

**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): **October 31, 2019**

Idera Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-31918
(Commission
File Number)

04-3072298
(I.R.S Employer
Identification No.)

505 Eagleview Blvd., Suite 212
Exton, Pennsylvania
(Address of Principal Executive
Offices)

19341
(Zip Code)

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

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

| <u>Title of each class</u> | <u>Trading Symbol</u> | <u>Name of each exchange on which registered</u> |
|--------------------------------------------------|-----------------------|--------------------------------------------------|
| 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 October 31, 2019, Idera Pharmaceuticals, Inc. (the “Company”) uploaded a presentation to its website, www.iderapharma.com, discussing the state of the Company. A copy of the presentation is attached to this Current Report on Form 8-K as Exhibit 99.1 (the “Presentation”).

The information contained in the Presentation is summary information that is intended to be considered in the context of the Company’s Securities and Exchange Commission (the “SEC”) filings and other public announcements that the Company may make, by press release or otherwise, from time to time. The Company undertakes no duty or obligation to publicly update or revise the information contained in this report, although it may do so from time to time as its management believes is warranted. Any such updating may be made through the filing of other reports or documents with the SEC, through press releases or through other public disclosure.

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, 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)

| <u>Exhibit No.</u> | <u>Exhibit Name</u> |
|--------------------|-----------------------------------------------|
| 99.1 | October 2019 Corporate Update |

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.

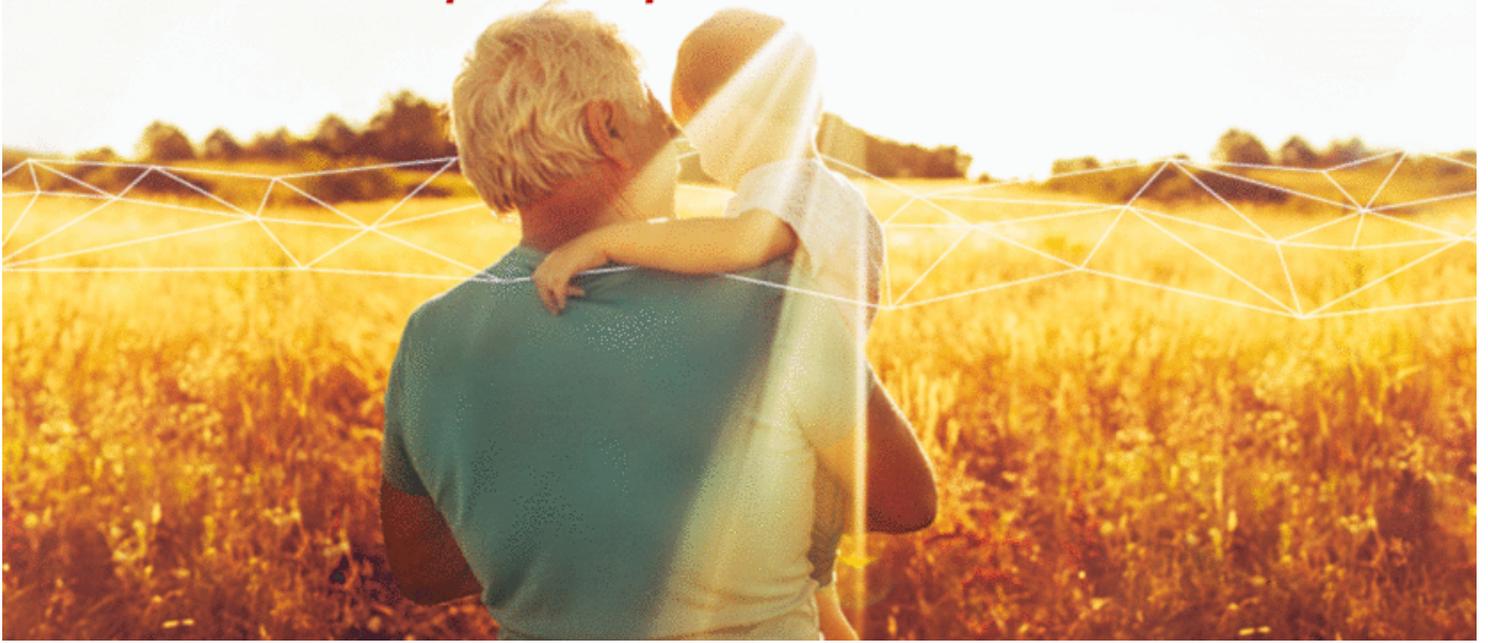
IDERA PHARMACEUTICALS, INC.

