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

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IMO-2125 Clinical Trial Data Update at ESMO in September

CAMBRIDGE, Mass. and EXTON, Pa., Aug. 07, 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 second quarter ended June 30, 2017.

Since April 1, 2017, the Company:

Presentations/Publications:

- Submitted and gained acceptance of an abstract (#1187P) for presentation of updated clinical trial data from the ongoing IMO-2125 Phase 2 clinical trial at the European Society of Medical Oncology (ESMO) 2017 Congress. The data will be presented by lead trial investigator, Adi Diab, MD of MD Anderson Cancer Center at 1:15 PM CEST (7:15 AM ET) on Sunday, September 10, 2017. The conference is being held in Madrid, SpainSeptember 8th through the 12th; and
- Submitted and gained acceptance of an abstract (#B240) for presentation of IMO-2125 pre-clinical data in a poster presentation entitled, "*Intratumoral IMO-2125 treatment in combination with anti-CTLA4 mAb induces durable anti-tumor responses associated with tumor-specific memory in pre-clinical studies*" at the Third Annual CRI-CIMT-EATI-AACR International Cancer Immunotherapy Conference. The presentation will be given by Idera Principal Scientist, Daquing Wang, Ph.D. at 6:15 PM on Friday, September 8, 2017. The conference is being held in Frankfurt, Germany from September 6th through 9th.

Clinical Trial Activities:

- Commenced enrollment of the Phase 2 portion of the clinical trial of 8 mg intratumoral IMO-2125 in combination with ipilimumab in anti-PD-1 refractory melanoma;
  - 21 patients planned for evaluation; 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 anti-PD-1 refractory metastatic melanoma;
- Initiated and commenced enrollment into the 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 approximately 20 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.

Regulatory Activity:

- Announced the granting of Orphan Drug Designation from the U.S Food and Drug

Administration (FDA) for IMO-2125 for the treatment of melanoma Stages IIb to IV.

"As we continue to advance through 2017, our organization is incredibly energized and focused on rapidly advancing IMO-2125 through the clinical development pathway and ultimately towards our intended goal of delivering this therapeutic option for patients, particularly those who have not derived benefit from prior checkpoint inhibition therapies and in many cases have run out of options," stated Vincent Milano, Idera's Chief Executive Officer. "This effort is consistent with our corporate mission to transform Idera into a company delivering commercially available options for patients suffering with life-threating conditions. Our efforts across all of our development pipeline programs continues to drive forward, and we look forward to the opportunities to provide updates in the months and quarters ahead as these programs continue to mature. We have several opportunities to present further updates from the IMO-2125 program between now and year end and also intend to provide additional specificity on our plans to expeditiously advance our first indication in PD-1 refractory melanoma."

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 (IDRA 008) 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 both pre-clinical data in multiple tumor types as well as emerging clinical results and translational research from ongoing trials.

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 exploring 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 anti-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 the intratumoral IMO-2125 plus 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 is currently enrolling patients in the dose-finding Phase 1 IMO-2125 plus pembrolizumab combination arm of the trial.

Additionally, during the first half of 2017, the company initiated a multi-center clinical trial of intratumoral IMO-2125 monotherapy in multiple tumor types, including melanoma. The purpose of this trial is to demonstrate the activity of single-agent IMO-2125 for regulatory filing purposes as well as to direct further clinical development in tumor types beyond refractory melanoma.

Lastly, 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 anti-PD-1 refractory metastatic melanoma patients. IMO-2125 has been granted Orphan Drug Designation from the U.S. Food and Drug Administration (FDA) for the treatment of melanoma Stages IIb to IV.

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 in many cases also results in debilitating muscle weakness. TLRs have been understood to play an important role in the pathogenesis of the disease.

This randomized, double-blind, placebo controlled Phase 2 trial is targeted to enroll 36 patients and is being conducted at approximately 20 clinical sites worldwide. The Company plans to complete enrollment of this trial by the end of 2017 and be in position to present the results of this trial in the first half of 2018.

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 several years, Idera's research organization 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.

In January of 2017, Idera announced selection of its first internal candidate (IDRA 008) 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 performing the required IND-enabling toxicology for this clinical development candidate and expects to file the IND and enter the clinic in 2018.

Additionally, the first partnering endeavor is demonstrated through Idera's collaboration with GSK to develop an undisclosed 3GA gene target for certain renal conditions. Idera and GSK entered into the collaboration in late 2015 and GSK's current plan is to reach selection of clinical development candidate in the fourth quarter of 2018.

Financial Results
Second Quarter Results
Net loss applicable to common stockholders for the three months ended June 30, 2017 was $21.5 million, or $0.14 per basic and diluted share, compared to a net loss applicable to common stockholders of $13.5 million, or $0.11 per basic and diluted share, for the same period in 2016. Research and development expenses for the three months ended June 30, 2017 totaled $17.9 million compared to $10.1 million for the same period in 2016. General and administrative expense for the three months ended June 30, 2017 and June 30, 2016 were $3.9 million and $3.8 million, respectively.

As of June 30, 2017, our cash, cash equivalents and investments totaled $77.2 million. We currently anticipate our cash position is capable of funding

our operations into the fourth 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 June 30, 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.

Idera Pharmaceuticals, Inc.
Condensed Statements of Operations
(In thousands, except per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Alliance Revenue	$ 187	$ 301	$ 565	$ 595
Operating Expenses:				
Research & Development	17,891	10,128	29,376	19,424
General & Administrative	3,888	3,778	7,969	7,694
Total Operating Expenses	21,779	13,906	37,345	27,118
Loss from Operations	(21,592)	(13,605)	(36,780)	(26,523)
Other Income (Expense), Net	121	120	252	215
Net Loss	$ (21,471)	$ (13,485)	$ (36,528)	$ (26,308)
Basic and diluted net loss per common share applicable to common stockholders	$ (0.14)	$ (0.11)	$ (0.24)	$ (0.22)
Shares used in computing basic and diluted net loss per common share applicable to common stockholders	149,412	121,323	149,257	121,304

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

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	At June 30, 2017	At December 31, 2016
Cash, Cash Equivalents & Investments	$ 77,235	$ 109,014
Other Assets	6,138	4,217
Total Assets	$ 83,373	$ 113,231
Total Liabilities	$ 8,501	$ 9,882
Total Stockholders' Equity	74,872	103,349
Total Liabilities & Stockholders' Equity	$ 83,373	$ 113,231

Source: Idera Pharmaceuticals, Inc.

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