Idera Pharmaceuticals Reports Fourth Quarter and Year End 2016 Financial Results and Provides Corporate Update

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- IMO-2125 Confirmed Responses in PD-1 Refractory Melanoma Appear Durable -

- First Third Generation Antisense (3GA) Target Selected; Poised to Enter Clinical Development in 2018 -

CAMBRIDGE, Mass. and EXTON, Pa., March 15, 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 fourth quarter and year ended December 31, 2016.

During 2016, 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;
  - Patients with confirmed clinical responses have been on study past one year; and
  - Supplementary patients being added to inform recommended phase 2 dose selection.
- Commenced 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;
- Created 22 specific 3GA compounds targeting 22 genes for potential internal clinical development or partnering opportunities;
- Selected the first clinical target for human development from the 3GA technology platform for an undisclosed liver target with expected initiation of clinical development targeted for 2018; IND-enabling activities underway;
- Initiated enrollment 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;
- Planned additional IMO-2125 clinical trials to further understand drug activity as a monotherapy in additional solid tumors as well as exploration of additional combinations and tumor types with both trials anticipated to commence in 2017;
- Executed an out-licensing agreement for Idera's Toll-like Receptor 7, 8 and 9 antagonist IMO-9200 granting Vivelix Pharmaceuticals, Ltd. worldwide rights to develop and market the compound for non-malignant gastrointestinal disorders. Idera received $15 million in upfront payment and is eligible for future development, regulatory and sales milestone payments up to $140 million along with royalties from global net sales;
- Generated estimated net proceeds of $49M, after deducting underwriters' discounts and commissions and estimated offering expenses, from a public offering of common stock;
- Presented positive clinical, translational and safety data from the initial cohorts of the phase 1 dose escalation portion of the Company's ongoing Phase 1/2 clinical trial of intratumoral IMO-2125 in combination with ipilimumab in patients with PD-1 refractory metastatic melanoma at the Society for Immunotherapy of Cancer (SITC) Annual Meeting in November;
- Presented pre-clinical data updates on both novel mechanism of action and selective targeting of single point mutations with 3rd Generation Antisense (3GA) at the Cold Springs Harbor Laboratory Conference on Regulatory & Non-Coding RNAs conference and the Annual

Meeting of the Oligonucleotide Therapeutic Society, respectively; and,
- Completed registrational development plan for IMO-2125 for PD-1 refractory metastatic melanoma.

“2016 was an incredibly important period for driving Idera’s future direction and opportunities for success,” stated Vincent Milano, Idera’s Chief Executive Officer. “And to that end, I am extremely proud of the contributions of every member of our team throughout 2016 as we now find ourselves exceedingly focused on our core priorities as we enter 2017 which is set up to be a pivotal year for our company, our patients and our shareholders."

Continued Milano, “As we begin 2017, we are now in position to gain further insight into the potential for IMO-2125 with additional data, clarify the path to registration for IMO-2125 for PD-1 refractory melanoma, commence understanding of IMO-2125’s opportunity beyond melanoma, complete enrollment of the IMO-8400 trial in dermatomyositis and continue to advance the 3GA platform technology towards its first clinical evaluation in 2018. We also along the way, will opportunistically explore collaborations for both IMO-2125 and the 3GA platform technology to maximize the potential value and importantly patient reach for these exciting therapeutic solutions.”

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 late 2015, the first two potential development targets from its proprietary 3GA technology platform: NLRP3 (NOD-like receptor family, pyrin domain containing protein 3) and DUX4 (Double Homeobox 4). The Company continues to evaluate these and other potential targets. The Company plans to take the first 3GA candidate into human proof of concept studies in 2017.

