



Idera Pharmaceuticals Enters into a Clinical Development Support Agreement with Pillar Partners Foundation to Expand the Clinical Research on IMO-2125 beyond PD-1 Refractory Melanoma

April 16, 2018 11:00 AM EDT

Pillar Partners to provide funding for up to three Investigator Initiated Clinical Trials

EXTON, Pa., April 16, 2018 (GLOBE NEWSWIRE) -- Idera Pharmaceuticals, Inc. ("Idera") (NASDAQ:IDRA), a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of novel oligonucleotide therapeutics for oncology and rare diseases, today announced it has entered into a clinical development support agreement with Pillar Partners Foundation ("Pillar Partners"). Under the terms of the agreement Pillar Partners will provide direct funding to support three investigator initiated clinical trials to further strategically expand the clinical research of IMO-2125, Idera's toll-like receptor ("TLR") 9 agonist into broader melanoma populations and other solid tumors. For these trials, Idera will provide IMO-2125. Idera is currently enrolling a Phase 3 ("ILLUMINATE-301") trial of intratumoral administration of IMO-2125 in combination with ipilimumab in patients with anti-PD-1 refractory metastatic melanoma.

The three trials within the terms of this agreement are:

- A Phase 1/2 open label study of intratumoral IMO-2125 in combination with intratumoral ipilimumab and IV nivolumab in a protocol open to multiple tumor types including non-small cell lung cancer ("NSCLC"), melanoma, squamous cell carcinoma of the head and neck and urothelial carcinoma. The principal investigator initiating this trial is Aurélien Marabelle, MD, PhD, Clinical Director of the Cancer Immunotherapy Program at Institut Gustave Roussy, Villejuif, France.
- A Phase 2 study of intratumoral IMO-2125 in combination with IV pembrolizumab in patients with NSCLC. The principal investigator initiating this trial is Arafat Tfayli, MD, FRCP, Professor of Clinical Medicine, Director of Research, NK Basile Cancer Institute, American University of Beirut Medical Center, Beirut, Lebanon.
- A Phase 2 placebo controlled study of intradermal administration of IMO-2125 in patients with T3/T4 primary melanoma scheduled to undergo a combined re-excision and sentinel node biopsy procedure. The principal investigators initiating this trial are Bas Koster, MD, Fons van den Eertwegh MD, PhD, and Tanja de Gruijl, PhD, who is Professor of Translational Tumor Immunology and Co-Director of the Cancer Immunology Program at the VU University Medical Center, Cancer Center Amsterdam, The Netherlands.

"We are eager to expand our knowledge and understanding of the various cancer types and combinations in which IMO-2125 can play a significant role in improving outcomes beyond our current registrational focus with our ILLUMINATE 301 program," stated Joanna Horobin, M.B., Ch. B., Idera's Chief Medical Officer. "We look forward to working with these investigators to provide the support they need to initiate these trials before the end of the year," said Shah Rahimian, MD, Idera's Oncology Medical Lead. "

"We have long believed and understood that the mechanism for IMO-2125 has broad potential and plays a central role in IO combinations beyond PD-1 refractory melanoma and through this financial grant, we are able to help light the spark to further expand our ability to test this hypothesis in multiple tumor types with expert clinical investigators," stated Youssef El Zein, Managing Partner, Pillar Invest Corporation.

About Idera

Harnessing the approach of the earliest researchers in immunotherapy and Idera's vast experience in developing proprietary immunology platforms, Idera's lead development program is focused on priming the immune system to play a more powerful role in fighting cancer, ultimately increasing the number of people who can benefit from immunotherapy. Idera continues to invest in research and development and is committed to working with investigators and partners who share the common goal of addressing the unmet needs of patients suffering from rare, life-threatening diseases. To learn more about Idera, visit www.iderapharma.com.

