Idera Pharmaceuticals Reports Fourth Quarter and Full Year 2019 Financial Results and Provides Corporate Update

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– Completed Enrollment in ILLUMINATE-301; Top-Line Overall Response Rate (ORR) Data Expected in Q1 2021 –

EXTON, Pa., March 12, 2020 (GLOBE NEWSWIRE) -- Idera Pharmaceuticals, Inc. ("Idera") (NASDAQ: IDRA) reported on March 11, 2020 its financial and operational results for the fourth quarter and year ended December 31, 2019.

"In 2019, we made great progress with ILLUMINATE-301, our registrational trial of tilsotolimod in combination with ipilimumab in anti-PD-1 refractory patients with advanced melanoma. This was the result of outstanding focus and dedication across our organization and enabled us to finish enrollment in the first quarter of 2020, earlier than anticipated. It also positions us to have initial data from the trial early next year," stated Vincent Milano, Idera's Chief Executive Officer. "2019 was also notable for our progress in taking tilsotolimod beyond melanoma through both our collaboration in squamous cell carcinoma of the head and neck and through our ILLUMINATE-206 trial, which we initiated in the microsatellite stable colorectal cancer cohort."

ILLUMINATE (tilsotolimod) Clinical Development Update

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

- Primary endpoint family of ORR per RECIST v1.1 and overall survival (OS);
- Trial initiated in March 2018;
- Enrollment completed in March 2020; and
- ORR and other preliminary data expected in Q1 2021.

ILLUMINATE-206: Phase 2, open-label, multicohort, multicenter study to test the safety and effectiveness of tilsotolimod in combination with ipilimumab and nivolumab for the treatment of solid tumors:

- Trial initiated in September 2019 with the microsatellite stable colorectal cancer (MSS-CRC) cohort;
- Initial safety run-in cohort of 10 patients with MSS-CRC fully enrolled; and
- Preliminary data from this cohort expected in Q2 2020.

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

- Enrollment completed in February 2019 at tilsotolimod 8 mg with ipilimumab; and
- Final top-line results from the ILLUMINATE-204 trial, to include ORR, median OS, duration of response (DOR), and safety, are expected to be released in Q2 2020.

Corporate Updates

Since September 30, 2019, the following corporate updates were announced:

- Received new U.S. Patent for tilsotolimod, providing exclusivity through September 2037 when tilsotolimod is used with certain checkpoint inhibitors.
- Entered into private placement financing of up to $97.7 million, with $10.1 million received in December 2019 from initial proceeds and option fees.
- Dr. Jonathan Yingling departed Idera as its Chief Scientific Officer effective January 31, 2020.

Financial Results

Fourth Quarter Results
Revenue in the fourth quarter of 2019 and 2018 was nominal. Research and development expenses for the three months ended December 31, 2019 totaled $8.4 million compared to $8.9 million for the same period in 2018. General and administrative expense for the three months ended December 31, 2019, totaled $3.4 million compared to $3.6 million for the same period in 2018.

Additionally, during the fourth quarter of 2019 the Company recorded $0.6 million and $11.0 million of non-cash warrant revaluation expense and non-cash future tranche right revaluation expense, respectively. These expenses were related to a private placement transaction consummated pursuant to a Securities Purchase Agreement, dated as of December 23, 2019, by and between us and certain institutional investors, whereby the Company sold shares of Series B1 convertible preferred stock and warrants to purchase common stock for $3.9 million and received an upfront option fee of approximately $6.2 million related to certain rights provided to such institutional investors to purchase shares of Series B2, Series B3, and Series B4 convertible preferred stock and warrants to purchase common stock in future tranches, subject to shareholder approval to increase authorized shares. The 2019 period also included non-cash deemed dividends of approximately $28.0 million, increasing net loss attributable to common stockholders, related to the transaction.

As a result of the factors above, net loss applicable to common stockholders for the three months ended December 31, 2019, was $51.3 million, or $1.76 per basic and diluted share, compared to net loss applicable to common stockholders of $12.2 million, or $0.45 per basic and diluted share, for the same period in 2018. Net loss applicable to common stockholders excluding non-cash expense of approximately $11.6 million and deemed dividends of approximately $28.0 million related to the Securities Purchase Agreement for the three months ended December 31, 2019 was $11.7 million, or $0.40 per basic and diluted share.

Full Year Results
Revenue for the year ended December 31, 2019, was $1.5 million compared to revenue of $0.7 million for the same period in 2018. Research and development expenses for the year ended December 31, 2019, totaled $34.9 million compared to $41.8 million for the same period in 2018. General and administrative expenses for the year ended December 31, 2019, totaled $12.5 million compared to $15.4 million for the same period in 2018. Merger-related costs, net for the year ended December 31, 2018, totaled $1.2 million. No such costs were incurred during 2019. Restructuring costs for the year ended December 31, 2019, totaled $0.2 million compared to $3.1 million for the same period in 2018 and related to our decision in July 2018 to wind-down our discovery operations.

