Idera Pharmaceuticals Provides Update on Corporate Strategy and Outlook

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EXTON, Pa., July 16, 2018 (GLOBE NEWSWIRE) -- Idera Pharmaceuticals, Inc. (NASDAQ:IDRA), a pharmaceutical company focused on the development and commercialization of its proprietary immune modulator, tilsotolimod, for the treatment of cancer, is providing an update on the company's corporate strategy and outlook following the recent termination of its proposed merger with BioCryst Pharmaceuticals.

Vincent Milano, Idera's Chief Executive Officer stated, "Today, we advance the next chapter of our company's future with a clear picture of our mission, which is to ultimately deliver tilsotolimod to as many patients suffering from cancer as we possibly can. We have generated a significant body of evidence for tilsotolimod, including pre-clinical studies, translational research and meaningful clinical data in our ongoing ILLUMINATE-204 trial in anti-PD-1 refractory melanoma, as well as Fast Track Designation from the Food and Drug Administration. This gives us a great deal of confidence in tilsotolimod's ability to prime the immune system to play a more powerful role in the fight against cancer, representing an exciting value proposition for both shareholders and patients."

Milano continued, "We are executing on the pivotal Phase 3 trial, ILLUMINATE-301, in anti-PD-1 refractory melanoma and are partnering with three separate planned investigators/institutions in support of their respective investigator sponsored trials (ISTs), each of which is exploring tilsotolimod in different patient populations. Through the body of data we've generated to date, as well as from our discussions with our key opinion leader advisors, it has become abundantly clear to us that tilsotolimod has the opportunity to play a more expanded role in the immuno-oncology landscape, particularly in tumor types with limited immunogenicity that have not previously responded well to check-point inhibition approaches."

Financial Outlook and Other Corporate Updates

Idera ended the 1st Quarter of 2018, with cash and cash equivalents totaling $107.5 million, which as of the reporting of the first quarter of 2018 is anticipated to fund current operations into the third quarter of 2019. Subsequently, Idera announced an agreement with Bristol-Myers Squibb related to the funding of ipilimumab for the ILLUMINATE-301 trial, the cost of which we had previously budgeted for in our cash forecast, and as a result of the terminated merger with BioCryst Pharmaceuticals we also received $6 million in related fees. These two items have not yet been reflected in the Company's financial runway and will be updated as the results of the 2 nd quarter of 2018 are reported.

In addition, as previously disclosed on June 20, 2018, shareholders voted to approve giving the Board of Directors discretion to implement a reverse stock split of not less than 1-for-4 and not more than 1-for-8.

Idera has Significant Near-term Milestones Representing Substantial Value Creation Opportunities:

• Continued updates on ILLUMINATE-204 Phase 2 trial of tilsotolimod in combination with ipilimumab in patients with PD-1 refractory melanoma at upcoming medical conferences;

- Recently increased trial sites open to enrollment to 7, (3 additional planned);
- Expected completion of enrollment (N=60 patients) by year end 2018;

• Data update following completion of ILLUMINATE-204 Pembrolizumab combination Phase 1 component of the trial;

• Data from ILLUMINATE-101 tilsotolimod monotherapy trial;

• Complete enrollment in ILLUMINATE-204 with topline data in mid-2019;

• Initiation of Investigator Sponsored Trials (IST):

- A Phase 1/2 open label study of intratumoral tilsotolimod in combination with intratumoral ipilimumab and IV nivolumab in a protocol open to multiple tumor types including non-small cell lung cancer (NSCLC), melanoma, squamous cell carcinoma of the head and neck and urothelial carcinoma. The principal investigator initiating this trial is Aurélien Marabelle, MD, PhD, Clinical Director of the Cancer Immunotherapy Program at Institut Gustave Roussy, Villejuif, France.
- A Phase 2 study of intratumoral tilsotolimod in combination with IV pembrolizumab in patients with NSCLC. The principal investigator initiating this trial is Arafat Tfayli, MD, Professor of Clinical Medicine, Director of Hematology/Oncology Fellowship Program at the American University of Beirut Medical Center (AUBMC), Lebanon.
- A Phase 2 placebo controlled study of intradermal administration of tilsotolimod in patients with T3/T4 primary melanoma scheduled to undergo a combined re-excision and sentinel node biopsy (SNB) procedure. The principal investigators initiating this are Bas Koster, MD and

Tanja de Gruijl, PhD at The VU University Medical Center, Amsterdam, the Netherlands, and

• Potential collaborations and or partnerships with immuno-oncology companies to further demonstrate the utility of tilsotolimod in treating solid tumors.

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 the checkpoint therapy. Intratumoral injections with tilsotolimod are 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.

Out of the 30 patients treated and evaluated across all four dosing cohorts from the beginning of the Phase 1 portion of the study through our presentation at ASCO 2018, in the ILLUMINATE-204 Phase 1/2 Ipilimumab combination arm, 9 patients have RECIST v1.1 responses (PR or CR) representing a 30% Overall Response Rate (ORR). Based on the combination of clinical responses and supportive translational evidence, the 8mg dose of tilsotolimod was selected for clinical development advancement in the anti-PD-1 refractory melanoma indication.

Key findings from the most recent data presented at ASCO in June 2018 related to the ILLUMINATE-204 Phase 2 trial assessing the combination of the 8mg dose of tilsotolimod in combination with ipilimumab in anti-PD-1 refractory metastatic melanoma included:

- 21 patients treated with the 8mg dose of tilsotolimod in combination with ipilimumab have had disease evaluations (as of May 9, 2018 data cut);
- RECIST v1.1 responses (including 2 Complete Response [CR]) were observed in 8 of these 21 patients (38.1%);
- Six of 8 responses are ongoing (1 CR ongoing for nearly 2 years); median duration of response has not yet been reached;
- Overall 15 out of these 21 patients (71.4%) experienced disease control (CR, PR, or SD);
- The combination regimen is generally well tolerated. 6 of 26 patients (23%) had immune-related toxicities indicating that tilsotolimod + ipilimumab does not appear to add toxicity versus treatment with ipilimumab alone.
- Injection-related toxicities were grade 1-2 transient fever and flu-like symptoms lasting <48 hours; and,
- 15 of 26 patients (57.7%) with lesions accessible only by image-guided injection (5 deep visceral lesions and 10 lymph nodes) were included.

About Idera Pharmaceuticals
Harnessing the approach of the earliest researchers in immunotherapy and Idera's experience in developing proprietary immunology technologies, 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 is committed to working with investigators and partners who share the common goal of addressing the unmet needs of patients suffering from difficult to treat, unmet cancers. 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, 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 Annual Report filed on Form 10-K for the period ended December 31, 2017 and the Company's Quarterly Report filed on Form 10-Q for the period ended March 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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