# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION
# WASHINGTON, D.C. 20549

## FORM 8-K

## CURRENT REPORT
## PURSUANT TO SECTION 13 OR 15(d) OF THE
## SECURITIES EXCHANGE ACT OF 1934

Date of report (Date of earliest event reported): **March 18, 2021**

## Idera Pharmaceuticals, Inc.
(Exact Name of Registrant as Specified in Charter)

| **Delaware** | **001-31918** | **04-3072298** |
|---|---|---|
| (State or Other Jurisdiction of Incorporation) | (Commission File Number) | (I.R.S. Employer Identification No.) |

| **505 Eagleview Blvd., Suite 212**<br>**Exton, Pennsylvania** | **19341** |
|---|---|
| (Address of Principal Executive Offices) | (Zip Code) |

Registrant's telephone number, including area code: **(484) 348-1600**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425).
☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12).
☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240-14d-2(b)).
☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240-13e-4(c)).

Securities registered pursuant to Section 12(b) of the Act:

| **Title of each class** | **Trading Symbol(s)** | **Name of each exchange on which registered** |
|---|---|---|
| Common Stock, par value $0.001 per share | IDRA | Nasdaq Capital Market |

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

**Item 8.01. Other Events.**

On March 18, 2021, Idera Pharmaceuticals, Inc. (the "Company") issued a press release announcing certain top-line results from the Company's registration trial, ILLUMINATE-301. The full text of the press release is attached to this Current Report on Form 8-K as Exhibit 99.1 and is incorporated herein by reference.

**Item 9.01. Financial Statements and Exhibits.**

(d) *Exhibits*.

| Exhibit Number | Description |
|---|---|
| 99.1 | Press Release dated March 18, 2021 |
| 104 | Cover Page Interactive Data File (embedded within the Inline XBRL document) |

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

**IDERA PHARMACEUTICALS, INC.**

Dated: March 18, 2021

By: /s/ Bryant D. Lim
Bryant D. Lim
Senior V.P., General Counsel

**Exhibit 99.1**

**Idera Pharmaceuticals Announces Results From ILLUMINATE-301 Trial of Tilsotolimod + Ipilimumab in anti-PD-1 Refractory Advanced Melanoma**

**– Objective Response Rate Endpoint Not Met –**

**EXTON, PA, March 18, 2021 —** Idera Pharmaceuticals, Inc. (Nasdaq: IDRA; the "Company") today is announcing that ILLUMINATE-301, the Company's pivotal registration trial of tilsotolimod in combination with ipilimumab versus ipilimumab alone in patients with anti-PD-1 refractory advanced melanoma, did not meet its primary endpoint of objective response rate (ORR). Idera is evaluating its next steps regarding continuation of the trial toward its overall survival (OS) endpoint, which includes evaluating the full data set when it is available. The Company also plans to continue its ILLUMINATE-206 Phase 2 study of tilsotolimod in combination with ipilimumab and nivolumab in patients with microsatellite stable colorectal cancer (MSS-CRC).

ILLUMINATE-301 is a randomized, global, multi-center, open label Phase 3 trial comparing the efficacy of 8 mg intratumoral tilsotolimod in combination with 3 mg/kg ipilimumab versus 3 mg/kg ipilimumab alone in 481 patients with anti-PD-1 refractory advanced melanoma. The trial has a primary endpoint family of ORR per RECIST v1.1 and OS. Although the primary endpoint of ORR was not met, if the study continues and reaches a positive OS outcome, the Company would expect to discuss with regulatory authorities a potential path forward in this indication.

**ILLUMINATE-301 Key Findings**:

Patients in the study were randomized and treated either with 8 mg of tilsotolimod in combination with ipilimumab or with ipilimumab alone. Topline results include:

- ORR of 8.8% for the combination arm and 8.6% for ipilimumab alone.
- Disease control rate (DCR, defined as stable disease or better) of 34.5% for the combination and 27.2% for ipilimumab alone.
- Treatment-emergent adverse events (TEAEs) (Grade 3 and above) occurred in 61.1% of patients who received the combination vs. 55.1% of patients who received ipilimumab alone. Immune-related TEAEs (Grade 3 and above) were reported in 37.6% vs. 30.1%, respectively.

