Idera Pharmaceuticals Reports Fourth Quarter and Year End 2018 Financial Results and Provides Corporate Update

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– ILLUMINATE-301 Enrollment on Track for Completion Q4 2019 –
– ILLUMINATE-204 Enrollment Complete; Data Anticipated Q4 2019 –
– ILLUMINATE-206 Trial Expected to Initiate Q2 2019 –
– Chief Medical Officer Dr. Joanna Horobin Announces Retirement Plan –
– Company to Present at Barclays Global Healthcare Conference Next Week –

EXTON, Pa., March 06, 2019 (GLOBE NEWSWIRE) -- Idera Pharmaceuticals, Inc. ("Idera") (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 fourth quarter and year ended December 31, 2018.

"2018 ended with incredibly positive momentum for tilsotolimod which carried into 2019 and continues today," stated Vincent Milano, Idera's chief executive officer. "Despite the challenges we faced in the first half of 2018, we emerged as a tightly focused organization with a clear understanding of our mission to bring tilsotolimod to the market in our initial indication of anti-PD-1 refractory metastatic melanoma. We also are exploring tilsotolimod as an investigational therapy for patients with other tumor types that have not been well-served by available immunotherapies to date," continued Milano. "The ILLUMINATE development program is making excellent progress across the board and I am incredibly proud of our team for their continued dedication and execution."

"As it pertains to Idera overall, we will continue business development efforts to identify and pursue assets and opportunities with the purpose of further growing our company for long-term success and value creation for our loyal shareholders. However, I cannot be any clearer that the advancement and future success of tilsotolimod is our highest priority, passion and focus."

ILLUMINATE (tilsotolimod) Clinical Development Update

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

• Overall Response Rate (ORR) and Overall Survival (OS) as primary endpoints;

• Trial initiated in the first quarter of 2018;

• Sites planned in 12 countries: 78 sites activated;

• Planned enrollment of approximately 300 patients; and

• Completion of enrollment expected during the fourth quarter of 2019.

ILLUMINATE 206 – Phase 2, multi-center trial to test the safety and effectiveness of tilsotolimod in combination with ipilimumab and nivolumab in treating patients with Squamous Cell Carcinoma of the Head and Neck (SCCHN) and Microsatellite Stable Colorectal Cancer (MSS-CRC).

• Received notice from the U.S. Food and Drug Administration that the company can proceed to implement the ILLUMINATE-206 clinical trial under a new Investigational New Drug (IND) application; and

• Both trial cohorts of SCCHN and MSS-CRC expected to initiate in the second quarter of 2019.

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

• Completed enrollment with 52 patients in Phase 2 expansion at 8 mg (RP2D) dose with ipilimumab;

• Completed target enrollment of at least 40 patients in the primary enrollment population constituting patients who are naïve to prior ipilimumab treatment in the metastatic setting;

• Presented an interim data update in December 2018 which showed:

  - 32.4% ORR of the first 34 patients evaluable for efficacy including 9% (N=3) achieve Complete Response (CR); 24% (N=8) achieving Partial Response (PR); and 76.5% (N=26) achieving disease control (CR, PR or Stable Disease [SD]); and

• Data from ILLUMINATE-204 expected in the fourth quarter of 2019.

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

• Completed enrollment in all dose cohorts of the trial; and

• Abstract accepted for presentation of translational data from this trial at the American Association for Cancer Research (AACR) 2019 Annual

Meeting, being held March 29 – April 3, 2019 in Atlanta, GA.

Corporate Updates:
The company today is announcing the planned retirement of Senior Vice President and Chief Medical Officer Joanna Horobin, M.B. Ch.B, given the consolidation of Idera's business operations and team in Pennsylvania. The retirement will be effective July 31, 2019. Dr. Horobin joined Idera in November 2015 and notably has led the advancement of the tilsotolimod ILLUMINATE program, advancing the program from pre-clinical into exploratory early phase clinical and translational evaluation through to the ongoing ILLUMINATE 301 phase 3 trial in anti-PD-1 refractory metastatic melanoma and most recently expanding into a study in patients SCCHN and MSS-CRC.

Dr. Horobin will assist Idera in the search to fill the role of Chief Medical Officer and will remain with the company in an advisory capacity following her July 31 retirement.

"I'm incredibly appreciative to Joanna for the critical role she has played as we transitioned Idera to a focused clinical development organization with a clear eye towards ultimate commercialization of products for patients suffering from life-threatening rare diseases," offered Milano. "We all wish Joanna the utmost happiness as she transitions to the next phase of her life following a tremendously productive and rewarding 35-year career developing critical medicines that have made a positive impact on countless patients' lives."

