Idera Pharmaceuticals Completes Enrollment in ILLUMINATE-301, its Registrational Trial of Tilsotolimod in Combination with Ipilimumab in Patients with Anti-PD-1 Refractory Advanced Melanoma

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Overall Response Rate (ORR) Data Anticipated Q1 2021

EXTON, Pa., March 05, 2020 (GLOBE NEWSWIRE) -- Idera Pharmaceuticals, Inc. (“Idera” or “the company”) (NASDAQ: IDRA) today announced completion of patient enrollment into ILLUMINATE-301, its registrational trial of tilsotolimod in combination with ipilimumab in patients with anti-PD-1 refractory advanced melanoma. The company expects to announce top-line overall response rate (ORR) and other preliminary data from ILLUMINATE-301 in Q1 2021.

“We are making outstanding progress in moving toward our goal of delivering tilsotolimod to the market in our lead indication for anti-PD-1 refractory advanced melanoma patients,” stated Vincent Milano, Idera’s Chief Executive Officer. “We achieved this critical milestone earlier than anticipated, which we believe is truly a testament to the high unmet need facing these patients.”

Added Elizabeth Tarka, M.D., Idera’s Chief Medical Officer, “We believe tilsotolimod in combination with ipilimumab may be an important new therapeutic option for these patients, and we are incredibly grateful to them, their families, and our investigators for their participation in ILLUMINATE-301. We look forward to sharing the results of this exciting trial soon.”

ILLUMINATE-301 is a randomized, phase 3 trial comparing the effectiveness of intratumoral tilsotolimod in combination with ipilimumab with ipilimumab alone in patients with anti-PD-1 refractory advanced melanoma, with a primary endpoint family of ORR per RECIST v1.1 and overall survival (OS). Key secondary endpoints include durable response rate, time to response, progression-free survival, patient-reported outcomes, and safety. ILLUMINATE-301 enrolled 481 patients across 80 sites in 11 countries.

About Anti-PD-1 Refractory Advanced Melanoma
Melanoma is a cancer that begins in a type of skin cell called melanocytes. While melanoma is one of the least common types of skin cancer, it has a poor prognosis when not detected and treated early. As is the case in many forms of cancer, melanoma becomes more difficult to treat once the disease has spread, or metastasized, beyond the skin to other parts of the body. According to the American Cancer Society, approximately 100,000 people in the US will be diagnosed with invasive melanoma this year. In recent years, pioneering immunotherapies known as checkpoint inhibitors (CPIs) have changed the treatment of advanced melanoma and have become the standard of care, with anti-PD-1 agents being the most commonly used immunotherapy in the first-line setting. These agents work by increasing the ability of the body’s immune system to help detect and fight cancer cells. However, due to primary or acquired resistance mechanisms that exclude or inhibit anti-tumor immune cells, as many as 60% of patients do not benefit from this type of therapy, and up to one-third of initial responders develop resistance to the therapy and ultimately experience disease progression. Today, these refractory patients are left with few options for further treatment, paving the way for novel investigational therapies such as tilsotolimod.

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. Thus, 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 has received both Fast Track designation and Orphan Drug designation from the FDA and 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 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 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, and clinical trial plans, including 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, 2018, 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.

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