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

Dated: October 31, 2019



**October 2019
Corporate Update**



Forward-Looking Statements & Other Important Cautions

This presentation contains forward-looking statements within the meaning of safe harbor of the Private Securities Litigation Reform Act of 1995 and the Federal securities laws including statements about our expectations for, and obligations under, the content contained in this presentation. All statements, other than statements of historical fact, included or incorporated in this presentation, including statements regarding the Company's strategy, future operations, collaborations, intellectual property, cash resources, financial position, future revenues, projected costs, prospects, 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 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 Idera's research regarding projected addressable patient population and sales estimates will prove correct; whether products based on Idera's technology will advance into or through the clinical trial process on a timely basis or at all and 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; and such other important factors as are set forth in the Company's filings with the Securities and Exchange Commission (SEC). 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.

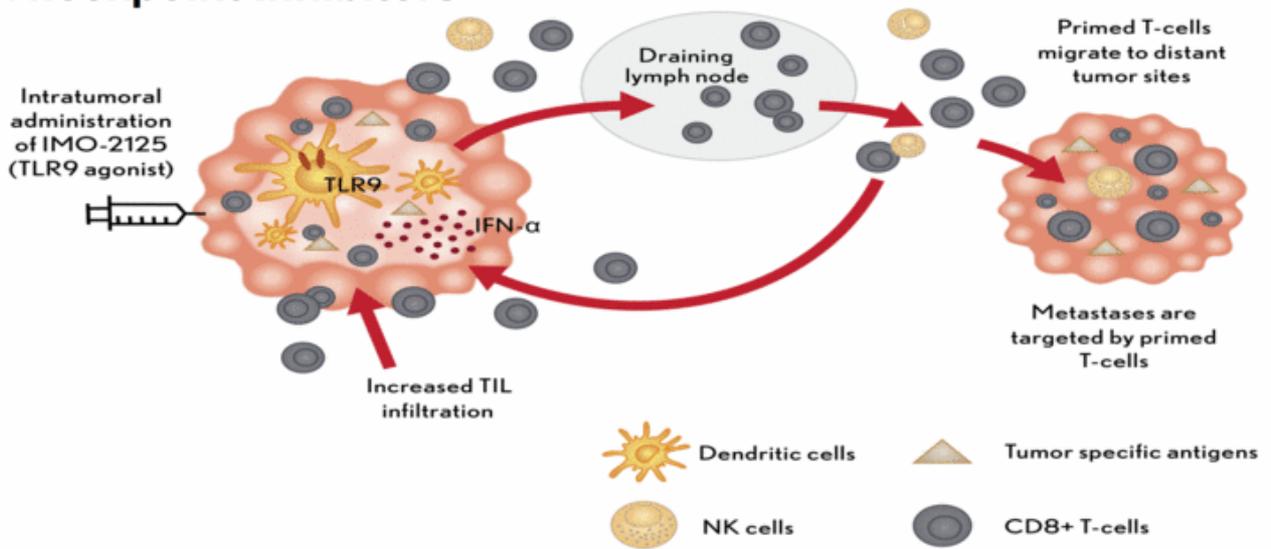


**Injecting a New
Solution to
Advance Cancer
Immunotherapy**

**Near Term Value Growth
Driven by Tilsotolimod**

- Phase 3 Trial 75% Enrolled
- Encouraging Clinical Outcomes
- Studies of Tumors Beyond Melanoma Underway
- Collaborations with BMS and AbbVie
- Strengthened Exclusivity Proposition

Designed to Stimulate the Immune System Locally to Potentially Lead to Better Systemic Patient Outcomes with Checkpoint Inhibitors