The 2019 period also included $0.6 million and $11.0 million of non-cash warrant revaluation expense and non-cash future tranche right revaluation expense, respectively, as well as non-cash deemed dividends of approximately $28.0 million, increasing net loss attributable to common stockholders, as further discussed above under fourth quarter results.

As a result of the factors above, net loss applicable to common stockholders for the year ended December 31, 2019, was $84.6 million or $2.96 per basic and diluted share, compared to net loss applicable to common stockholders of $59.9 million, or $2.25 per basic and diluted share, for the same period in 2018. Net loss applicable to common stockholders excluding non-cash expense of approximately $11.6 million and deemed dividends of approximately $28.0 million related to the Securities Purchase Agreement for the three months ended December 31, 2019 was $45.0 million, or $1.57 per basic and diluted share.

As of December 31, 2019, our cash, cash equivalents, and short-term investments totaled $42.8 million, which includes a $6.2 million contingently refundable option fee received in connection with the December 2019 private placement transaction, discussed above. We currently anticipate that, based on our current operating plan, our current cash, cash equivalents, and short-term investments, excluding the $6.2 million contingently refundable option fee, will fund our operations into the first quarter of 2021.

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 the safe harbor of the Private Securities Litigation Reform Act of 1995 and the Federal securities laws. All statements, other than statements of historical fact, included or incorporated in this press release, including statements regarding the Company's strategy, financial position and clinical trial plans, including enrollment and timing of results, are forward-looking statements. The words "believes," "anticipates," "estimates," "plans," "expects," "intends," "may," "could," "should," "potential," "likely," "projects," "continue," "will," "schedule," and "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements are predictions based on the Company's current expectations and projections about future events and various assumptions. 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. These forward-looking statements involve known and unknown risks, uncertainties, and other factors, which may be beyond Idera's control, and which may cause the actual results, performance, or achievements of the Company to be materially different from future results, performance, or achievements expressed or implied by such 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, without limitation: 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; 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, 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 FDA or equivalent foreign regulatory agencies; whether, if the Company's products receive approval, they will be successfully distributed and marketed; and whether the Company's collaborations will be successful. All forward-looking statements included in this release are made as of the date hereof, and are expressly qualified in their entirety by this cautionary notice, including, without limitation, those risks and uncertainties described in the Company's Annual Report on Form 10-K for the year ended December 31, 2019, and otherwise in the Company's filings and reports filed with Securities and Exchange Commission. While 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, except as may be required by law.

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

	Three Months Ended	Twelve Months Ended

	December 31, 2019	December 31, 2018	December 31, 2019	December 31, 2018
Alliance revenue	$ -	$ 99	$ 1,448	$ 662
Operating expenses:				
Research and development	8,368	8,929	34,853	41,841
General and administrative	3,420	3,571	12,481	15,420
Merger-related costs, net	-	-	-	1,245
Restructuring costs	-	95	181	3,112
Total operating expenses	11,788	12,595	47,515	61,618
Loss from operations	(11,788)	(12,496)	(46,067)	(60,956)
Other income (expense)				
Warrant revaluation expense	(598)	-	(598)	-
Future tranche right revaluation expense	(10,964)	-	(10,964)	-
Other income (expense), net	118	346	1,114	1,075
Net loss	$ (23,232)	$ (12,150)	$ (56,515)	$ (59,881)
Deemed dividend related to December 2019 Private Placement	(28,043)	-	(28,043)	-
Net loss attributable to common stockholders	$ (51,275)	$ (12,150)	$ (84,558)	$ (59,881)
Net loss per common share applicable to common stockholders — basic and diluted	$ (1.76)	$ (0.45)	$ (2.96)	$ (2.25)
Weighted-average number of common shares used in computing net loss per share applicable to common stockholders — basic and diluted	29,177	27,183	28,545	26,601

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

	December 31, 2019	December 31, 2018
Cash, cash equivalents and short-term investments	$ 42,793	$ 71,431
Other assets	4,696	1,592
Total assets	$ 47,489	$ 73,023
Total liabilities	$ 58,657	$ 9,029
Total stockholders' equity (deficit)	(11,168)	63,994
Total liabilities and stockholders' equity (deficit)	$ 47,489	$ 73,023

Source: Idera Pharmaceuticals, Inc.

IDERA PHARMACEUTICALS Contacts:

Jill Conwell
Investor Relations &
Corporate Communications

Phone (484) 348-1675
JCONWELL@IDERAPHARMA.COM

John J. Kirby
Chief Financial Officer
Phone (484) 348-1627
JKIRBY@IDERAPHARMA.COM

Source: Idera Pharmaceuticals, Inc.