Idera Pharmaceuticals Advances Investigational Treatment – Intratumoral IMO-2125 in Combination with Ipilimumab - for Unmet Need in Anti-PD-1 Refractory Metastatic Melanoma

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All objectives successfully met in Phase 1 portion of combination trial and the company is now enrolling the Phase 2 trial

CAMBRIDGE, Mass. and EXTON, Pa., April 11, 2017 (GLOBE NEWSWIRE) -- Idera Pharmaceuticals, Inc. (Nasdaq:IDRA), a clinical-stage biopharmaceutical company developing toll-like receptor and RNA therapeutics for patients with cancer and rare diseases, today announces successful completion of the phase 1 portion of the ongoing Phase 1/2 clinical trial of intratumoral IMO-2125. Intratumoral IMO-2125 is an agonist of TLR9, in combination with ipilimumab for the treatment of anti-PD-1 refractory metastatic melanoma. Enrollment has begun for the Phase 2 portion of the trial with the 8mg dose of intratumoral IMO-2125. The Phase 1 dose escalation of IMO-2125 in combination with pembrolizumab is ongoing.

"We are very pleased with the progress to date in the Phase 1 dose escalation trial of IMO-2125 in combination with ipilimumab, and with the outcomes observed," stated Joanna Horobin, M.B., Ch.B., Idera's Chief Medical Officer. "IMO-2125 in combination with ipilimumab demonstrated preliminary evidence of meaningful clinical activity in this anti-PD-1 refractory metastatic melanoma patient population which represents a high unmet medical need. All dose levels have been well tolerated and did not exacerbate the safety issues commonly observed with ipilimumab. Furthermore, data from multiple parameters of immune markers from tumor biopsies have been very informative in establishing proof-of-mechanism and supporting the dose selection for the Phase 2 portion of trial."

The Phase 2 portion of the trial utilizes a Simon two-stage design to evaluate the objective response rate of IMO-2125 in combination with ipilimumab, compared to historical data for ipilimumab alone in the anti-PD-1 refractory metastatic melanoma population. The ipilimumab arm of IMO-2125-204 has already met the pre-specified futility assessment to advance immediately into the second stage of the Phase 2 portion of the trial given that 2 patients treated at the Phase 2 dose experienced confirmed responses, including one complete response (CR).

All dose levels of IMO-2125 in the Phase 1 portion of the trial have been well tolerated; however the 8 mg dose level has been selected for the Phase 2 portion of the trial based on its safety, clinical efficacy, and data from multiple translational immune parameters supporting the mechanism. Phase 2 will evaluate twenty-one patients dosed at 8mg, of which 9 are already enrolled. The MD Anderson Cancer Center will continue to lead the trial and will be joined by additional centers. In addition to potential interim updates, the company expects to have overall response rate (ORR) data available in the first quarter of 2018.

Additionally, the company has begun and will continue to engage in discussions with regulatory authorities regarding the path to registration for IMO-2125 in combination with ipilimumab in PD-1 refractory metastatic melanoma patients.

The Phase 1 clinical trial of intratumoral IMO-2125 in combination with pembrolizumab in PD-1 refractory melanoma patients is enrolling as expected, and patient enrollment in a phase 1 trial of intratumoral IMO-2125 monotherapy in multiple tumor types has been activated and the first patient is expected to enroll early this quarter.

"I am very encouraged by the tremendous progress that has been made to date to advance us to this important stage in IMO-2125's development cycle," stated Vincent Milano, Idera's Chief Executive Officer. "There is a very clear unmet medical need for those patients for whom current checkpoint inhibitor therapies are not providing adequate solutions. We are incredibly focused on advancing this program as rapidly as possible for these patients, and we are also looking forward to exploring areas outside of melanoma in which intratumoral IMO-2125 may also serve an important role through its unique mechanism of action within the tumor microenvironment."

About the Phase 1/2 trial of IMO-2125 in combination with ipilimumab

The Phase 1/2 trial of intratumoral IMO-2125 in combination with ipilimumab is being conducted in patients who are refractory to anti-PD-1 therapy. The phase 1 portion of the trial was conducted at MD Anderson Cancer Center and the phase 2 portion of the trial will expand to include additional centers. In the Phase 1 portion of the trial, four dose levels of IMO-2125 (4, 8, 16 and 32 mg) have been administered intratumorally in one targeted lesion at weeks 1, 2, 3, 5, 8 and 11, in combination with the standard dosing regimen of ipilimumab, beginning on week 2. The Phase 2 expansion portion of the trial utilizes a Simon two-stage design. If at least 2 of the first 10 patients treated at the Phase 2 dose experience confirmed response the futility hurdle has been met and the trial may continue to enroll. Phase 2 will evaluate 21 patients at the phase 2 dose. Tumor biopsies have been collected pre- and post-24 hours of the first dose of IMO-2125, as well as at 8 and 13 weeks to evaluate multiple immune markers. Clinical activity has been evaluated by the RECIST v1.1 criteria. Clinical data from this study has been presented at SITC 2017, ASCO-SITC 2017 and AACR 2017, and can be found also on Idera's corporate website at http://www.iderapharma.com/our-approach/key-publications/.

About IMO-2125

Toll-like receptors (TLRs) play a central role in the innate immune system, the body's first line of defense against invading pathogens, as well as damaged or dysfunctional cells including cancer cells. The innate immune system is also involved in activating the adaptive immune system, which marshals highly specific immune responses to target pathogens or tissue. Cancer cells may exploit regulatory checkpoint pathways to avoid being recognized by the immune system, thereby shielding the tumor from immune attack. Checkpoint inhibitors such as agents targeting CTLA4 or programmed cell death protein 1 (PD1) are designed to enable the immune system to recognize tumor cells. In this setting, intratumoral TLR9 agonist administration may increase the tumor-infiltrating lymphocytes (TILs), and thereby potentiate anti-cancer activity of checkpoint inhibitors in the injected tumor as well as systemically.

IMO-2125, Idera's TLR9 agonist, has been created using the company's proprietary chemistry-based discovery platform. IMO-2125 has been shown in various scientific presentations and publications to activate dendritic cells and induce interferon. Idera selected IMO-2125 to advance into clinical development in combination with checkpoint inhibitors based on this immunological profile. In previously completed clinical trials, subcutaneous administration of IMO-2125 was very well tolerated in about 114 patients with hepatitis C. Idera has conducted further preclinical and clinical research evaluating the potential of IMO-2125 to enhance the anti-tumor activity of other checkpoint inhibitors in cancer immunotherapy with data has been presented at several scientific and medical conferences during the past few years. The posters from these presentations can be found at http://www.iderapharma.com/our-approach/key-publications.

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 by through the lymphatic system (metastatic disease). Melanoma accounts for only one percent of skin cancer cases, but causes a large majority of skin cancer deaths. The American Cancer Society estimates that in 2017, there will be 87,110 new cases of melanoma in the U.S., and about 9,730 will die of this disease. Based on proprietary Idera research, the company anticipates by the year 2025, there will be roughly 13,000 anti-PD-1 refractory metastatic melanoma patients.

About Idera Pharmaceuticals
Idera Pharmaceuticals is a clinical-stage biopharmaceutical company developing novel nucleic acid-based therapies for the treatment of certain cancers and rare diseases. Idera's proprietary technology involves designing synthetic oligonucleotide-based drug candidates to modulate the activity of specific TLRs. In addition to its TLR programs, Idera has used its proprietary knowledge to create a third generation antisense technology platform which inhibits the production of disease-associated proteins by targeting RNA. 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.

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