Idera Pharmaceuticals Presents Positive Translational and Clinical Data Update from Ongoing IMO-2125 Development Program at the 2017 Society for Immunotherapy of Cancer Annual Meeting (SITC)

November 9, 2017 12:30 PM EST

- Available Translational Data Continue to Demonstrate Correlation between Proliferation and Clonal Expansion of T-Cells to Clinical Responses -

- An additional 5th Unconfirmed RECIST v1.1 Response Observed in 10th Evaluable Patient from Ongoing IMO-2125 8mg Phase 2 Dose Expansion Cohort -

CAMBRIDGE, Mass. and EXTON, Pa., Nov. 09, 2017 (GLOBE NEWSWIRE) -- Idera Pharmaceuticals, Inc. (NASDAQ:IDRA), a clinical-stage biopharmaceutical company developing toll-like receptor and RNA therapeutics for patients with rare cancers and rare diseases, today announced updated translational data from the ongoing Phase 1/2 study of intratumoral IMO-2125 in combination with ipilimumab for the treatment of anti-PD-1 refractory metastatic melanoma. These data will be presented at 4:45 P.M. E.T. on Saturday, November 11th in Maryland Ballroom A at the Gaylord National Hotel & Conference Center as part of Concurrent Session 207: Clinical Trials: Novel Combinations at the 2017 Society for Immunotherapy of Cancer Annual Meeting being held in National Harbor, MD.

In the oral presentation entitled, "TLR9 agonist harnesses innate immunity to drive tumor-infiltrating T-cell expansion in distant lesions in a Phase 1/2 study of intratumoral IMO-2125 plus ipilimumab in anti-PD-1 refractory melanoma patients," Cara Haymaker, Ph.D., from The University of Texas, MD Anderson Cancer Center, will present an update of the essential translational findings from the Ongoing Phase 1/2 trial of IMO-2125. Adults with anti-PD-1 refractory, unresectable stage III/IV melanoma were enrolled. IMO-2125, escalating from 4 – 32 mg is administered under image guidance, intratumorally on weeks 1, 2, 3, 5, 8, and 11 with standard ipilimumab. Biopsies were obtained in both the injected and distant tumor at baseline, 1 day and 8 weeks (W8) post injection. Immune analyses included phenotypic, activation, and functional characterization of DC subsets and T cells. T-cell repertoire diversity was evaluated by high-throughput CDR3 sequencing and changes in gene expression signatures were assessed by nanoString.

Key Highlights to be Presented Include:

- IMO-2125 induces a strong Type 1 interferon gene signature, macrophage influx and robust dendritic cell (DC) maturation post-injection;
- Combination therapy induces CD8+ T-cell proliferation and activation that is preferential to the tumor;
- The hallmark of observed tumor shrinkage appears to be the presence of Ki67+ CD8+ T-cell effector cells in the distant/un-injected tumor;
- Major T-cell clones expanding on therapy in responding patients are shared between local/injected and distant/un-injected lesions, indicating that priming/reactivation is to a shared antigen;
- Additionally, the company announced that since the last clinical data update provided at the European Society of Medical Oncology Conference in September, an additional (5th) unconfirmed RECIST v.1.1 response has been observed in the 10th evaluable patient to date.

"These important translational findings continue to strengthen our understanding of the critical role of intratumoral IMO-2125 therapy in the priming of T-cells and activation of the tumor microenvironment to produce durable tumor shrinkage when administered with ipilimumab in patients with anti PD-1 refractory metastatic melanoma," stated Joanna Horobin, M.B., Ch.B., Idera's Chief Medical Officer. "Our team at Idera is driving this program forward with purpose and rigor in order to bring this approach to patients rapidly. I look forward to the initiation of the phase 3 study in the first quarter of 2018."

A copy of the oral presentation as well as a related poster will be available Saturday, November 11, 2017 at 4:45 P.M. E.T. on Idera's corporate website at http://www.iderapharma.com/our-approach/key-publications/.

About the Phase 1/2 trial of IMO-2125 in combination with ipilimumab (NCT02644967)
Study 2125-204 is a Phase 1/2 open-label study of intratumoral IMO-2125 given in combination with either ipilimumab or pembrolizumab to patients with PD-(L)1 refractory melanoma with a planned enrollment of approximately 90 patients. IMO-2125 is given in escalating dosages from 4 to 32 mg combined with either ipilimumab (3 mg/kg i.v. every 3 weeks for 4 doses) or pembrolizumab (2 mg/kg i.v. every 3 weeks). Study endpoints are safety, tumor response, pharmacodynamics, and pharmacokinetics. Serial biopsies of both the injected and a distant tumor are being performed for translational immunologic studies. Preliminary data, presented at SITC 2016, ASCO-SITC 2017, AACR 2017, and CRI-CIMT-EATI-AACR 2017 are available on Idera's website (http://www.iderapharma.com/our-approach/key-publications/).

About IMO-2125
IMO-2125 is a toll-like receptor (TLR) 9 agonist that received orphan drug designation from the FDA in 2017 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 in refractory melanoma patients. Currently approved immuno-oncology treatments for patients with metastatic melanoma, 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 the checkpoint therapy making them so-called "refractory". The combination of ipilimumab and IMO-2125 appears to activate an immune response in these patients who have exhausted all options. Intratumoral injections with IMO-2125 is designed to selectively enable the 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 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 the lymphatic system (metastatic disease). Because melanoma occurs in younger individuals, the years of life lost to melanoma are also disproportionately high when compared with other cancers. Although melanoma is a rare form of skin cancer, it comprises over 75% of skin cancer deaths. The American Cancer Society estimates that there were approximately 76,000 new invasive melanoma cases and 10,000 deaths from the disease in the USA in 2016. Additionally, according to the World Health Organization, about 132,000 new cases of melanoma are diagnosed around the world every year.

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 continues to invest in research and development, and is committed to working with investigators and partners who share the common goal of addressing the unmet needs of patients suffering from rare, life-threatening diseases. 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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