Idera Pharmaceuticals Reports First Quarter 2017 Financial Results and Provides Corporate Update

May 4, 2017 8:01 PM EDT

IMO-2125 Advances to Phase 2 Clinical Trial in PD-1 Refractory Melanoma

CAMBRIDGE, Mass. and EXTON, Pa., May 04, 2017 (GLOBE NEWSWIRE) -- Idera Pharmaceuticals, Inc. (NASDAQ:IDRA), a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of novel nucleic acid-based therapeutics for oncology and rare diseases, today reported its financial and operational results for the first quarter ended March 31, 2017.

Since January 1, 2017, the Company:

• Completed enrollment in the dose escalation cohorts of the ipilimumab combination arm of the ongoing Phase 1/2 clinical trial of intratumoral IMO-2125 in PD-1 refractory metastatic melanoma;

- No dose-limiting toxicity reported in studied dose levels; MTD not reached; and
- Durable responses of over a year have been observed;

• Commenced enrollment of the Phase 2 portion of the clinical trial of 8mg intratumoral IMO-2125 in combination with ipilimumab in PD-1 refractory melanoma;

- 21 patients planned for evaluation, with 9 already enrolled; and
- Overall Response Rate (ORR) data expected to be available in first quarter of 2018;

• Continued enrollment into the dose escalation cohorts of the pembrolizumab combination arm of the Phase 1/2 clinical trial of intratumoral IMO-2125 in PD-1 refractory metastatic melanoma;

• Commenced and will continue to engage in discussions with global regulatory authorities regarding the path to registration for IMO-2125 in combination with ipilimumab in PD-1 refractory metastatic melanoma;

• Activated first site for Phase 1 clinical trial of intratumoral IMO-2125 monotherapy in multiple tumor types;

• Continued accruing patients into the IMO-8400 Phase 2 clinical trial in dermatomyositis which is being conducted at 22 sites both in the U.S. and abroad and is expected to complete enrollment in 2017 with data planned for the first half of 2018; and

• Continued all pre-clinical and IND-enabling activities for IDRA 008, Idera's first clinical candidate from the Third Generation Antisense (3GA) technology platform, with expected IND filing and initiation of human proof-of-concept clinical trial in the first half of 2018.

"We are very focused on bringing the first treatment option to PD1 refractory metastatic melanoma patients. Having selected our phase 2 dose earlier than we planned is good example of this focus," stated Vincent Milano, Idera's Chief Executive Officer. "We set very clear objectives in the beginning of this year for each of our programs, and I am very pleased with the output and progress through the first several months of 2017."

Research and Development Program Updates
IMO-2125 and IMO-8400 are the Company's lead clinical development drug candidates. IMO-2125 is an oligonucleotide-based agonist of Toll-like receptor (TLR) 9. IMO-8400 is an oligonucleotide-based antagonist of TLRs 7, 8, and 9. The Company also announced, in early 2017, the selection of the first development target from its proprietary 3GA technology platform. The company plans to disclose the specific target, disease and clinical pathway in the second half of 2017. The Company plans to take the first 3GA candidate into human proof of concept studies in 2018.

Toll-like Receptor (TLR) Agonism
Immuno-Oncology Program
Idera's development program in immuno-oncology is based on the rationale that intra-tumoral injections of IMO-2125, a TLR9 agonist, will activate dendritic cells and modulate the tumor microenvironment to potentiate the anti-tumor activity of checkpoint inhibitors and other immunotherapies. This rationale is supported by pre-clinical data in multiple tumor types.

Idera is currently conducting a Phase 2 clinical trial of intratumoral IMO-2125 in combination with ipilimumab, a CTLA4 antibody, and in a separate arm exploration of the combination of intratumoral IMO-2125 with pembrolizumab, an anti-PD1 antibody. The Phase 1 dose exploration portion of the trial was conducted at the University of Texas MD Anderson Cancer Center and the Phase 2 portion of the trial is being conducted at multiple centers. This trial is being conducted in patients with relapsed or refractory metastatic melanoma who have failed prior PD-1 therapy. In the second half of 2016, the Company announced positive preliminary clinical data from the initial dosing cohorts in the ipilimumab arm of the dose escalation portion of the trial. The company has completed the dose escalation of intratumoral IMO-2125 in the ipilimumab arm of the trial and the combination appears generally well tolerated across all doses explored, without any dose-limiting toxicity and without reaching a maximally tolerated dose. The company selected the 8mg dose for Phase 2 and enrollment is underway. The company has also continued enrollment into the pembrolizumab combination arm of the trial.

Additionally, the company has begun and will continue to engage in discussions with regulatory authorities regarding the path to registration for IMO-2125 in combination with ipilimumab in PD-1 refractory metastatic melanoma patients.

Also during the first quarter of 2017, the phase 1 trial of intratumoral IMO-2125 monotherapy in multiple tumor types has been activated and the first patient is expected to enroll early in the second quarter of 2017.

At the 2017 ASCO-SITC Clinical Immuno-Oncology Symposium held February 23 through February 25, in Orlando, FL, Marc Uemura, M.D. of MD Anderson Cancer Center, presented an update of the ongoing IMO-2125 clinical trial in combination with ipilimumab in PD-1 refractory melanoma.