"I am tremendously proud of the progress we've made at Idera over the past several years. We have shown clinical proof-of-concept of tilsotolimod to prime the immune system to better respond to checkpoint inhibition which may enable tilsotolimod to benefit more patients," stated Dr. Horobin. "It's been a great honor to work with so many talented individuals during my time at Idera and I look forward to continuing to assist in an advisory capacity as the opportunities for tilsotolimod expand."

Additionally, since September 30, 2018, the following corporate updates were announced:

• The company entered into an at the market offering (ATM) agreement with JMP Securities LLC under which the company may elect to sell shares of its common stock having an aggregate offering price of up to $50 million;

• The company entered into a common stock purchase agreement and registration rights agreement with Lincoln Park Capital (LPC) Fund, LLC, under which the company has the right to sell an aggregate of up to $35 million of its common stock at the company's discretion; and

• Carol A. Schafer was appointed to Idera's Board of Directors on December 18, 2018, filling the seat of Mr. William Reardon, who will be resigning from the Board effective March 10, 2019.

Upcoming Investor Conference:
The company will participate in the 2019 Barclays Global Healthcare Conference on Tuesday, March 12, 2019 at 11:15 a.m. Eastern Time at the Loews Miami Beach Hotel in Florida.

Live audio webcast of Idera's presentations will be accessible in the Investors and Media section of Idera's website at http://www.iderapharma.com. Archived versions will also be available on the Company's website after the event for 90 days.

Financial Results
Fourth Quarter Results
Net loss applicable to common stockholders for the three months ended December 31, 2018 was $12.2 million, or $0.45 per basic and diluted share, compared to net loss applicable to common stockholders of $14.9 million, or $0.66 per basic and diluted share, for the same period in 2017. Revenue in the fourth quarter of 2018 was nominal. Research and development expenses for the three months ended December 31, 2018 totaled $8.9 million compared to $10.4 million for the same period in 2017. General and administrative expense for the three months ended December 31, 2018 totaled $3.6 million compared to $3.7 million for the same period in 2017.

Full Year Results
Net loss applicable to common stockholders for the year ended December 31, 2018 was $59.9 million or $2.25 per basic and diluted share, compared to net loss applicable to common stockholders of $66.0 million, or $3.35 per basic and diluted share, for the same period in 2017. Revenue for the year ended December 31, 2018 was $0.7 million compared to revenue of $0.9 million for the same period in 2017. Research and development expenses for the year ended December 31, 2018 totaled $41.8 million compared to $50.7 million for the same period in 2017. General and administrative expenses for the year ended December 31, 2018 totaled $15.4 million compared to $15.6 million for the same period in 2017. Merger-related costs, net for the year ended December 31, 2018 totaled $1.2 million compared to $1.1 million for the same period in 2017. Restructuring costs for the year ended December 31, 2018 totaled $3.1 million and related to our decision in July 2018 to wind-down our discovery operations. No such costs were incurred in 2017.

As of December 31, 2018, our cash and cash equivalents totaled $71.4 million compared to $112.6 million as of December 31, 2017. We currently anticipate that, based on our current operating plan, our existing cash, cash equivalents and investments will fund our 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 year ended December 31, 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 December 31,		Twelve Months Ended December 31,	
	2018	**2017**	**2018**	**2017**
Alliance revenue	$ 99	$ 173	$ 662	$ 902
Operating expenses:				
Research and development	8,929	10,365	41,841	50,653
General and administrative	3,571	3,700	15,420	15,588
Merger-related costs, net	-	1,128	1,245	1,128
Restructuring costs	95	-	3,112	-
Total operating expenses	12,595	15,193	61,618	67,369
Loss from operations	(12,496)	(15,020)	(60,956)	(66,467)
Other income (expense), net	346	94	1,075	483
Net loss	$ (12,150)	$ (14,926)	$ (59,881)	$ (65,984)
Net loss per common share applicable to common stockholders — basic and diluted	$ (0.45)	$ (0.66)	$ (2.25)	$ (3.35)
Weighted-average number of common shares used in computing net loss per share applicable to common stockholders — basic and diluted	27,183	22,647	26,601	19,675

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

	December 31,	
	2018	**2017**
Cash and cash equivalents	$ 71,431	$ 112,629
Other assets	1,592	5,788
Total assets	$ 73,023	$ 118,417
Total liabilities	$ 9,029	$ 10,722
Total stockholders' equity	63,994	107,695
Total liabilities and stockholders' equity	$ 73,023	$ 118,417

Source: Idera Pharmaceuticals, Inc.

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Source: Idera Pharmaceuticals, Inc.