Randomized Phase 3 Study of Tilsotolimod in Combination With Ipilimumab Compared With Ipilimumab Alone in Patients With Advanced Melanoma Following Progression On or After Anti-PD-1 Therapy



High unmet medical need in metastatic melanoma for patients who progress after PD-1 inhibitors

Historical Data of 321 Patients Suggest ORR Range of 4-16%*

| N= | ORR | References |
|----|-----|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 97 | 13% | Long, et al., Presentation at Society for Melanoma Research 2016 Congress, 2016 (post-hoc analysis of KEYNOTE-006 patients who received ipilimumab monotherapy following failure of pembrolizumab) |
| 60 | 4% | Fujisawa, et al., Retrospective study of advanced melanoma patients treated with ipilimumab after nivolumab: Analysis of 60 Japanese patients, J. Dermatol. Sci. 2018 Jan ; 89(1): 60-66 |
| 47 | 4% | Weichenthal, et al., Presentation at the 2019 ASCO Annual Meeting, Salvage Therapy after Failure From Anti PD-1 Single Agent Treatment, A Study by the German ADOReg Melanoma Registry |
| 47 | 16% | Zimmer, et al., Ipilimumab alone or in combination with nivolumab after progression on anti PD-1 therapy in advanced melanoma, Eur. J. Cancer 2017; 75-47-55 |
| 40 | 10% | Bowyer, et al., Efficacy and toxicity of treatment with the anti-CTLA-4 antibody ipilimumab in patients with metastatic melanoma after prior anti-PD-1 therapy. Br. J. Cancer. 2016;114(10):1084–1089. |
| 30 | 7% | Muto, et al., Investigation of clinical factors associated with longer overall survival in advanced melanoma patients treated with sequential ipilimumab, J. Dermatology, 2019; 46; 498-506 |

* There are three additional studies of n=9, n=8, n=7 respectively: Aya, et al., Future Oncol. 2016; 12(23):2683-2688 (ORR=22%); Jacobssoone-Ulrich et al., Melanoma Research 2016, 26:2 (2016) (ORR=50%); Saijo, et al., Tohoku J. Exp. Med., 2019, 248, 37-43 (ORR=0%)

ILLUMINATE-301 – Trial Design

PD-1 Refractory Metastatic Melanoma

Patient Stratification

- Duration of prior anti-PD-1 therapy (<12 or ≥12 weeks)
- Metastasis stage (M1c or other)
- BRAF mutation status and prior targeted therapy
BRAF wild type, mutation positive
with, or without prior targeted

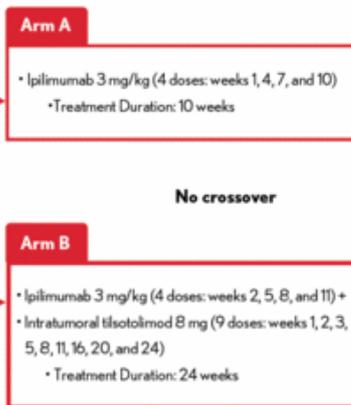
Key Inclusion Criteria:

- Age ≥ 18 years
- Stage III or Stage IV melanoma
- ≥ 1 measurable lesion accessible for injection
- ECOG PS ≤ 1
- Adequate organ function

Key Exclusion Criteria:

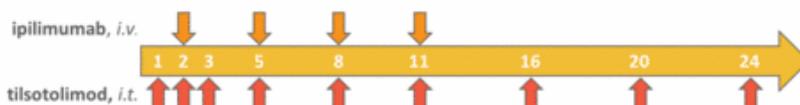
- Prior TLR agonists
- Prior ipilimumab
- CNS disease

Randomization
1:1
N=454



Endpoints

- Primary endpoint family**
- ORR by independent review per RECIST v1.1
 - OS
- Key secondary endpoints**
- Durable response rate
 - Time to response
 - Progression-free survival
 - Patient-reported outcomes
 - Safety



i.v., intravenous; *i.t.*, intratumoral; ORR, overall response rate; OS, overall survival.



