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

November 6, 2017 9:02 PM EST

– IMO 2125 Translational Data Update at SITC on November 11 –
– Completes Public Offering, extends runway into second quarter 2019 –

CAMBRIDGE, Mass., Nov. 06, 2017 (GLOBE NEWSWIRE) -- Idera Pharmaceuticals, Inc. (NASDAQ:IDRA), a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of novel oligonucleotide therapeutics for oncology and rare diseases, today reported its financial and operational results for the third quarter ended September 30, 2017.

Since July 1, 2017, the Company:

Presentations/Publications:

- Submitted and gained acceptance of an abstract for oral presentation of updated translational data from the ongoing IMO-2125 Phase 2 clinical trial at the Society for Immunotherapy of Cancer (SITC)'s 32 nd Annual Meeting. The data will be presented by lead trial investigator, Cara Haymaker, Ph.D. of MD Anderson Cancer Center at 4:45 PM EST on Saturday, November 11, 2017. The conference is being held in National Harbor, MD, November 8th through the 12th.
- Presented updated clinical data from the ongoing Phase 2 trial of IMO-2125 in combination with ipilimumab in metastatic melanoma patients refractory to anti-PD-1 treatment at the European Society of Medical Oncology (ESMO) 2017 Congress:
  - 9 patients were treated at the Recommended Phase 2 Dose (RP2D) of 8 mg IMO-2125 (in combination with ipilimumab);
  - Confirmed RECIST v1.1 responses (including 1 Complete Response (CR) ≥ 1 year) were observed in 4 of these 9 subjects (44%);
  - Overall 6 patients out of 9 treated at the RP2D (67%) experienced disease control (CR, Partial Response (PR), or durable stable disease);
  - A RECIST v1.1 PR of > 1 year duration is ongoing in a patient treated with IMO-2125 4 mg (in combination with ipilimumab);
  - IMO-2125 in combination with ipilimumab is tolerable at all dose levels studied;
  - IMO-2125 was safely administered via deep injection (using interventional radiology guidance) in patients lacking superficially accessible disease for injection, and;
  - Dose escalation with IMO-2125 and pembrolizumab is ongoing; one patient has an ongoing PR by RECIST (v1.1).

Clinical Trial Activities:

- Expanded planned 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;
  - Up to 60 patients planned for evaluation; and
  - Rolling data updates anticipated throughout 2018;
- Phase 3 trial of IMO-2125 in combination with ipilimumab in PD-1 refractory melanoma initiation planned for 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;

- Continued enrollment into the Phase 1 clinical trial of intratumoral IMO-2125 monotherapy in multiple tumor types;
- Completed enrollment in the Phase 2 trial of IMO-8400 in dermatomyositis. Clinical data results from this trial expected in the second quarter of 2018; and
- Continued all pre-clinical and IND-enabling activities for IDRA-008, Idera's first clinical candidate from the Company's 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.

"Our number one mission at Idera is to develop solutions for patients suffering from diseases without good options. The responses that have been experienced so far in the development of IMO-2125 and the impact that can have on those patients is incredibly humbling to us and inspiring to our entire organization," stated Vincent Milano, Idera's Chief Executive Officer. "We're driven to move as rapidly as possible to bring IMO-2125 to the market with the goal to extend the lives of many patients so they have more time to spend with their families and fulfill their dreams. Our team is entirely focused on executing both the ongoing Phase 2 trial as well as initiating the Phase 3 trial in the first quarter of next year with urgency and precision, so we can deliver this solution and ultimately achieve this mission."

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 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 intratumoral 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, an anti-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 September of 2017, the Company announced positive preliminary clinical data from the Phase 2 8mg dosing cohort in the ipilimumab arm of the trial. As a result of these positive data, the Company has elected to expand the planned size of the Phase 2 trial to enroll up to 60 patients. Additionally the Company plans to initiate the Phase 3 trial for this development program in the first quarter of 2018. The Company is also currently enrolling patients in the dose-finding Phase 1 IMO-2125 plus pembrolizumab combination arm of the trial and has announced that the first RECIST v.1.1 response has been observed in this arm of the trial as well.

Additionally, during the first half of this year, 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. Enrollment in this trial is underway.

Lastly, the Company has engaged 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.

The Company has completed enrollment into this trial and expects to present results during the second quarter 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. 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 a clinical development candidate in the fourth quarter of 2018.

Financial Results
Third Quarter Results
Net loss applicable to common stockholders for the three months ended September 30, 2017 was $14.5 million, or $0.10 per basic and diluted share, compared to a net loss applicable to common stockholders of $12.9 million, or $0.10 per basic and diluted share, for the same period in 2016. Research and development expenses for the three months ended September 30, 2017 totaled $10.9 million compared to $9.4 million for the same

period in 2016. General and administrative expense for both the three months ended September 30, 2017 and September 30, 2016 were $3.9 million.

As of September 30, 2017, our cash, cash equivalents and investments totaled $65.3 million. In October 2017 we announced the closing of an underwritten public offering of our common stock. We generated net proceeds of approximately $53.8 million from the offering and over allotment. Also in October 2017, Pillar Invest, Inc. exercised the remainder of outstanding warrants which generated an additional $4.8 million. We currently anticipate our cash position is capable of funding our operations into the second quarter of 2019.

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, 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 September 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 September 30,		Nine Months Ended September 30,	
	2017	**2016**	**2017**	**2016**
Alliance Revenue	$ 164	$ 323	$ 729	$ 918
Operating Expenses:				
Research and Development	10,912	9,393	40,288	28,817
General and Administrative	3,919	3,907	11,888	11,601
Total Operating Expenses	14,831	13,300	52,176	40,418
Loss from Operations	(14,667)	(12,977)	(51,447)	(39,500)
Other Income (Expense), Net	137	74	389	289
Net Loss	$ (14,530)	$ (12,903)	$ (51,058)	$ (39,211)
Basic and diluted net loss per common share applicable to common stockholders	$ (0.10)	$ (0.10)	$ (0.34)	$ (0.32)
Shares used in computing basic and diluted net loss per common share applicable to common stockholders	149,638	121,389	149,385	121,332

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

	September 30, 2017	December 31, 2016
Cash, Cash Equivalents and Investments	$ 65,341	$ 109,014
Other Assets	5,408	4,217
Total Assets	$ 70,749	$ 113,231
Total Liabilities	$ 8,669	$ 9,882
Total Stockholders' Equity	62,080	103,349
Total Liabilities and Stockholders' Equity	$ 70,749	$ 113,231

Source: Idera Pharmaceuticals, Inc.

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Source: Idera Pharmaceuticals, Inc.