At the 2017 American Academy of Cancer Research (AACR) Annual Meeting held, April 1 through April 5, in Washington, DC, Dr. Cara Haymaker of MD Anderson Cancer Center presented an update on the translational data outcomes in a poster presentation entitled, “Translational evidence of reactivated innate and adaptive immunity with intratumoral IMO-2125 in combination with systemic checkpoint inhibitors form a Phase 1/2 study in patients with anti-PD-1 refractory metastatic melanoma.”

Additionally, on the same day, Daqing Wang, Ph.D., Principal Scientist, Idera Pharmaceuticals presented new IMO-2125 pre-clinical data in a poster entitled, “Local treatment with novel TLR9 agonist IMO-2125 demonstrates anti-tumor activity in preclinical models of pancreatic cancer.”

Third Generation Antisense Platform (3GA)
Idera’s proprietary third-generation antisense (3GA) platform technology is focused on silencing the mRNA associated with disease causing genes. Idera has designed 3GA oligonucleotides to overcome specific challenges associated with earlier generation antisense technologies and RNAi technologies such as immunotoxicities and less than optimal therapeutic index.

Over the past two years, Idera has generated 22 unique compounds developed to target specific genes across a wide variety of therapeutic areas such as rare diseases, oncology, autoimmune disorders, metabolic conditions and diseases driven by a single point mutation. The company is currently conducting activities ranging from cell culture through IND-enabling toxicology. The current portfolio is designed to create both internal development candidates as well as partnering opportunities for disease areas outside of Idera’s stated focus.

The first partnering endeavor is demonstrated through Idera’s collaboration with GSK developing an undisclosed 3GA gene target for renal conditions. Idera and GSK entered into the collaboration in late 2015 and GSK’s stated goal is to achieve selection of clinical development candidate in the first quarter of 2018.

Additionally, in January of 2017, Idera announced selection of its first internal candidate to enter clinical development. For strategic and competitive purposes, Idera is withholding naming the specific target until the second half of 2017. Idera has selected a well-established liver target, with available, validated pre-clinical animal models, well-understood clinical endpoints, which has the potential for both rare and broader disease applications. Idera is currently conducting the IND-enabling toxicology for this program and expects to file and IND and enter the clinic in 2018.

Toll-like Receptor (TLR) Antagonism
Dermatomyositis Clinical Development Program
In late 2015, Idera announced the initiation of a Phase 2 clinical trial of IMO-8400 in patients with dermatomyositis, a rare auto-immune condition, which negatively affects skin and may result in debilitating muscle weakness. TLRs have been reported to play an important role in the pathogenesis of the disease. This randomized, double-blind, placebo controlled Phase 2 trial is expected to enroll 36 patients and is being conducted at 22 clinical sites worldwide. The Company plans to complete enrollment of this trial by the end of 2017 and have clinical data available in 2018.

Financial Results
First Quarter Results
Net loss applicable to common stockholders for the three months ended March 31, 2017 was $15.1 million, or $0.10 per basic and diluted share, compared to a net loss applicable to common stockholders of $12.8 million, or $0.11 per basic and diluted share, for the same period in 2016. Research and development expenses for the three months ended March 31, 2017 totaled $11.5 million compared to $9.3 million for the same period in 2016. General and administrative expense for the three months ended March 31, 2017 and March 31, 2016 were $4.1 million and $3.9 million, respectively.

As of March 31, 2017, our cash, cash equivalents and investments totaled $91.3 million. We currently anticipate our cash position is capable of funding our operations into the second quarter of 2018.

About Idera Pharmaceuticals, Inc.
Idera Pharmaceuticals is a clinical-stage biopharmaceutical company developing novel nucleic acid-based therapies for the treatment of certain cancers and rare diseases. Idera’s proprietary technology involves using a TLR-targeting technology, to design synthetic oligonucleotide-based drug candidates to act by modulating the activity of specific TLRs. In addition to its TLR programs, Idera has created a third generation antisense technology platform using its proprietary technology to inhibit the production of disease-associated proteins by targeting RNA. 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, 2016 and the Quarterly Report on Form 10-Q for the period ended March 31, 2017. 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.

Condensed Statements of Operations
(In thousands, except per share data)

	Three Months Ended March 31,	
	2017	2016
Alliance Revenue	$ 378	$ 294
Operating Expenses		
Research & Development	11,485	9,296
General & Administrative	4,081	3,916
Total Operating Expenses	15,566	13,212
Loss from Operations	(15,188)	(12,918)
Other Income (Expense), Net	131	95
Net Loss	$ (15,057)	$ (12,823)
Basic and diluted net loss per common share applicable to common stockholders	$ (0.10)	$ (0.11)
Shares used in computing basic and diluted net loss per common share applicable to common stockholders	149,100	121,284

Idera Pharmaceuticals, Inc.
Condensed Balance Sheet Data
(In thousands)

	At March 31 2017	At December 31, 2016
Cash, Cash Equivalents & Investments	$ 91,262	$ 109,014
Other Assets	6,311	4,217
Total Assets	$ 97,573	$ 113,231
Total Liabilities	$ 7,382	$ 9,882
Total Stockholders' Equity	90,191	103,349
Total Liabilities & Stockholders' Equity	$ 97,573	$ 113,231

IDERA PHARMACEUTICALS Contact:

Robert A. Doody, Jr.
VP, Investor Relations & Communications
Phone (617) 679-5515
RDOODY@IDERAPHARMA.COM

Idera Pharmaceuticals, Inc.