- **342 patients enrolled;**
- **Enrollment completion expected 1H 2020**

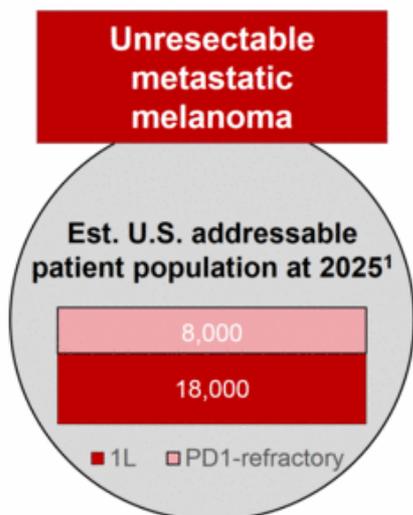
* Enrollment Update as of 10/23/2019

Exclusivity

Three Sources of Exclusivity for Tilsotolimod

- Composition of Matter Patent Exclusivity
 - Provides exclusivity until 2030 (estimated), inclusive of patent term extension
- Method-of-Use Patent
 - Covers certain melanoma treatments in combination with therapies targeting CTLA-4, PD-1, or PD-L1
 - Estimated expiration in September 2037
- Orphan Drug Designation
 - Granted *“for treatment of melanoma Stages IIb to IV.”*

1st Indication Commercial Opportunity



- High unmet need in anti-PD1-refractory patients
- **U.S. Peak year sales estimate > \$500 million,² if approved**

¹ Proprietary Idera Commercial Research

² Based on current company forecast through 2030



Reasons to Believe

- Encouraging Clinical Data
- Translational Data



A Phase 1/2 Study to Assess the Safety and Efficacy of Intratumoral Tilsotolimod in Combination with Ipilimumab or Pembrolizumab in Patients with Metastatic Melanoma

- Primary objectives
 - Phase 1: to determine the recommended phase 2 dose
 - Phase 2: to assess preliminary clinical activity of tilsotolimod in combination with ipilimumab at the recommended phase 2 dose in patients with metastatic melanoma that is not responsive to PD-1 inhibitor therapy, using RECIST v1.1
- Secondary objectives include:
 - Phase 2: to further assess the safety and tolerability of tilsotolimod in combination with ipilimumab or pembrolizumab (pembrolizumab combination not studied in this phase)

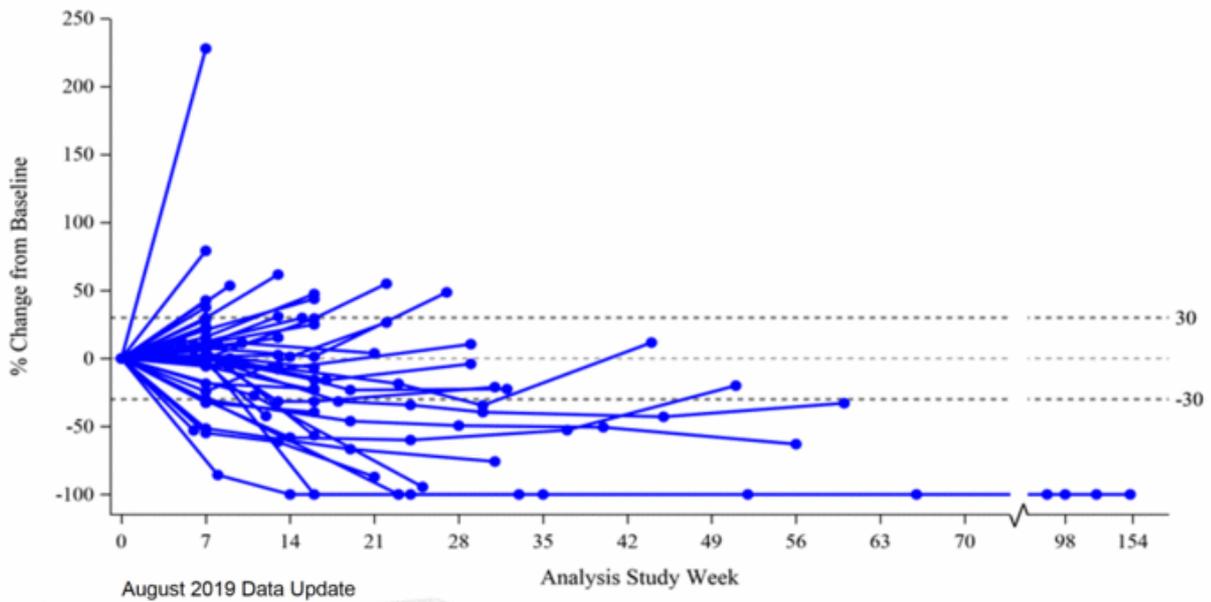
ILLUMINATE-204 Results to Date Imply Potential for Clinically Meaningful Benefit

