Idera Pharmaceuticals Reports Third Quarter 2018 Financial Results and Provides Corporate Update

November 6, 2018 9:30 PM EST

– Company to Provide ILLUMINATE 204 Data Update in the First Half of December 2018 –
– Cash runway into first quarter of 2020 –

EXTON, Pa., Nov. 06, 2018 (GLOBE NEWSWIRE) -- Idera Pharmaceuticals, Inc. (NASDAQ: IDRA), a clinical-stage biopharmaceutical company focused on the development, and ultimately the commercialization, of therapeutic drug candidates for both oncology and rare disease indications characterized by small, well-defined patient populations with serious unmet medical needs, today reported its financial and operational results for the third quarter ended September 30, 2018.

“The third quarter of 2018 was marked by continued focus and execution throughout our company advancing the tilsotolimod ILLUMINATE 301 trial toward approval in our lead indication in anti-PD-1 refractory or relapsed metastatic melanoma. We also made significant progress framing our plans to expand the development of tilsotolimod to additional tumor types,” stated Vincent Milano, Idera’s Chief Executive Officer.

“Over these past several years, through all of the preclinical studies, translational data collections and ultimately our early clinical experiences, it’s becoming clearer to us that the potential utility of tilsotolimod is not limited to melanoma and is certainly not limited by the location or type of tumor,” continued Milano. “We look forward to providing our next clinical update from the ILLUMINATE 204 trial in the first half of December as well as laying out our expansion plans for the program in the beginning of 2019.”

“The majority of our company’s focus is and will remain towards maximizing the opportunity with, and more importantly, the number of patients that can benefit from, tilsotolimod. At the same time, we recognize and embrace the concept of continuing to build Idera for the future. To that end, we will continue to be aggressive in our pursuit of additional assets to further drive value for our shareholders, and more importantly, meet the needs of patients suffering from rare diseases with serious unmet needs.”

Clinical Development Program Updates:

ILLUMINATE (tilsotolimod) Clinical Development

ILLUMINATE 301 – Randomized Phase 3 trial of intratumoral tilsotolimod in combination with ipilimumab versus ipilimumab alone in patients with PD-1 refractory/relapsed metastatic melanoma:

- Trial initiated in the first quarter of 2018;
- 42 of the planned up to 110 sites across 12 countries have been activated for the randomization of patients into the trial;
- ILLUMINATE 301 Trials in Progress (TiPS) presentation on trial design featured at the 2018 Congress of the European Society of Medical Oncology (ESMO);
- Planned enrollment of approximately 300 patients with Overall Response Rate (“ORR”) and Overall Survival as primary endpoints; and
- U.S. Food and Drug Administration granted Fast Track Designation in fourth quarter of 2017 for tilsotolimod in combination with ipilimumab for the treatment of patients with unresectable or metastatic melanoma following failure of PD-1 inhibitor treatment.

ILLUMINATE 204 – Phase 1/2 trial of intratumoral tilsotolimod in combination with either ipilimumab or pembrolizumab in patients with PD-1 refractory/relapsed metastatic melanoma:

Ipilimumab Combination Arm – Phase 2 Recruitment Ongoing

- Enrollment continues at 10 U.S. clinical trial sites;
- Two additional sites planned for initiation in November 2018;
- ILLUMINATE 204 Trial Data update presented at ESMO 2018 demonstrated both abscopal effect as well as the potential of intratumoral tilsotolimod to overcome known resistance mechanisms to ipilimumab treatment as a monotherapy.
- Earlier this year at the American Society of Clinical Oncology (ASCO) Annual Meeting, the company presented clinical efficacy and safety data from the first 21 evaluable patients demonstrating:
    - Confirmed RECIST v1.1 responses (including 2 Complete Responses [CR]) were

observed in 8 of these 21 subjects (38.1%);
    - Overall 15 patients out of 21 evaluable for efficacy (71.4%) experienced disease control (CR, PR, or SD);
    - The combination regimen was generally well tolerated. 6/26 subjects (23%) had immune-related toxicities indicating that IMO-2125 + ipilimumab does not appear to add toxicity versus ipilimumab alone;
    - Injection-related toxicities were grade 1-2 transient fever and flu-like symptoms lasting <48 hours;
    - 15/26 patients (57.7%) with lesions accessible only by image-guided injection (5 deep visceral lesions and 10 lymph nodes) were included; and
- The company plans to provide a data update on up to 35 evaluable patients in first half of December 2018.

Pembrolizumab Combination Arm – Phase 1 Dose Escalation Ongoing

- Enrollment in the last dosing cohort (32 mg) ongoing with one patient remaining to complete enrollment (priority enrollment has been towards the ipilimumab combination arm of ILLUMINATE 204).
- One patient in the cohort testing 16mg intratumoral tilsotolimod in combination with pembrolizumab continues on study with a confirmed complete response (CR).

