Idera Pharmaceuticals Reports Third Quarter Financial Results and Provides Corporate Update

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ILLUMINATE-301 Continues on Track and Beyond Melanoma Strategy Advances

EXTON, Pa., Oct. 29, 2020 (GLOBE NEWSWIRE) -- Idera Pharmaceuticals, Inc. ("Idera" or the "Company") (Nasdaq: IDRA) today reported its financial and operational results for the third quarter ended September 30, 2020.

"Tilsotolimod is the most advanced TLR-9 agonist therapy in development, and we have made tremendous strides against our objectives for 2020," stated Vincent Milano, Idera's Chief Executive Officer. "We continue to work diligently against our timelines for ILLUMINATE-301, which currently remain on track for data in the first quarter of 2021. In addition, our recent patent and allowed application for tilsotolimod method-of-use in colorectal and head and neck cancers as well as the continuation of ILLUMINATE-206 reinforce our 'beyond melanoma' strategy. We also have the financing to help our outstanding team continue to execute these key objectives."

Corporate Update
Since June 30, 2020, the following corporate updates were announced:

- The Company entered into a private placement of up to $20.0 million, with $5.1 million received in July 2020. The Company anticipates that its current cash, cash equivalents, and short-term investments will fund our operations through the second quarter of 2021. With this private placement, the Company has now entered into three financing vehicles since December 2019, which it believes could provide proceeds of up to $118.2 million to fund the potential NDA filing and commercial launch of tilsotolimod.
- The Company received a new U.S. Patent and allowed application for tilsotolimod, providing exclusivity through September 2037 when intratumoral tilsotolimod is used with certain immune checkpoint inhibitors in treating colorectal cancer (CRC) and head and neck squamous cell carcinoma (HNSCC).

ILLUMINATE (tilsotolimod) Clinical Development Updates

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

- Primary endpoint family of overall response rate (ORR) by blinded independent central review using 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 the first quarter of 2021.

ILLUMINATE-206: Phase 2, open-label, multicohort, multicenter study to test the safety and effectiveness of tilsotolimod in combination with Yervoy® and Opdivo®* (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 of 10 patients, which included Yervoy® at 1 mg/kg every 8 weeks and Opdivo® at 3 mg/kg every 2 weeks, showed that the regimen was generally well tolerated;
- Changes in the study design intended to improve potential outcomes in this patient population include increasing Yervoy® dosing frequency to every 3 weeks and limiting the number of allowed prior lines of treatment to 2; and
- The Company has opened enrollment for the next 10 patients under the modified study design, with data anticipated in the second quarter of 2021.

ILLUMINATE-204: Phase 1/2 trial of tilsotolimod in combination with Yervoy® or Keytruda®± (pembrolizumab) in patients with anti-PD-1 refractory advanced melanoma:

- Final results from the recommended phase 2 dose (RP2D) of 8 mg of tilsotolimod in combination with Yervoy®, which is the treatment regimen being evaluated in the Company's registrational trial, ILLUMINATE-301, were shared in a Mini Oral presentation at the ESMO Virtual Congress in September 2020.

Third Quarter Financial Results
Research and development expenses for the three months ended September 30, 2020, totaled $4.8 million compared to $8.4 million for the same period in 2019. General and administrative expense for the three months ended September 30, 2020, totaled $2.7 million compared to $3.0 million for the same period in 2019. Additionally, during the three months ended September 30, 2020, we recorded $0.7 million and $12.4 million non-cash warrant revaluation loss and non-cash future tranche right revaluation loss, respectively, related to securities issued in connection with our December 2019 private placement transaction.

As a result of the factors above, net loss applicable to common stockholders for the three months ended September 30, 2020, was $20.6 million, or $0.59 per basic and diluted share, compared to net loss applicable to common stockholders of $11.1 million, or $0.39 per basic and diluted share, for the same period in 2019. Excluding the non-cash loss of approximately $13.1 million for the three months ended September 30, 2020, related to the securities issued in connection with the December 2019 private placement transaction, net loss applicable to common stockholders was $7.5 million, or $0.21 per basic and diluted share (calculated based upon the basic weighted-average number of common shares, due to the antidilutive effect of net loss).

As of September 30, 2020, our cash, cash equivalents, and short-term investments totaled $29.0 million. Based on our current operating plan, we anticipate that our current cash, cash equivalents, and short-term investments, will fund our operations through the second 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 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, funding for continued operations, and clinical trials, including the enrollment, timing, and future results thereof, 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; whether the Company's collaborations will be successful; and the impact of public health crises, including the novel coronavirus (COVID-19) global pandemic. 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.

*Yervoy (ipilimumab) and Opdivo (nivolumab) are registered trademarks of Bristol Myers Squibb.

±Keytruda (pembrolizumab) is a registered trademark of Merck Sharp & Dohme, a subsidiary Merck & Co., Inc.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	**2019**	**2020**	**2019**
Alliance revenue	$ -	$ -	$ -	$ 1,448

Operating expenses:				
Research and development	4,766	8,359	19,655	26,485
General and administrative	2,718	3,023	8,992	9,061
Restructuring costs	-	5	-	181
Total operating expenses	7,484	11,387	28,647	35,727
Loss from operations	(7,484)	(11,387)	(28,647)	(34,279)
Other income (expense)				
Warrant revaluation loss	(683)	-	(495)	-
Future tranche right revaluation loss	(12,350)	-	(6,988)	-
Other income (expense), net	(35)	254	169	996
Net loss	$ (20,552)	$ (11,133)	$ (35,961)	$ (33,283)
Net loss per common share applicable to common stockholders— basic and diluted	$ (0.59)	$ (0.39)	$ (1.09)	$ (1.17)
Weighted-average number of common shares used in computing net loss per share applicable to common stockholders— basic and diluted	35,091	28,847	32,999	28,332

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

	September 30, 2020	December 31, 2019
Cash, cash equivalents, and short-term investments	$ 28,979	$ 42,793
Other assets	3,359	4,696
Total assets	$ 32,338	$ 47,489
Total liabilities	$ 64,773	$ 58,657
Total stockholders' deficit	(32,435)	(11,168)
Total liabilities and stockholders' deficit	$ 32,338	$ 47,489

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