U.S. FDA Grants Fast Track Designation for Idera Pharmaceuticals' IMO-2125 in Combination with Ipilimumab for Treatment of PD-1 Refractory Metastatic Melanoma

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Phase 3 Trial Initiation Planned for First Quarter 2018

CAMBRIDGE, Mass. and EXTON, Pa., Nov. 29, 2017 (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, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for the company's lead development candidate IMO-2125 in combination with Ipilimumab for the treatment of anti-PD-1 refractory metastatic melanoma in combination with ipilimumab therapy. FDA's Fast Track program is designed to expedite the development and review of drugs and biologics to treat serious or life-threatening conditions with non-clinical or clinical data demonstrating the potential to address unmet medical needs. Such drugs may qualify for Fast Track designation.[1]

"This Fast Track designation represents another positive step for the development of IMO-2125 and is a clear recognition of the serious unmet need that exists for patients who do not benefit from anti-PD-1 therapy," stated Joanna Horobin, M.B., Ch.B., Idera's Chief Medical Officer. "We're thrilled with the dramatic response rate that has been observed to date so far with IMO-2125 in combination with ipilimumab and are eager to continue enrolling more patients through both the Phase 2 expansion of our ongoing trial and initiating the Phase 3 trial early next year."

About Fast Track Designation[1]

Fast Track designation is intended to facilitate development and expedite review of drugs to treat serious or life-threatening conditions. A drug that is intended to treat a serious or life-threatening condition with nonclinical or clinical data that demonstrate the potential to address an unmet medical need may qualify for Fast Track designation. When Fast Track designation is requested later in development, available clinical data should demonstrate the potential to address an unmet medical need. There are opportunities for frequent interactions with the review team for a fast track product. In addition, such a product could be eligible for priority review if supported by clinical data at the time of BLA, NDA, or efficacy supplement submission.

About IMO-2125

IMO-2125 is a toll-like receptor (TLR) 9 agonist that received orphan drug designation from the 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 checkpoint 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, 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 interim results from a clinical trial, such as 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 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 IMO-2125 will successfully advance 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; and such other important factors as are set forth under the caption "Risk Factors" in the Company's Annual Report on form 10K 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] http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM358301.pdf

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

Source: Idera Pharmaceuticals, Inc.