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 1/2 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 is being conducted at the University of Texas MD Anderson Cancer Center. 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 trial is currently enrolling additional patients with the goal to select the dose and commence the multi-center phase 2 portion of the trial in the second quarter of 2017. The company has also commenced enrollment into the pembrolizumab combination arm of the trial. The Company has requested and expects to conduct an end of phase 1 meeting with the U.S. Food and Drug Administration during the first quarter of 2017 to discuss the plans for registration trials and regulatory pathways for intratumoral IMO-2125 in PD1 refractory metastatic melanoma.

Additionally, in 2017 the company plans to initiate trials exploring IMO-2125 as a monotherapy agent in multiple solid tumor types and exploration of intratumoral IMO-2125 in combination with other checkpoint inhibitors in various solid tumor types.

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 upcoming American Association for Cancer Research (AACR) 2017 Annual Meeting being held April 1-5, in Washington DC, there will be two presentations related to IMO-2125.

On Wednesday, April 5, 2017, Dr. Cara Haymaker of MD Anderson Cancer Center will present 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 will present 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 single point mutations. 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 will be conducted at approximately 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
Fourth Quarter Results
Net income applicable to common stockholders for the three months ended December 31, 2016 was $0.8 million, or $0.01 per basic and diluted share, compared to a net loss applicable to common stockholders of $12.0 million, or $0.10 per basic and diluted share, for the same period in 2015. Revenue in the fourth quarter of 2016 was $15.3 million, primarily related to our Vivelix Agreement entered into in November 2016. There was nominal revenue recognized in the fourth quarter of 2015. Research and development expenses for the three months ended December 31, 2016 totaled $11.0 million compared to $8.6 million for the same period in 2015. General and administrative expense for the three months ended December 31, 2016 and December 31, 2015 were $3.5 million and $3.7 million, respectively.

Full Year Results
Net loss applicable to common stockholders for the year ended December 31, 2016 was $38.4 million or $0.30 per basic and diluted share, compared to net loss applicable to common stockholders of $48.6 million, or $0.42 per basic and diluted share, for the same period in 2015. Revenue for the year ended December 31, 2016 was $16.2 million, primarily related to our Vivelix Agreement entered into in November 2016. There was nominal revenue recognized for the year ended December 31, 2015. Research and development expenses for the year ended December 31, 2016 totaled $39.8 million compared to $33.7 million for the same period in 2015. General and administrative expenses for the year ended December 31, 2016 totaled $15.1 million compared to $15.4 million for the same period in 2015.

As of December 31, 2016, our cash, cash equivalents and investments totaled $109.0 million compared to $87.2 million as of December 31, 2015. 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 on Form 10-K 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.

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

	Three Months Ended December 31,		Years Ended December 31,	
	2016	**2015**	**2016**	**2015**
Alliance Revenue	$ 15,281	$ 190	$ 16,199	$ 249
Operating Expenses				
Research & Development	11,007	8,565	39,824	33,699
General & Administrative	3,531	3,708	15,132	15,396
Total Operating Expenses	14,538	12,273	54,956	49,095
Income (loss) from Operations	743	(12,083)	(38,757)	(48,846)

Other Income (Expense), Net	79	93	368	291
Net Income (Loss)	$ 822	$ (11,990)	$ (38,389)	$ (48,555)
Basic net income (loss) per common share applicable to common stockholders	$ 0.01	$ (0.10)	$ (0.30)	$ (0.42)
Shares used in computing basic net income (loss) per common share applicable to common stockholders	146,255	118,865	127,597	115,092
Diluted net income (loss) per common share applicable to common stockholders	$ 0.01	$ (0.10)	$ (0.30)	$ (0.42)
Shares used in computing diluted net income (loss) per common share applicable to common stockholders	151,930	118,865	127,597	115,092

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

	At December 31,	
	2016	2015
Cash, Cash Equivalents & Investments	$ 109,014	$ 87,157
Other Assets	4,217	5,119
Total Assets	$ 113,231	$ 92,276
Total Liabilities	$ 9,882	$ 8,694
Total Stockholders' Equity	103,349	83,582
Total Liabilities & Stockholders' Equity	$ 113,231	$ 92,276

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