



Idera Pharmaceuticals Reports Second Quarter Financial Results and Provides Corporate Update

August 4, 2020 8:10 PM EDT

Enhanced Financial Flexibility as ILLUMINATE-301 Continues on Track

EXTON, Pa., Aug. 04, 2020 (GLOBE NEWSWIRE) -- Idera Pharmaceuticals, Inc. ("Idera" or the "Company") (Nasdaq: IDRA) today reported its financial and operational results for the second quarter ended June 30, 2020.

"Idera meaningfully advanced its clinical pipeline and strengthened its financial resources in the first part of 2020. Further encouraged by data from ILLUMINATE-204, which we reported in the second quarter, we continue to work diligently against our timelines for ILLUMINATE-301. Those timelines currently remain on track for data in the first quarter of 2021, despite disruptions from the global impact of COVID-19," stated Vincent Milano, Idera's Chief Executive Officer. "In addition, as part of our 'beyond melanoma' strategy, early data from ILLUMINATE-206 reinforces our optimism in the potential of tilsotolimod in patients with micro-satellite stable colorectal cancer. Lastly, our team's outstanding perseverance and dedication to our patients combined with the further financing we recently secured will help us continue to execute these key objectives and potentially beyond."

Corporate Update

Since March 31, 2020, the Company entered into two private placement financings of up to \$40.7 million, with \$5.0 million received in April 2020 and \$5.1 million received in July 2020. The Company anticipates that its current cash, cash equivalents, and short-term investments will fund our operations into the second quarter of 2021. With the Company's current financing vehicles, there exists the possibility to extend that runway through subsequent proceeds to fund the potential NDA filing and commercial launch of tilsotolimod.

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 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;
- Planned 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
- Enrollment of the next 10 patients is targeted to begin in the fourth quarter of 2020, 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 topline results released in [April 2020](#) 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; and
- Final data from the trial will be shared in a Mini Oral presentation at the ESMO Virtual Congress 2020, to be held September 19-21, 2020.

Second Quarter Financial Results

Research and development expenses for the three months ended June 30, 2020 totaled \$5.4 million compared to \$10.0 million for the same period in 2019. General and administrative expense for the three months ended June 30, 2020 totaled \$2.6 million compared to \$2.9 million for the same period in 2019. Additionally, during the three months ended June 30, 2020, we recorded \$0.9 million and \$15.3 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 June 30, 2020 was \$24.2 million, or \$0.72 per basic and diluted share, compared to net loss applicable to common stockholders of \$11.2 million, or \$0.39 per basic and diluted share, for the same period in 2019. Excluding the non-cash loss of approximately \$16.3 million for the three months ended June 30, 2020 related to the securities issued in connection with the December 2019 private placement transaction, net loss applicable to common stockholders was \$8.0 million, or \$0.24 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 June 30, 2020, our cash, cash equivalents, and short-term investments totaled \$31.0 million. Based on our current operating plan, we anticipate that our current cash, cash equivalents, and short-term investments, including \$5.1 million gross proceeds in cash received in July 2020 pursuant to the July 2020 Securities Purchase Agreement, will fund our operations into 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 June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Alliance revenue	\$ -	\$ 1,448	\$ -	\$ 1,448
Operating expenses:				
Research and development	5,379	10,024	14,889	18,126
General and administrative	2,632	2,895	6,274	6,038
Restructuring costs	-	45	-	176
Total operating expenses	8,011	12,964	21,163	24,340
Loss from operations	(8,011)	(11,516)	(21,163)	(22,892)

Other income (expense)				
Warrant revaluation (loss) gain	(913)	-	188	-
Future tranche right revaluation (loss) gain	(15,349)	-	5,362	-
Other income (expense), net	<u>47</u>	<u>340</u>	<u>204</u>	<u>742</u>
Net loss	<u>\$ (24,226)</u>	<u>\$ (11,176)</u>	<u>\$ (15,409)</u>	<u>\$ (22,150)</u>
Net loss per common share applicable to common stockholders				
— basic	<u>\$ (0.72)</u>	<u>\$ (0.39)</u>	<u>\$ (0.48)</u>	<u>\$ (0.79)</u>
— diluted	<u>\$ (0.72)</u>	<u>\$ (0.39)</u>	<u>\$ (0.52)</u>	<u>\$ (0.79)</u>
Weighted-average number of common shares used in computing net loss per share applicable to common stockholders				
— basic	<u>33,583</u>	<u>28,461</u>	<u>31,941</u>	<u>28,070</u>
— diluted	<u>33,583</u>	<u>28,461</u>	<u>34,123</u>	<u>28,070</u>

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

	June 30, 2020	December 31, 2019
Cash, cash equivalents, and short-term investments	\$ 31,006	\$ 42,793
Other assets	<u>3,779</u>	<u>4,696</u>
Total assets	<u>\$ 34,785</u>	<u>\$ 47,489</u>
Total liabilities	\$ 52,476	\$ 58,657
Total stockholders' deficit	<u>(17,691)</u>	<u>(11,168)</u>
Total liabilities and stockholders' deficit	<u>\$ 34,785</u>	<u>\$ 47,489</u>

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.