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): April 21, 2020

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 Exton, Pennsylvania		**19341**
(Address of Principal Executive Offices)		(Zip Code)

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

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

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

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:

☐ 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))

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 7.01 Regulation FD Disclosure.

On April 21, 2020, Idera Pharmaceuticals, Inc. (the "Company," "we," "us," and "our") issued a press release announcing final topline data from the ILLUMINATE-204 trial investigating intratumoral tilsotolimod. A copy of the press release is attached to this Current Report on Form 8-K as Exhibit 99.1.

The Company is furnishing the information in this Item 7.01 and the related Exhibit 99.1 filed herewith to comply with Regulation FD. Such information shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, and shall not be deemed to be incorporated by reference into any of the Company's filings under the Securities Act of 1933, as amended, whether made before or after the date hereof and regardless of any general incorporation language in such filings, except to the extent expressly set forth by specific reference in such a filing. This Item 7.01 will not be deemed an admission as to the materiality of any information herein (including Exhibit 99.1) that is required to be disclosed solely by Regulation FD.

Item 9.01. Financial Statements and Exhibits.

(d)

Exhibit No.	Exhibit Name
99.1	Press Release dated April 21, 2020.

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.

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

Dated: April 21, 2020

Exhibit 99.1

IDERA PHARMACEUTICALS Contacts:

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Idera Pharmaceuticals Announces Final Clinical Safety and Efficacy Data from ILLUMINATE-204 Trial in Advanced Melanoma

– Overall response rate of 22% –
– Disease control rate of 71% –
– Median overall survival of 21 months –
– Key topline data from ILLUMINATE-301 expected in Q1 2021 –

EXTON, PA, April 21, 2020 — Idera Pharmaceuticals, Inc. (NASDAQ: IDRA) (the Company) today is announcing final topline data from the ILLUMINATE-204 trial investigating intratumoral tilsotolimod, Idera's investigational Toll-like receptor 9 (TLR9) agonist.

ILLUMINATE-204 is a multi-center, two-arm phase 1/2 trial in patients with anti-PD-1 refractory advanced melanoma. The phase 1 portion of the trial tested the safety and efficacy of increasing doses of tilsotolimod in combination with either Yervoy®* (ipilimumab) or Keytruda®$^{\pm}$ (pembrolizumab). The phase 2 expansion of the trial enrolled additional patients at the recommended phase 2 dose (RP2D) of 8 mg of tilsotolimod in combination with Yervoy®, which is the treatment regimen being evaluated for the same indication in the Company's registrational trial, ILLUMINATE-301.

"The clinical benefit suggested for these anti-PD-1 refractory melanoma patients with limited treatment options includes stabilization of disease and even responses, which is creating hope that this combination might be of benefit to patients in the PD-1 refractory setting," stated Joseph Markowitz, M.D., Ph.D., from the H. Lee Moffitt Cancer Center & Research Center in Tampa, Florida. "We eagerly await the outcome of the ongoing phase 3 trial to see whether this combination treatment with ipilimumab will represent an additional option for patients with advanced melanoma."

ILLUMINATE-204 Key Findings:

The study included 52 patients treated with 8 mg of tilsotolimod in combination with Yervoy®.

- 49 patients were evaluable for efficacy.
- Median overall survival (OS) was 21.0 months (95% confidence interval (CI): 9.8 months-not reached (NR)).
- The overall response rate (ORR) per Response Evaluation Criteria in Solid Tumors (RECIST v1.1) was 22.4%, including 2 complete responses (95% CI: 11.8-36.6%).

- The disease control rate (stable disease or better) was 71.4% (95% CI: 56.7%-83.4%).
- Median duration of response was 11.4 months (95% CI: 3.3 months-NR).
- 7 of 11 RECIST v1.1 responses were durable for greater than 6 months.
- Tumor reduction was observed in both injected and noninjected tumors.

· The combination regimen was generally well tolerated among the 62 patients receiving tilsotolimod at any dose in combination with Yervoy®.
- 48% of patients reported a maximum Grade 3 or 4 treatment emergent adverse event (TEAE).
- The most common serious TEAEs were autoimmune hepatitis, hyponatremia, and hypophysitis (n=2 for each).
- 26% of patients reported immune-related toxicities, suggesting that tilsotolimod + Yervoy® does not add immune-related toxicity versus Yervoy® alone.
- There were no TEAEs leading to discontinuation or death.

Final data from ILLUMINATE-204 is planned for submission to a medical meeting in the second half of 2020.

“The outcomes from this study encourage our belief that the combination of tilsotolimod and ipilimumab may provide a much-needed treatment option for advanced melanoma patients who have limited available therapies,” stated Elizabeth Tarka, M.D., Idera’s Chief Medical Officer. “We are looking forward to completing our registrational trial for this indication, ILLUMINATE-301, where a comparator arm is included, and moving this potential therapy one step closer to patients in need.”

Continued Dr. Tarka, “As with many of our peers, we are intently monitoring the COVID-19 pandemic and its potential effect on the ILLUMINATE-301 trial. We are working closely with our investigators and partners and taking proactive steps to help protect the safety of our study participants and clinical trial staff while also ensuring the scientific integrity of the trial data. Based on what we know today, and while recognizing the environment could rapidly change, we currently expect to achieve our target of sharing key topline data from the trial in the first quarter of 2021.”

About ILLUMINATE-204

ILLUMINATE-204 is a multi-center, two-arm Phase 1/2 trial that tested the safety and effectiveness of tilsotolimod in combination with either Yervoy® (ipilimumab) or Keytruda® (pembrolizumab) in patients with anti-PD-1 refractory metastatic melanoma. For more information on ILLUMINATE-204, please refer to ClinicalTrials.gov (NCT02644967).

About ILLUMINATE-301

ILLUMINATE-301 is a randomized, phase 3 trial comparing the effectiveness of intratumoral tilsotolimod in combination with ipilimumab with ipilimumab alone in approximately 450 patients with anti-PD-1 refractory advanced melanoma, with a primary endpoint family of ORR per RECIST v1.1 and OS. Key secondary endpoints include durable response rate, time to response, progression-free survival, patient-reported outcomes, and safety. For more information on ILLUMINATE-301, please refer to ClinicalTrials.gov (NCT03445533).

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, pioneering immunotherapies known as checkpoint inhibitors (CPIs) have changed the treatment of advanced melanoma and have become the standard of care, with anti-PD-1 agents 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 do not benefit from this type of therapy, and up to one-third of initial responders 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 Tilsotolimod (IMO-2125)

Tilsotolimod is an investigational, synthetic Toll-like receptor 9 agonist. Intratumoral injection of tilsotolimod has been shown to promote both innate and adaptive immune activation. Tumors with an active immune response appear to respond better to CPIs than those that exclude or inhibit anti-tumor immune cells. Tilsotolimod in combination with CPIs may cause regression of locally injected and distant tumor lesions and 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 ClinicalTrials.gov.

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 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, plans, and objectives of management, are forward-looking statements. The words "believes," "expects," "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 the further development of the Company's programs for the period anticipated; whether interim results from a clinical trial, such as the preliminary 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, 2019. 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.

*Yervoy (ipilimumab) is a registered trademark of Bristol Myers Squibb.

[±]Keytruda (pembrolizumab) is a registered trademark of Merck Sharp & Dohme, a subsidiary Merck & Co., Inc.

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