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

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EXTON, Pa., May 02, 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 financial and operational results for the first quarter ended March 31, 2019.

“The first quarter of this year represented another period of solid execution from everyone on our team,” stated Vincent Milano, Idera’s Chief Executive Officer. “During this quarter, we completed enrollment of ILLUMINATE-204, positioning ourselves to provide a full analysis from this trial in the fourth quarter of this year. We’ve also made significant progress with the enrollment of Idera’s first pivotal trial, ILLUMINATE-301, for which we expect to complete accrual during the fourth quarter. And, we recently presented the data from the ILLUMINATE-101 monotherapy trial at AACR, strengthening the body of translational and clinical evidence that tilsotolimod stimulates an immune response within the tumor microenvironment. We believe that this may be a key to enhancing the outcomes of existing immunotherapy regimens.”

Milano continued, “Lastly, we’ve made great strides in preparing to initiate the expansion of activities for tilsotolimod through the ILLUMINATE-206 multi-cohort trial, which we anticipate will launch this quarter. We appreciate the financial commitment and teamwork from our collaboration partner, Bristol-Myers Squibb, which assisted us in taking on this endeavor. Overall, this has been a highly productive quarter for our team and the momentum continues to swell as we advance towards these critical catalysts for our company.”

ILLUMINATE (tilsotolimod) Clinical Development

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: 85 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).

- On March 11, 2019 entered into a second clinical trial collaboration with Bristol-Myers Squibb (BMS) in which BMS has agreed to manufacture and supply YERVOY (ipilimumab) and OPDIVO (nivolumab) at its cost and for no charge for use in ILLUMINATE-206;
- Received notice from the U.S. Food and Drug Administration that we 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 dosed in Phase 2 expansion at tilsotolimod 8 mg 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
- Final overall response rate (ORR) data from the ipilimumab combination arm of 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
- Poster presented at the American Association for Cancer Research (AACR) 2019 Annual Meeting on April 2, 2019 which demonstrated:

Safety Data

- No dose limiting toxicities or treatment-related adverse events were observed;
- No treatment-emergent adverse events (TEAEs) leading to treatment or study discontinuation or death occurred; and
- The most common grade 3/4 TEAEs were anemia, hyponatremia, pain, sepsis (n=3 each), fatigue and thrombocytopenia (n=2 each).

Efficacy Data

- Of 29 evaluable patients, 13 (45%) had a RECIST v1.1 disease assessment of stable disease (SD), with a disease control rate of 45%;
- Of the 13 patients with SD, 5 (38%) had maximum tumor shrinkage >10% below baseline;
- Duration of SD ranged from 1.3 to 9.7+ months from start of treatment, with 3 patients ongoing; and
- No correlations between dose and efficacy were observed.

Translational Data

- Fresh flow cytometry in 2 of 3 analyzed patients showed HLA-DR (MHC Class II) upregulation at 24 hours compared with pre-treatment; and
- Robust activation and upregulation of type I IFN pathway was observed across analyzed tumor types, demonstrated by increased IRF7, IFIT1, and IFIT2 gene expression, and early increases in type I IFN signaling.

Financial Results
First Quarter Results
Net loss applicable to common stockholders for the three months ended March 31, 2019 was $11.0 million, or $0.40 per basic and diluted share, compared to net loss applicable to common stockholders of $20.1 million, or $0.81 per basic and diluted share, for the same period in 2018. Revenue for each of the three months ended March 31, 2019 and 2018 was nominal. Research and development expenses for the three months ended March 31, 2019 totaled $8.1 million compared to $13.6 million for the same period in 2018. General and administrative expense for the three months ended March 31, 2019 totaled $3.1 million compared to $3.5 million for the same period in 2018. Merger-related costs, net for the three months ended March 31, 2018 totaled $3.4 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 March 31, 2019 was 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 March 31, 2019, our cash, cash equivalents and investments totaled $59.9 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.

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 period 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 March 31,	
	2019	**2018**
Alliance revenue	$ -	$ 255
Operating expenses:		
Research and development	8,102	13,556
General and administrative	3,143	3,481
Merger-related costs, net	-	3,498
Restructuring costs	131	-
Total operating expenses	11,376	20,535
Loss from operations	(11,376)	(20,280)
Other income (expense), net	402	185
Net loss	$ (10,974)	$ (20,095)
Net loss per common share applicable to common stockholders — basic and diluted	$ (0.40)	$ (0.81)
Weighted-average number of common shares used in computing net loss per share applicable to common stockholders — basic and diluted	27,676	24,879

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

	March 31, 2019	**December 31, 2018**
Cash, cash equivalents and short-term investments	$ 59,864	$ 71,431
Other assets	2,137	1,592
Total assets	$ 62,001	$ 73,023
Total liabilities	$ 6,329	$ 9,029
Total stockholders' equity	55,672	63,994
Total liabilities and stockholders' equity	$ 62,001	$ 73,023

Source: Idera Pharmaceuticals, Inc.

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Source: Idera Pharmaceuticals, Inc.