



Idera Pharmaceuticals Provides Corporate Update and Reports Second Quarter 2019 Financial Results

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EXTON, Pa., Aug. 08, 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, today reported its operational and financial results for the second quarter ended June 30, 2019.

"Our team has demonstrated remarkable focus on execution during the first half of this year. We have made significant progress developing tilsotolimod and advancing it forward for patients facing the challenges of late-stage, anti-PD-1 refractory metastatic melanoma," stated Vincent Milano, Idera's Chief Executive Officer. "Our accrual rate in the registrational ILLUMINATE-301 trial has exceeded our expectations, which is reflective of the high unmet need in this patient population."

Milano continued, "Additionally, we are providing data from the ILLUMINATE-204 trial, which we believe is informative as to the probability of success in the registrational trial. We also are advancing toward initiation of our first combination therapy trial in areas beyond melanoma, ILLUMINATE-206, which we expect will provide additional opportunities and milestones for data updates next year."

ILLUMINATE (tilsotolimod) Clinical Development

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

- Overall Response Rate (ORR) and Overall Survival (OS) as family of primary endpoints;
- Trial initiated in the first quarter of 2018;
- Sites active in 11 countries: Approximately 100 sites participating.

Based on feedback from the ILLUMINATE-301 steering committee and global melanoma and immunology experts, we have elected to make the following modifications to the ILLUMINATE 301 trial design:

- Median OS improvement over ipilimumab alone of greater than or equal to 4.6 months from prior delta of improvement of 6.6 months;
- ORR improvement of 10 percentage points over ipilimumab alone from prior delta of improvement of 20 percentage points;
- Target effect size/hazard ratio adjusted to 0.71 from 0.63; resulting in a planned enrollment of approximately 450 patients from 308, of which 294 are currently enrolled; and
- Targeting completion of enrollment during the first half of 2020.

We along with our collaboration partner, BMS, have amended the prior Clinical Trial Collaboration and Supply Agreement to accommodate the increase in supply of ipilimumab for the ILLUMINATE-301 trial.

Additionally, we have solicited feedback from the U.S. Food and Drug Administration and they do not object to these changes. We also have solicited feedback from other global health authorities related to these changes.

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 at tilsotolimod 8 mg with ipilimumab in February 2019;
- Data as of August 5, 2019 on endpoints:
 - 27% ORR (n=13) of the 49 patients evaluable for efficacy; 74% (36) achieving disease control (best response of CR, PR or Stable Disease (SD));
 - Durable responses (>6 mos.) observed in 8 of 13 responders;
 - Median OS has not yet been reached (min/max: 1.6 mos. – 35 mos.);
- The safety profile observed in this analysis was consistent with previously reported results, with no emergence of new safety signals;
- 43% (n=21) of patients enrolled into trial presented at baseline with Eastern Cooperative Oncology Group (ECOG) performance status 2; and

- Final results from the ILLUMINATE 204 trial are expected to be submitted for an abstract at a medical conference during the first half of 2020.

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).

- On March 11, 2019, we entered into a second clinical trial collaboration with BMS in which BMS has agreed to manufacture and supply YERVOY (ipilimumab) and OPDIVO (nivolumab) for no charge for use in ILLUMINATE-206;
- Trial expected to initiate in the third quarter of 2019 beginning with the MSS-CRC cohort.

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

- Completed enrollment in all dose cohorts of the trial;
- Initial data presented at American Academy for Cancer Research (AACR) 2019 conference;
 - Of 29 evaluable patients, 13 (45%) had a RECIST v1.1 disease assessment of stable disease (SD), with a disease control rate of 45%;
 - One patient with uterine leiomyosarcoma has been on tilsotolimod treatment for more than a year with durable stable disease and is continuing under a treatment investigational new drug;
- One patient in the melanoma cohort achieved an unconfirmed RECIST v.1.1 partial response (PR) with 35% tumor shrinkage in the target lesion; and
- Abstract submission accepted for poster presentation at the European Society for Medical Oncology 2019 Conference being held in Barcelona, Spain in September 2019.