More detailed results from ILLUMINATE-301 may be submitted for future publication or presentation.

"We are surprised and disappointed that the response data from ILLUMINATE-301 do not lead us to an accelerated path to a new and much-needed treatment option for these patients," stated Vincent Milano, Idera's Chief Executive Officer. "We would like to extend our deepest gratitude to everyone involved in this study, especially the many courageous patients who participated and continue in follow up."

Continued Mr. Milano, “Despite today’s news, we are continuing to explore tilsotolimod via our ongoing ILLUMINATE-206 study in order to understand its potential to lead to better outcomes for patients with MSS-CRC.”

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

Tilsotolimod is an investigational, synthetic Toll-like receptor 9 agonist. Intratumoral injection of tilsotolimod has been shown to promote both innate (Type-I IFN, antigen presentation) and adaptive (T cells) immune activation. Tumors with an active immune response appear to respond better to checkpoint inhibitors (CPIs) than those that exclude or inhibit anti-tumor immune cells. Tilsotolimod in combination with CPIs may increase the number of patients who benefit from immunotherapy.

Tilsotolimod has received both Fast Track designation and Orphan Drug designation from the FDA and is being evaluated in multiple tumor types and in combination with multiple checkpoint inhibitors. For more information on tilsotolimod trials, please visit www.clinicaltrials.gov.

***About Anti-PD-1 Refractory Advanced Melanoma***

Melanoma is a cancer that begins in a type of skin cell called melanocytes. While melanoma is the least common type of skin cancer, it has a poor prognosis when not detected and treated early. As is the case in many forms of cancer, melanoma becomes more difficult to treat once the disease has spread, or metastasized, beyond the skin to other parts of the body. According to the American Cancer Society, approximately 100,000 people in the US will be diagnosed with invasive melanoma this year. In recent years, immunotherapies known as CPIs have changed the treatment of advanced melanoma, with anti-PD-1 agents, alone or in combination with anti-CTLA-4, being the most commonly used immunotherapy in the first-line setting. These agents work by increasing the ability of the body’s immune system to help detect and fight cancer cells. However, due to primary or acquired resistance mechanisms that exclude or inhibit anti-tumor immune cells, as many as 60% of patients may not benefit from this type of therapy when used as monotherapy, and up to one-third of initial responders may develop resistance to the therapy and ultimately experience disease progression. Today, these refractory patients are left with few options for further treatment, paving the way for novel investigational therapies such as tilsotolimod.

***About MSS-CRC***

Colorectal cancer involves the abnormal growth of cells in the colon or rectum. This type of cancer is typically tested to determine its “MSI” status, which will inform treatment approach and prognosis. MSI stands for “microsatellite instable.” MSI-High (MSI-H) means that there is a high amount of instability in a tumor, whereas MSS tumors are “microsatellite stable.” The American Cancer Society estimates that, annually in the United States, approximately 140,000 people are diagnosed with CRC, of which 85% are MSS, and approximately 50,000 people die due to CRC. MSS-CRC has been shown to be highly immunosuppressive; there are no approved immunotherapy options, and a prior trial of ipilimumab plus nivolumab (Bristol Myers Squibb’s CheckMate 142) yielded overall response rates of 0-10%. Given tilsotolimod’s mechanism of action of activating dendritic cells and therefore triggering innate and adaptive immune responses, it may serve a complementary function to ipilimumab and nivolumab within the immunosuppressive tumor microenvironment of MSS-CRC patients.

***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 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, intellectual property, cash resources, financial position, future revenues, projected costs, prospects, clinical trials and related endpoints, 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. Factors that may cause such a difference include: whether the Company’s cash resources will be sufficient to fund the Company’s continuing operations and further development of the Company’s programs for the period anticipated; whether topline results from a clinical trial, such as the results reported in this release, will be predictive of the final results of the trial; whether results obtained in preclinical studies and clinical trials such as the results described in this release 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 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 as are set forth under the caption "Risk Factors" in the Company’s Annual Report filed on Form 10-K for the period ended December 31, 2020 and in the Company’s other filings with the Securities and Exchange Commission. 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.

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