| Best Overall Response | tilsotolimod + ipilimumab (N=49) ¹ | ipilimumab monotherapy post PD-1 (N=321) ² <i>(pooled post-hoc analysis of six studies)</i> |
|--------------------------------------|-----------------------------------------------|-----------------------------------------------------------------------------------------------------------|
| Overall Response Rate (CR or PR) | 24% (12) | 4-16% |
| Disease Control Rate (CR, PR, or SD) | 71% (35) | 17-45% |

- 11 of 12 responses confirmed per RECIST v1.1
 - 3 Confirmed Complete Responses (CR)
- 5 of 10 RECIST v1.1 responses evaluable for durability (>6 mos.) to date
- Median OS (overall survival) not yet reached (min/max: 1.6 – 35 mos.)
- Safety profile observed consistent with previously reported results

¹ 49 of 53 subjects had at least 1 post-baseline disease assessment at time of October 2019 data update
² References available on Slide 7

ILLUMINATE 204: Percent (%) Change from Baseline in All Target Tumors

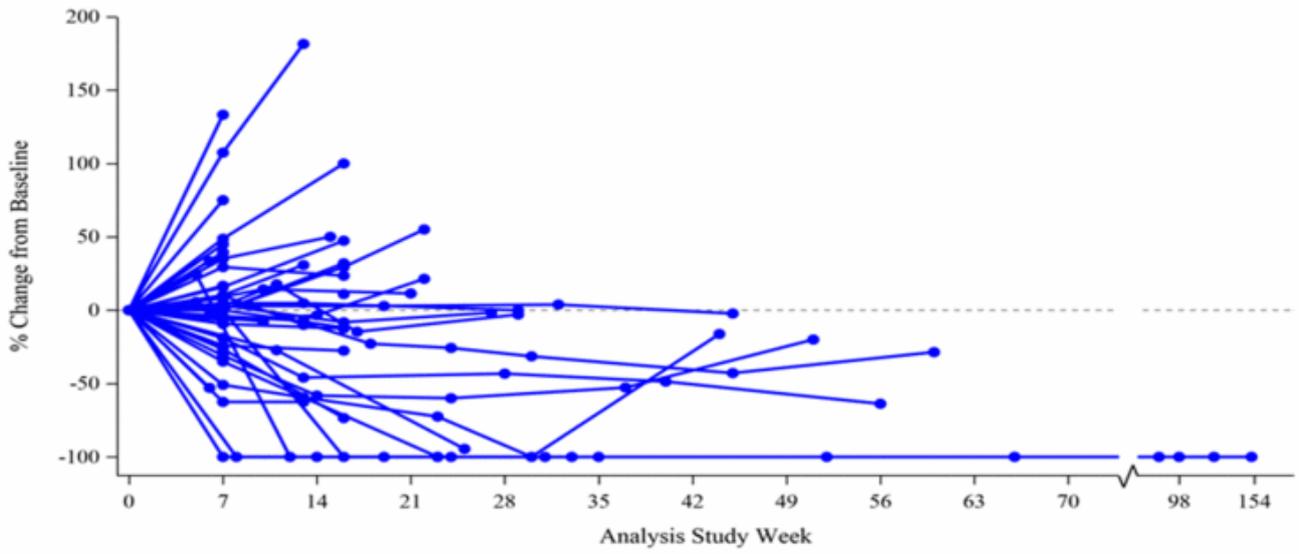


August 2019 Data Update

Analysis Study Week