Corporate Updates:

- Elizabeth A. Tarka, MD, FACC was appointed as Chief Medical Officer effective July 22, 2019; and
- John J. Kirby was appointed as Chief Financial Officer effective July 22, 2019.

Upcoming Investor Presentation:

- The company will be presenting at the 2019 Wedbush PacGrow Healthcare Conference on Tuesday, August 13, 2019 at 1:20 PM ET. The conference is being held at the Parker New York Hotel. The webcast can be accessed live or in archived form in the “Investors” section of the company’s website at www.iderapharma.com.

Financial Results

Second Quarter Results

Net loss applicable to common stockholders for the three months ended June 30, 2019 was \$11.2 million, or \$0.39 per basic and diluted share, compared to net loss applicable to common stockholders of \$16.0 million, or \$0.59 per basic and diluted share, for the same period in 2018. Revenue for the three months ended June 30, 2019 was \$1.4 million, compared to \$0.2 million for the same period in 2018. Research and development expenses for the three months ended June 30, 2019 totaled \$10.0 million compared to \$10.9 million for the same period in 2018. General and administrative expense for the three months ended June 30, 2019 totaled \$2.9 million compared to \$4.0 million for the same period in 2018. Merger-related costs, net for the three months ended June 30, 2018 totaled \$1.6 million and related to our contemplated merger transaction. No such costs were incurred for the same period in 2019. Restructuring costs for the three months ended June 30, 2019 were nominal and related to our decision in July 2018 to wind-down our discovery operations. No such costs were incurred for the same period in 2018.

As of June 30, 2019, our cash, cash equivalents and short-term investments totaled \$52.4 million compared to \$71.4 million as of December 31, 2018. We currently anticipate that, based on our current operating plan, our existing cash, cash equivalents and investments will fund our operations into the second quarter of 2020.

Investor Event and Webcast

Idera will host a conference call and live webcast today, Thursday, August 8, 2019, at 10:00 A.M. EST to provide an overview of today’s update along with a question and answer session. To participate in the conference call, please dial (844) 882-7837 (domestic) and (574) 990-9824 (international). The webcast can be accessed live or in archived form in the “Investors” section of the company’s website at www.iderapharma.com.

About Idera Pharmaceuticals

Harnessing the approach of the earliest researchers in immunotherapy and the company’s vast experience in developing proprietary immunomodulatory platforms, Idera’s TLR agonist 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 fiscal 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		Six Months Ended	
	June 30,		June 30,	
	2019	2018	2019	2018
Alliance revenue	\$ 1,448	\$ 163	\$ 1,448	\$ 418
Operating expenses:				
Research and development	10,024	10,880	18,126	24,436
General and administrative	2,895	4,000	6,038	7,481
Merger-related costs, net	-	1,583	-	5,081
Restructuring costs	45	-	176	-
Total operating expenses	12,964	16,463	24,340	36,998
Loss from operations	(11,516)	(16,300)	(22,892)	(36,580)
Other income (expense), net	340	269	742	454
Net loss	<u>\$ (11,176)</u>	<u>\$ (16,031)</u>	<u>\$ (22,150)</u>	<u>\$ (36,126)</u>
Net loss per common share applicable to common stockholders — basic and diluted	<u>\$ (0.39)</u>	<u>\$ (0.59)</u>	<u>\$ (0.79)</u>	<u>\$ (1.39)</u>
Weighted-average number of common shares used in computing net loss per share applicable to common stockholders — basic and diluted	<u>28,461</u>	<u>27,133</u>	<u>28,070</u>	<u>26,012</u>

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

	June 30, 2019	December 31, 2018
Cash, cash equivalents and short-term investments	\$ 52,373	\$ 71,431

Other assets	1,959	1,592
Total assets	<u>\$ 54,332</u>	<u>\$ 73,023</u>
Total liabilities	\$ 6,597	\$ 9,029
Total stockholders' equity	47,735	63,994
Total liabilities and stockholders' equity	<u>\$ 54,332</u>	<u>\$ 73,023</u>

Source: Idera Pharmaceuticals, Inc.

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Source: Idera Pharmaceuticals, Inc.