ILLUMINATE 101 – Phase 1b trial of intratumoral tilsotolimod monotherapy in patients with refractory solid tumors:

- Completed enrollment in all four dose ranging cohorts; 41 patients enrolled;
- Continuing enrollment into the refractory melanoma cohort at the 8 mg dose of intratumoral tilsotolimod as monotherapy;
- Translational data continues to be collected, analyzed and is planned to be submitted for presentation at a medical oncology conference in 2019.

Investigator Sponsored Trials (IST)
Idera is supportive of several Investigator Sponsored Trials and continues to evaluate additional proposals:

- 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; and
- 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 trial are Bas Koster, MD and Tanja de Gruijl, PhD at The VU University Medical Center, Amsterdam, the Netherlands.

Corporate Updates:
During the quarter, the following Corporate Organizational Changes were announced:

- Howard Pien appointment to Idera's Board of Directors on September 18, 2018, filling the seat previously held by Julian Baker.
- Bryant D. Lim joined Idera as General Counsel and Secretary to the Board of Directors, effective September 10, 2018;
- Chief Financial Officer Louis J. Arcudi III's planned departure from the company related to the company's consolidation to PA headquarters, effective October 31, 2018;

- Vice President of Finance John J. Kirby's appointment as Principal Financial Officer and Principal Accounting Officer, effective October 31, 2018; and

Financial Results
Third Quarter Results
Net loss applicable to common stockholders for the three months ended September 30, 2018 was $11.6 million, or $0.43 per basic and diluted share, compared to net loss applicable to common stockholders of $14.5 million, or $0.78 per basic and diluted share, for the same period in 2017. Revenue in each of the three months ended September 30, 2018 and 2017 was nominal. Research and development expenses for the three months ended September 30, 2018 totaled $8.9 million compared to $10.9 million for the same period in 2017. General and administrative expense for the three months ended September 30, 2018 totaled $4.0 million compared to $3.9 million for the same period in 2017. Merger-related costs, net for the three months ended September 30, 2018 amounted to a net credit of $3.8 million and was comprised of a $6.0 million fixed expense reimbursement received in connection with the termination of the company's proposed merger with BioCryst Pharmaceuticals, Inc., which was terminated in July 2018; partially offset by $2.2 million of expenses incurred in connection with the transactions contemplated by the related merger agreement. No such costs were incurred during 2017. Restructuring costs for the three months ended September 30, 2018 totaled $3.0 million and are a result of our decision in July 2018 to wind-down our discovery operations, reduce the workforce in Cambridge, Massachusetts that supported such operations, and close our Cambridge facility. No such costs were incurred during 2017.

As of September 30, 2018, the company's cash and cash equivalents totaled $82.5 million. The company currently anticipates that, based on its current operating plan, its existing cash and cash equivalents will be sufficient to fund company operations into the first quarter of 2020.

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 also continues to focus on the acquisition, development and ultimate commercialization of drug candidates for both oncology and rare disease indications characterized by small, well-defined patient populations with serious unmet needs. 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, 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, including 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 will be predictive of the final results of the trial; whether results obtained in preclinical studies and clinical trials will be indicative of the results that will be generated in future clinical trials; whether products based on the Company'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 set forth under the caption "Risk Factors" in the Company's Annual Report on Form 10-K for the period ended December 31, 2017 and in the Company's Quarterly Report on Form 10-Q for the period ended September 30, 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.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	**2017**	**2018**	**2017**
Alliance revenue	$ 145	$ 164	$ 563	$ 729
Operating expenses:				
Research and development	8,860	10,912	32,912	40,288
General and administrative	3,984	3,919	11,849	11,888
Merger-related costs, net	(3,836)	-	1,245	-
Restructuring costs	3,017	-	3,017	-

Total operating expenses	12,025	14,831	49,023	52,176
Loss from operations	(11,880)	(14,667)	(48,460)	(51,447)
Other income (expense), net	275	137	729	389
Net loss	$(11,605)	$(14,530)	$(47,731)	$(51,058)
Net loss per common share applicable to common stockholders — basic and diluted	$ (0.43)	$ (0.78)	$ (1.81)	$ (2.73)
Weighted-average number of common shares used in computing net loss per share applicable to common stockholders — basic and diluted	27,175	18,704	26,404	18,673

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

	September 30, 2018	December 31, 2017
Cash and cash equivalents	$ 82,462	$ 112,629
Other assets	2,768	5,788
Total assets	$ 85,230	$ 118,417
Total liabilities	$ 10,364	$ 10,722
Total stockholders' equity	74,866	107,695
Total liabilities and stockholders' equity	$ 85,230	$ 118,417

Source: Idera Pharmaceuticals, Inc.

Idera Pharmaceuticals Contact:

Robert A. Doody, Jr.
VP, Investor Relations & Communications
Phone (484) 348-1677
rdoody@iderapharma.com

Source: Idera Pharmaceuticals, Inc.