About IMO-2125

IMO-2125 is a TLR 9 agonist that received Fast Track Designation from the US Food and Drug Administration ("FDA") in 2017 for the treatment of PD-1 refractory melanoma, in combination with ipilimumab as well as orphan drug designation from the FDA for the treatment of melanoma Stages IIb to IV. It signals the immune system to create and activate cancer-fighting cells ("T-cells") to target solid tumors. Currently approved immuno-oncology treatments, specifically check-point inhibitors, work for some but not all, as many patients' immune response is missing or weak and thus they do not benefit from the checkpoint therapy. Intratumoral injections with IMO-2125 are designed to selectively enable the T-cells to recognize and attack

cancers that remained elusive and unrecognized by the immune system exposed to checkpoint inhibitors alone, while limiting toxicity or impact on healthy cells in the body.

About ILLUMINATE-204

The Illuminate 204 study (2125-204) is for patients who have metastatic melanoma for whom treatment with an anti-PD-1 drug like Keytruda® (pembrolizumab) or Opdivo® (nivolumab) has failed. Melanoma is the most dangerous type of skin cancer. When it is metastatic, it means that the melanoma has spread to different parts of the body. Illuminate 204 is a multi-center, two-arm Phase 1/2 study that tests the safety and effectiveness of IMO-2125 in combination with either ipilimumab (Yervoy®) or pembrolizumab (Keytruda®) for the treatment of patients with PD-1 refractory metastatic melanoma.

For additional details about Illuminate 204, please go to clinicaltrials.gov and search for study identifier NCT02644967.

About ILLUMINATE-301

The Illuminate 301 study (2125-MEL-301) is for patients who have metastatic melanoma for whom treatment with an anti-PD-1 drug like Keytruda® (pembrolizumab) or Opdivo® (nivolumab) has failed. Illuminate 301 is a multi-center, randomized Phase 3 study that compares the effectiveness and safety between two treatment groups: IMO-2125 combined with ipilimumab (Yervoy®) versus ipilimumab given alone.

For additional details about Illuminate 301, please go to clinicaltrials.gov and search for study identifier NCT03445533.

About Pillar Partners Foundation

Pillar Partners Foundation is the philanthropic arm of Pillar Partners, a private investment group committed under the management of Youssef El Zein and Abude Umari to the development of proprietary biotechnologies that address large unmet medical needs. The Pillar Partners Foundation has made numerous charitable contributions to pioneering medical research in the fields of innate immunity and gene therapy and to the advancement of the clinical development of immuno-oncology, including the creation of the Pillar Chair in Biomedical Research at the University of Massachusetts Medical School and the Pillar Genomics Institute of Precision Medicine at the American University of Beirut Medical Center.

Forward Looking Statements

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements, other than statements of historical fact, included or incorporated in this press release, including statements regarding the Company's strategy, future operations, collaborations, intellectual property, cash resources, financial position, future revenues, projected costs, prospects, clinical trials, plans, and objectives of management, are forward-looking statements. The words "believes," "anticipates," "estimates," "plans," "expects," "intends," "may," "could," "should," "potential," "likely," "projects," "continue," "will," and "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Idera cannot guarantee that it will actually achieve the plans, intentions or expectations disclosed in its forward-looking statements and you should not place undue reliance on the Company's forward-looking statements. There are a number of important factors that could cause Idera's actual results to differ materially from those indicated or implied by its forward-looking statements. Factors that may cause such a difference include: whether the Company's cash resources will be sufficient to fund the Company's continuing operations and the further development of the Company's programs for the period anticipated; whether interim results from a clinical trial, such as the preliminary results reported in this release, will be predictive of the final results of the trial; whether results obtained in preclinical studies and clinical trials such as the results described in this release will be indicative of the results that will be generated in future clinical trials, including in clinical trials in different disease indications; whether products based on Idera's technology will advance into or through the clinical trial process when anticipated or at all or warrant submission for regulatory approval; whether such products will receive approval from the U.S. 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; and such other important factors as are set forth under the caption "Risk factors" in the Company's Annual Report filed on Form 10-K for the period ended December 31, 2017. Although Idera may elect to do so at some point in the future, the Company does not assume any obligation to update any forward-looking statements and it disclaims any intention or obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

Idera Pharmaceuticals Contact:

Robert A. Doody, Jr.
VP, Investor Relations & Communications
Phone (484) 639-7235
rdoody@iderapharma.com



Source: Idera Pharmaceuticals, Inc.