# Idera Pharmaceuticals Announces Launch of Global Phase 3 Trial Evaluating IMO-2125 in Combination with Ipilimumab for the Treatment of Anti-PD-1 Refractory Melanoma (ILLUMINATE 301)

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## - Clinical trial targeting enrollment of approximately 300 anti-PD-1 refractory melanoma patients at approximately 80 global trial sites -

EXTON, Pa. and CAMBRIDGE, Mass., March 01, 2018 (GLOBE NEWSWIRE) -- Idera Pharmaceuticals, Inc. (NASDAQ:IDRA), a clinical-stage biopharmaceutical company developing toll-like receptor and RNA therapeutics for patients with rare cancers and rare diseases, announced the start of a Phase 3 global, multi-center, open-label clinical trial to evaluate the efficacy and safety of intratumoral IMO-2125 in combination with ipilimumab (Yervoy®) versus ipilimumab alone in subjects with anti-PD-1 refractory melanoma (NCT03445533). The initiation of the Phase 3 trial follows the announcement that IMO-2125 was granted Fast-Track designation by the U.S. Food and Drug Administration, a designation designed to expedite the development and review of drugs with the potential to treat serious or life-threatening conditions such as refractory metastatic melanoma.

Results presented at the 2017 European Society for Medical Oncology Congress (ESMO) meeting from the completed phase 1 portion of the ongoing Phase 1/2 clinical trial of intratumoral IMO-2125 in combination with ipilimumab (NCT02644967) show the combination to be well-tolerated over the entire range of IMO 2125 doses tested, with biopsy evidence for dendritic cell activation followed by infiltration of tumor specific immune cells. These results included 9 patients treated with the Recommended Phase 2 Dose (RP2D) of 8mg of which 4 (44%) achieved RECIST v1.1 responses, including one durable Complete Response (CR), with 6 of 9 (67%) patients experiencing disease control (CR, PR, or SD ≥ 12 weeks).

“For our advanced melanoma patients who have not benefited from anti-PD-1 therapy and in BRAF mutant melanoma, BRAF targeted therapy, there are very few, limited options available today,” stated Ahmad Tarhini, M.D., Ph.D, Director, Melanoma and Skin Cancer Program, Cleveland Clinic Taussig Cancer Institute. “I am encouraged by the data that has been demonstrated to date with IMO-2125 and am hopeful that this Phase 3 trial offers hope to this large group of patients whose treatment options are very limited.”

“We are excited to initiate the ILLUMINATE 301 Trial, grateful to our advisors who have worked with us to design this pivotal trial and very encouraged by the enthusiasm of investigators to participate in the study. We look forward to working together to conduct and complete this trial, so that we may bring IMO-2125 to the market as soon as possible for patients who are not benefiting from anti-PD-1 therapy,” stated Joanna Horobin, M.B., Ch.B., Idera’s Chief Medical Officer.

***ILLUMINATE 301 Trial Design***

ILLUMINATE 301 is planned in approximately 80 sites, across 10 countries, and expected to enroll approximately 300 subjects with advanced melanoma who have confirmed disease progression while on nivolumab (Opdivo®) or pembrolizumab (Keytruda®). Subjects will be randomized into two treatment arms (IMO-2125 in combination with ipilimumab vs. ipilimumab monotherapy). Subjects must have histologically confirmed metastatic melanoma with measurable (by Response Evaluation Criteria in Solid Tumors [RECIST] v1.1), Stage III (lymph node or in transit lesions) or Stage IVA, IVB, or IVC disease, and at least one lesion that is accessible for injection.

This Phase 3 study is being performed to provide definitive evidence for superiority of the IMO-2125 and ipilimumab combination over ipilimumab. The reported overall response rate for ipilimumab monotherapy following anti-PD-1 therapy is 13%[1]. The primary endpoint family includes overall survival and overall response rate. For more information on the study and patient qualifications, visit www.ideraclinicaltrials.com.

***About IMO-2125***

IMO-2125 is a toll-like receptor (TLR) 9 agonist that received orphan drug designation from the US Food and Drug Administration (FDA) in 2017 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 in refractory melanoma patients. Currently approved immuno-oncology treatments for patients with metastatic melanoma, 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 making them so-called “refractory.” The combination of ipilimumab and IMO-2125 appears to activate an immune response in these patients who have exhausted all options. 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 Metastatic Melanoma***

Melanoma is a type of skin cancer that begins in a type of skin cell called melanocytes. As is the case in many forms of cancer, melanoma becomes more difficult to treat once the disease has spread beyond the skin to other parts of the body such as the lymphatic system (metastatic disease). Because melanoma occurs in younger individuals, the years of life lost to melanoma are also disproportionately high when compared with other cancers. Although melanoma is a rare form of skin cancer, it comprises over 75% of skin cancer deaths. The American Cancer Society estimates that there were approximately 76,000 new invasive melanoma cases and 10,000 deaths from the disease in the USA in 2016. Additionally, according to the World Health Organization, about 132,000 new cases of melanoma are diagnosed around the world every year.

***About Idera Pharmaceuticals***

Harnessing the approach of the earliest researchers in immunotherapy and the Company’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.

***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, 2016. 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.

[1]Long, SMR, Nov. 2016.

***Investor and Media Contact***
Robert Doody
Vice President, Investor Relations and Corporate Communications
Office: 617-679-5515
Mobile: 484-639-7235
rdoody@iderapharma.com

Theresa Dolge
Chief Media Relations Officer
Tonic Life Communications
Office: 215-928-2748
Theresa.dolge@toniclc.com

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