



## **Idera Pharmaceuticals Provides 2020 Update and Outlook**

January 14, 2020 12:00 PM EST

**Company to Present at the 38th Annual J.P. Morgan Healthcare Conference on Thursday, January 16, 2020 at 7:30 AM PT/10:30 AM ET**

EXTON, Pa., Jan. 14, 2020 (GLOBE NEWSWIRE) -- Idera Pharmaceuticals, Inc. (Nasdaq: IDRA), or Idera or the Company, today is providing an update on its tilsotolimod clinical development program and providing a corporate outlook for 2020.

"We made tremendous progress last year with the tilsotolimod clinical development program, and we are positioned well going into this pivotal year," stated Vincent Milano, Idera's Chief Executive Officer. "Our ILLUMINATE-301 registrational trial of tilsotolimod in anti-PD-1 refractory metastatic melanoma is enrolling at a rate that dramatically exceeded our expectations. We expect to complete enrollment this quarter, setting up the possibility of data before the end of this year. We believe the rapid enrollment in this randomized trial is a testament to the critical unmet need for this patient group as well as to the growing appreciation from global investigators for both intratumoral administration and the mechanism of action of tilsotolimod."

Continued Milano, "We also will add to the overall body of clinical evidence for tilsotolimod with additional data readouts expected in the second quarter. Final analysis of ILLUMINATE-204 will include median overall survival (OS) for the first time, and ILLUMINATE-206 will provide safety and preliminary efficacy in microsatellite-stable colorectal cancer (MSS-CRC) as a triple combination of ipilimumab, nivolumab and tilsotolimod in this immunorefractory indication."

"Lastly, we recently entered into a financing agreement that provides financial resources for these critical catalysts and beyond. Overall, we are looking forward to 2020 and delivering on the goals we set for patients and our investors when we initiated the development of tilsotolimod."

### **ILLUMINATE (tilsotolimod) Clinical Development Program**

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

- Approximately 100 sites active in 11 countries;
- Planned enrollment target of 454 patients;
- As of January 13, 2020, 427 patients enrolled, representing 94% enrollment; and
- Targeting completion of enrollment during Q1 2020; and data in Q4 2020/Q1 2021.

**ILLUMINATE 206** – Phase 2, open-label, multi-cohort, multi-center study to test the safety and effectiveness of tilsotolimod in combination with ipilimumab and nivolumab for the treatment of solid tumors:

- Trial initiated on September 30, 2019, leading with the MSS-CRC cohort;
- Initial safety run-in cohort of 10 patients with MSS-CRC fully enrolled; and
- Preliminary objective response rate (ORR) and safety 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 metastatic melanoma:

- Completed enrollment with 52 patients (49 evaluable) at tilsotolimod 8 mg with ipilimumab in February 2019; and
- Final results from the ILLUMINATE 204 trial are expected to be released in Q2 2020;
  - Data to be presented include ORR, median OS, duration of response (DOR) and safety.

### **Upcoming Corporate Presentation**

Idera Chief Executive Officer Vincent Milano will provide a corporate overview at the 38<sup>th</sup> Annual J.P. Morgan Healthcare Conference on Thursday, January 16, 2020 at 7:30 AM PT/ 10:30 AM ET. The conference is being held at the Westin St. Francis Hotel in San Francisco, CA. A copy of the Company's J.P. Morgan corporate presentation will be posted on the Investors' page of the Company's corporate website on Wednesday January 15, 2020 prior to the opening of the U.S. markets.

Live audio webcast of Idera's presentations will be accessible in the Investors section of Idera's website at <http://www.iderapharma.com>. Archived versions will also be available on the Company's website after the event for 90 days.

### **About Tilsotolimod (IMO-2125)**

Tilsotolimod is an investigational TLR 9 agonist that received Fast Track Designation from the U.S. Food and Drug Administration (FDA) in 2017 for the treatment of anti-PD-1 refractory melanoma, in combination with ipilimumab as well as orphan drug designation from the FDA for the treatment of

melanoma Stages IIb to IV. It signals the immune system to create and activate cancer-fighting cells (T-cells) to target solid tumors. Currently approved immuno-oncology treatments, specifically check-point inhibitors, provide benefit for some patients, but these therapies are limited in patients whose immune responses are missing or weak. Intratumoral injections with tilsotolimod are designed to selectively enable the tumor-specific T-cells to recognize and attack cancers that remain elusive and unrecognized by the immune system exposed to checkpoint inhibitors alone, while limiting toxicity or impact on healthy cells in the body.

#### **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](http://www.iderapharma.com).

#### **Idera 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, 2018, 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 Contacts:**

Robert A. Doody, Jr.  
SVP, Investor Relations & Communications  
Phone (484) 348-1677  
[rdoody@iderapharma.com](mailto:rdoody@iderapharma.com)

John J. Kirby  
SVP, Chief Financial Officer  
Phone (484) 348-1627  
[jkirby@iderapharma.com](mailto:jkirby@iderapharma.com)



Source: Idera Pharmaceuticals, Inc.