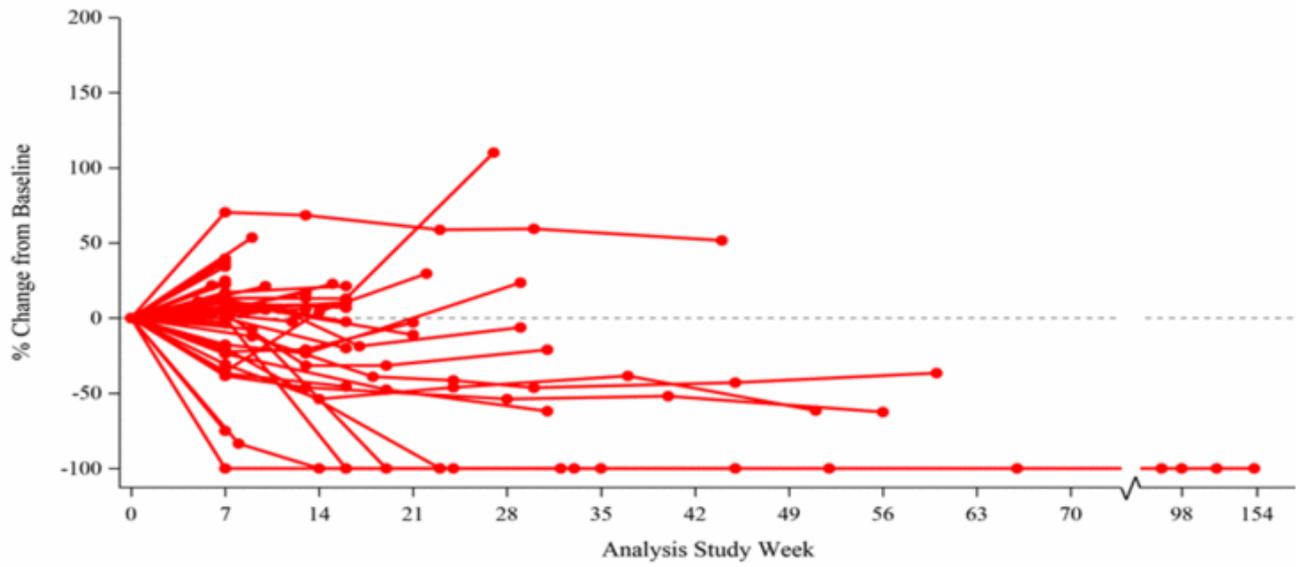


ILLUMINATE 204: Percent (%) Change from Baseline in Injected Tumors



August 2019 Data Update

ILLUMINATE-204: Percent (%) Change from Baseline Uninjected Tumors Demonstrating Abscopal Effect



August 2019 Data Update

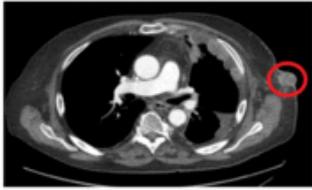
ILLUMINATE-204 – Safety Analysis

| | N=72 | % |
|------------------------------------------------------|------|------|
| Subjects with at least one AE | 71 | 98.6 |
| Subjects with at least one SAE | 27 | 37.5 |
| Subjects with at least one ≥ 3 AE | 36 | 50.0 |
| Subjects with an AE leading to Study drug withdrawn | 8 | 11.1 |
| Subjects with an AE leading to Study discontinuation | 1 | 1.4 |
| Subjects with Death related to AE | 0 | 0.0 |

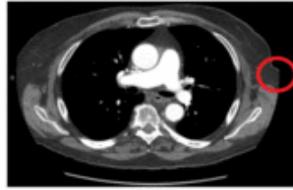
| Maximum Severity | N=72 | % |
|------------------|------|------|
| Grade 1 | 14 | 19.4 |
| Grade 2 | 21 | 29.2 |
| Grade 3 | 29 | 40.3 |
| Grade 4 | 7 | 9.7 |
| Grade 5 | 0 | 0.0 |

ILLUMINATE-204 Case Studies

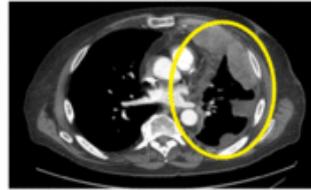
Complete response (68 years old)



