.

Idera Pharmaceuticals applies its proprietary Toll-like Receptor (TLR) drug discovery platform to create immunomodulatory drug candidates. The Company's TLR-targeted candidates are being developed to treat autoimmune and inflammatory diseases, cancer, and for use as vaccine adjuvants. Additionally, the Company is advancing its gene-silencing oligonucleotide (GSO) technology for the purpose of inhibiting the expression of disease-promoting genes. For more information, visit <a href="http://www.iderapharma.com">http://www.iderapharma.com</a>.

## **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 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 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 quarter ended September 30, 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.

Idera Pharmaceuticals, Inc.
Lou Arcudi, 617-679-5517

larcudi@iderapharma.com
or

MacDougall Biomedical Communications
Chris Erdman, 781-235-3060
cerdman@macbiocom.com