



Idera Pharmaceuticals Announces Preliminary Data From and Planned Continuation of the ILLUMINATE-206 Trial for the Treatment of Micro-Satellite Stable Colorectal Cancer

June 2, 2020 12:15 PM EDT

EXTON, Pa., June 02, 2020 (GLOBE NEWSWIRE) -- Idera Pharmaceuticals, Inc. (Nasdaq: IDRA; the "Company") today announced preliminary data from the first 10 patients in the safety cohort of ILLUMINATE-206, a Phase 2, open-label, multi-center study to evaluate tilsotolimod in combination with Opdivo® (nivolumab) and Yervoy®* (ipilimumab) in immunotherapy-naïve micro-satellite stable colorectal cancer (MSS-CRC) patients. Based on data to date, the Company plans to expand the study to further evaluate this triplet combination in MSS-CRC.

To investigate the safety profile of this triplet combination, ILLUMINATE-206 was designed with a stepwise approach to Yervoy® dosage. Patients in this initial safety cohort of the study, many of whom were heavily pre-treated and rapidly progressing, received 8 mg of intratumoral tilsotolimod and 3 mg/kg of intravenous (IV) Opdivo® every 2 weeks, along with 1 mg/kg of IV Yervoy® every 8 weeks. This regimen was generally well tolerated; no patients discontinued treatment due to adverse events (AEs) and none experienced Grade 4 or 5 AEs. One patient experienced stable disease per RECIST v1.1 criteria, and 9 patients progressed as defined by RECIST v1.1. Investigators reported that 6 of the progressing patients had stability or reduction in size of injected lesions and 6 had stability or reduction in overall size of uninjected lesions.

Based on these results, the Company plans to enroll additional patients in this MSS-CRC cohort of ILLUMINATE-206. Planned changes in the study design intended to improve potential outcomes in this patient population include increasing the frequency of Yervoy® dosing and limiting the number of allowed prior lines of treatment to two or fewer. Enrollment of the next 10 patients is targeted to begin in the fourth quarter of 2020, with data anticipated in the second quarter of 2021. Pending data from those patients, the trial may be expanded further.

"We are encouraged by the initial safety profile of this first-time triplet combination," stated Elizabeth A. Tarka, M.D., Idera's Chief Medical Officer. "We look forward to continuing to explore the potential clinical benefit of tilsotolimod in combination with ipilimumab and nivolumab in MSS-CRC, possibly yielding a treatment alternative for these patients with few current options."

For more information about ILLUMINATE-206, visit www.ClinicalTrials.gov.

About Tilsotolimod (IMO-2125)

Tilsotolimod is an investigational, synthetic Toll-like receptor 9 agonist. Intratumoral injection of tilsotolimod has been shown to promote both innate (Type-I IFN, antigen presentation) and adaptive (T cells) immune activation. Tumors with an active immune response appear to respond better to CPIs than those that exclude or inhibit anti-tumor immune cells. Tilsotolimod in combination with CPIs may cause regression of locally injected and distant tumor lesions and increase the number of patients who benefit from immunotherapy.

Tilsotolimod received Fast Track Designation from the U.S. Food and Drug Administration (FDA) for the treatment of anti-PD-1 refractory melanoma, in combination with ipilimumab, as well as Orphan Drug Designation for the treatment of stage IIb-IV melanoma. It is being evaluated in multiple tumor types and in combination with multiple checkpoint inhibitors. For more information on tilsotolimod trials, please visit www.ClinicalTrials.gov.

About MSS-CRC

Colorectal cancer involves the abnormal growth of cells in the colon or rectum. This type of cancer is typically tested to determine its "MSI" status, which will inform treatment approach and prognosis. MSI stands for "microsatellite instable." MSI-High (MSI-H) means that there is a high amount of instability in a tumor, whereas MSS tumors are "microsatellite stable." According to the American Cancer Society and other references, annually in the United States, approximately 140,000 people are diagnosed with CRC, of which 85% are MSS, and approximately 50,000 deaths are attributed to CRC. MSS-CRC has been shown to be highly immunosuppressive; there are no approved immunotherapy options, and a prior trial of Yervoy® plus Opdivo® (Bristol Myer Squibb's CheckMate 142) yielded overall response rates of 0-10%. Given tilsotolimod's mechanism of action of activating dendritic cells, it may serve a complementary function to Yervoy® and Opdivo® within the immunosuppressive tumor microenvironment of MSS-CRC patients.

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 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 also continues to focus on the acquisition, development, and ultimate commercialization of drug candidates for both oncology and rare disease indications characterized by small, well-defined patient populations with serious unmet needs. To learn more about Idera, visit www.iderapharma.com.

Forward Looking Statements

This press release contains forward-looking statements within the meaning of the safe harbor of the Private Securities Litigation Reform Act of 1995 and the Federal securities laws. All statements, other than statements of historical fact, included or incorporated in this press release, including statements regarding the Company's strategy, financial position and clinical trial plans, including enrollment and timing of results, are forward-looking statements. The words "believes," "anticipates," "estimates," "plans," "expects," "intends," "may," "could," "should," "potential," "likely," "projects," "continue," "will," "schedule," and "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements are predictions based on the Company's current expectations and projections about future events and various assumptions. 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. These forward-looking statements involve known and unknown risks, uncertainties, and other factors, which may be beyond Idera's control, and which may cause the actual results, performance, or achievements of the Company to be materially different from future results, performance, or achievements expressed or implied by such 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 including, without limitation: 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; whether interim results from a clinical trial 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 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 FDA or equivalent foreign regulatory agencies; whether, if the Company's products receive approval, they will be successfully distributed and marketed; and whether the Company's collaborations will be successful. All forward-looking statements included in this release are made as of the date hereof, and are expressly qualified in their entirety by this cautionary notice, including, without limitation, those risks and uncertainties described in the Company's Annual Report on Form 10-K for the year ended December 31, 2019, and otherwise in the Company's filings and reports filed with Securities and Exchange Commission. While 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, except as may be required by law.

*Opdivo (nivolumab) and Yervoy (ipilimumab) are registered trademarks of Bristol Myers Squibb.

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Source: Idera Pharmaceuticals, Inc.