Idera Pharmaceuticals Announces Initiation of the ILLUMINATE-206 Trial Evaluating Tilsotolimod in Combination with Nivolumab and Ipilimumab for the Treatment of Solid Tumors

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EXTON, Pa., Sept. 30, 2019 (GLOBE NEWSWIRE) -- Idera Pharmaceuticals, Inc. (NASDAQ: IDRA) announced today the initiation of a phase 2 trial, ILLUMINATE-206 which will evaluate tilsotolimod, a toll-like receptor 9 (TLR9) agonist, in combination with nivolumab, a programmed death receptor-1 (PD-1) blocking antibody, and ipilimumab, a human cytotoxic T-lymphocyte antigen 4 (CTLA-4) blocking antibody for the treatment of solid tumors.

The primary objective of this phase 2, open-label, global, study is to demonstrate efficacy (measured by overall response rate [ORR] based on RECIST v.1.1). Secondary and exploratory objectives include safety, tolerability, immunogenicity and translational data evaluations.

The initial cohort of the trial will be patients with immunotherapy-naive Microsatellite Stable Colorectal Cancer (MSS-CRC). The second planned cohort of ILLUMINATE-206 will focus on treating patients with anti-PD(L)-1 refractory Squamous Cell Carcinoma of the Head and Neck (RM-SCCHN), which will initiate in the fourth quarter of this year.

“Initiation of this Phase 2 study is an important step toward understanding the broader applications of tilsotolimod,” stated Elizabeth A. Tarka, M.D., F.A.C.C., Idera’s Chief Medical Officer. “Demonstrating the potential benefit of tilsotolimod in patients with specific solid tumors where the disease setting under investigation have no approved immunotherapies, would be a significant contribution to the treatment paradigm.”

The basis for this trial is supported by data generated from the ILLUMINATE-101 trial, which studied intratumoral tilsotolimod monotherapy in 45 evaluable patients with a variety of solid tumor types in which 33% (n=15) achieved stable disease. Translational research in ILLUMINATE-101, demonstrated that tilsotolimod increased dendritic cell activation and upregulated MHC class II and IFN-α signaling which suggests improved antigen presentation. These findings are consistent with those observed in the ILLUMINATE-204 trial in anti-PD-1 refractory metastatic melanoma patients. Therefore, the mechanism of action for tilsotolimod may be tumor-type agnostic and potentially beneficial in combination with checkpoint modulation in a variety of tumor types.

A poster presentation from ILLUMINATE-101 is being presented at the European Society for Medical Oncology (ESMO) 2019 Congress in Barcelona, Spain today and can be found in the Key Publications section of Idera’s Corporate website, www.iderapharma.com.

On March 11, 2019, Idera and Bristol-Myers Squibb (BMS) entered into a clinical trial collaboration and supply agreement in which BMS has agreed to supply YERVOY* (ipilimumab) and OPDIVO (nivolumab) for no charge for use in ILLUMINATE-206.

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.

Idera 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 including statements regarding our expectations for the ILLUMINATE-206 Trial. 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 filings with the 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.

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

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