Idera Pharmaceuticals Presents ILLUMINATE-101 Data Demonstrating Tilsotolimod Activates Innate and Adaptive Immunity as Monotherapy in Patients with Refractory Solid Tumors at the American Association for Cancer Research (AACR) 2019 Annual Meeting

April 2, 2019 11:00 AM EDT

– Tilsotolimod activated IFN-α and MHC class II genes in the tumor microenvironment across multiple tumor types –

EXTON, Pa., April 02, 2019 (GLOBE NEWSWIRE) -- Idera Pharmaceuticals, Inc. ("Idera") (NASDAQ: IDRA), a clinical-stage biopharmaceutical company focused on the development, and ultimately the commercialization, of therapeutic drugs for both oncology and rare disease indications, today is reporting clinical and translational data from the ILLUMINATE-101 Phase 1 study which explored the role of investigational tilsotolimod as monotherapy in patients with various refractory solid tumors. Data will be presented at the AACR 2019 Annual Meeting being held in Atlanta, GA.

In the poster presentation entitled, "Activation of Innate and Adaptive Immunity Using Intratumoral Tilsotolimod (IMO-2125) as Monotherapy in Patients with Refractory Solid Tumors: a Phase 1b Study (ILLUMINATE-101)" (abstract number 4062), Hani Babiker, M.D., Assistant Professor of Medicine and Associate Director of the Phase 1 Program at the University of Arizona Cancer Center, presented results from this study.

"Tilsotolimod's therapeutic mission is to alter the immune conditions within the tumor microenvironment to help provide more favorable conditions for checkpoint inhibitors to help achieve successful outcomes for patients," stated Dr. Babiker. "We typically would not expect to see substantial tumor reduction with tilsotolimod monotherapy; however, it is highly encouraging to see the number and duration of stable diseases, including some with tumor reductions, from this study across a wide spectrum of difficult-to-treat refractory solid tumor types. The finding from this study bodes well for both the ILLUMINATE-301 Phase 3 trial and the upcoming ILLUMINATE-206 trial of tilsotolimod in combination with ipilimumab and nivolumab in multiple planned tumor types, including those that have not responded favorably to immunotherapy to date."

The poster will be presented on Tuesday, April 2, 2019 during the Biomarkers and Immune Monitoring poster session from 1:00 PM to 5:00 PM at the Georgia World Congress Center, Exhibit Hall B.

In the ILLUMINATE-101 study, patients with histologically or cytologically confirmed diagnosis of metastatic refractory solid tumors were enrolled into 4 ascending dose cohorts to receive tilsotolimod (8mg, 16mg, 23mg and 32mg) injected into a single lesion. Tumor biopsies of injected and distant lesions were obtained at baseline and at 24 hours and 6 weeks after commencing treatment.

ILLUMINATE-101 FINDINGS
Safety Data

- No dose limiting toxicities or treatment-related adverse events were observed;
- No treatment-emergent adverse events (TEAEs) leading to treatment or study discontinuation or death occurred; and
- The most common grade 3/4 TEAEs were anemia, hyponatremia, pain, sepsis (n=3 each), fatigue and thrombocytopenia (n=2 each).

Efficacy Data

- Of 29 evaluable patients, 13 (45%) had a RECIST v1.1 disease assessment of stable disease (SD), with a disease control rate of 45%;
- Of the 13 patients with SD, 5 (38%) had maximum tumor shrinkage >10% below baseline;
- Duration of SD ranged from 1.3 to 9.7+ months from start of treatment, with 3 patients ongoing; and
- No correlations between dose and efficacy were observed.

Translational Data

- Fresh flow cytometry in 2 of 3 analyzed patients showed HLA-DR (MHC Class II) upregulation at 24 hours compared with pre-treatment; and
- Robust activation and upregulation of type I IFN pathway was observed across analyzed tumor types, demonstrated by increased IRF7, IFIT1, and IFIT2 gene expression, and early increases in type I IFN signaling.

"The findings from ILLUMINATE-101 further strengthen the body of clinical evidence showing that tilsotolimod alters the immune landscape within the

tumor microenvironment, setting the stage for potentially higher response rates when combined with other immune-oncology agents," stated Joanna Horobin, M.B. Ch.B, Idera's Senior Vice President, Chief Medical Officer. "This approach appears to induce upregulation of antigen presentation regardless of tumor type which increases our confidence as we initiate the ILLUMINATE-206 trial (NCT03865082) initially focused on treating patients with squamous cell carcinoma of the head and neck (SCCHN) and microsatellite stable colorectal cancer (MSS-CRC)."

A copy of the poster presentation is available on Idera's corporate website at http://www.iderapharma.com/our-approach/key-publications/.

About Tilsotolimod (IMO-2125)
Tilsotolimod is a TLR 9 agonist that received Fast Track Designation from the US Food and Drug Administration (FDA) in 2017 for the treatment of anti-PD-1 refractory melanoma, in combination with ipilimumab as well as orphan drug designation from the FDA 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. Currently approved immuno-oncology treatments, specifically check-point inhibitors, work for some but not all, as many patients' immune response is missing or weak and thus they do not benefit from checkpoint therapy. Intratumoral injections with tilsotolimod are designed to selectively enable the tumor-specific 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 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 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, 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, including 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 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; whether products based on the company'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 set forth under the caption "Risk Factors" in the company's Annual Report on Form 10-K for the year ended December 31, 2018. 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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