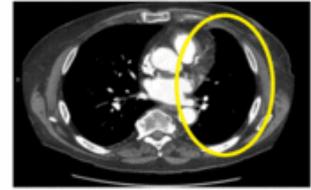
Pretreatment
Injected tumor



Posttreatment 24 weeks
Injected tumor



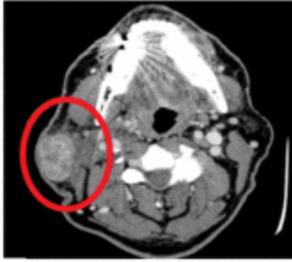
Pretreatment
Uninjected tumor



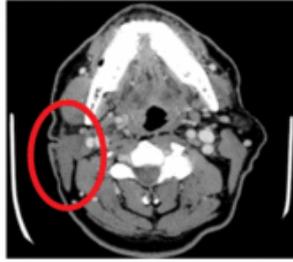
Posttreatment 24 weeks
Uninjected tumor

ILLUMINATE-204 Case Studies

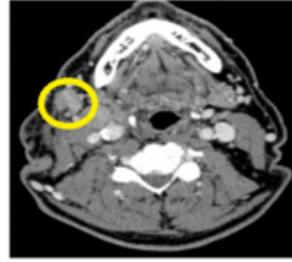
Partial response (62 years old)



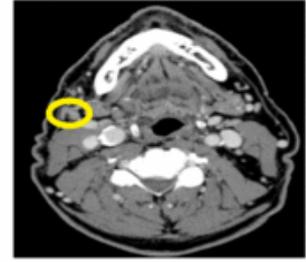
Pretreatment
Injected tumor



Posttreatment 56 weeks
Injected tumor



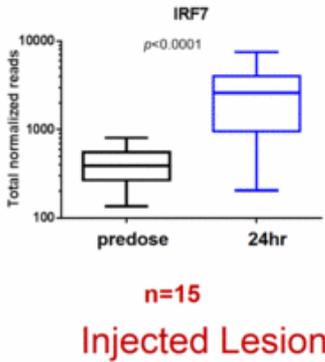
Pretreatment
Uninjected tumor



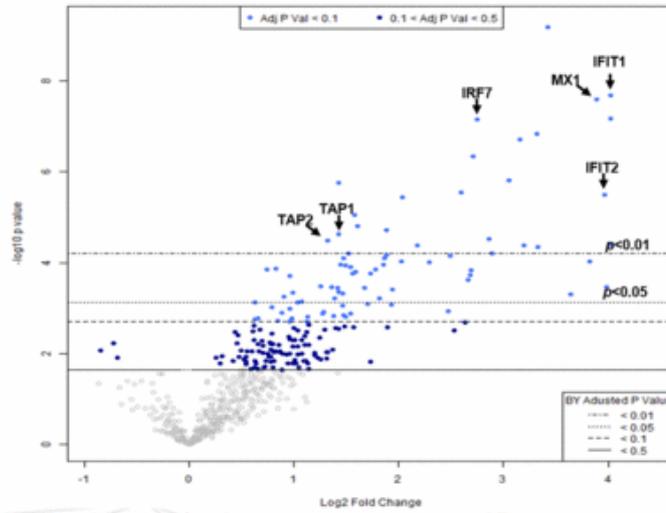
Posttreatment 56 weeks
Uninjected tumor

Tilsotolimod activates local IFN α -response gene signature and combination with ipilimumab therapy induces proliferation of T-cells in distant lesion

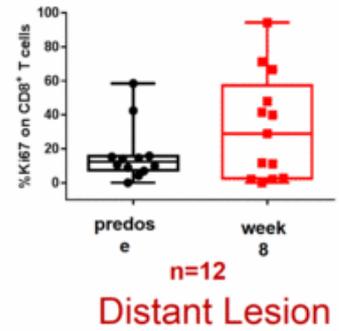
**tilsotolimod only
(prior to ipilimumab)**



**tilsotolimod only
(prior to ipilimumab)**



tilsotolimod + ipilimumab



Injected Lesion

20

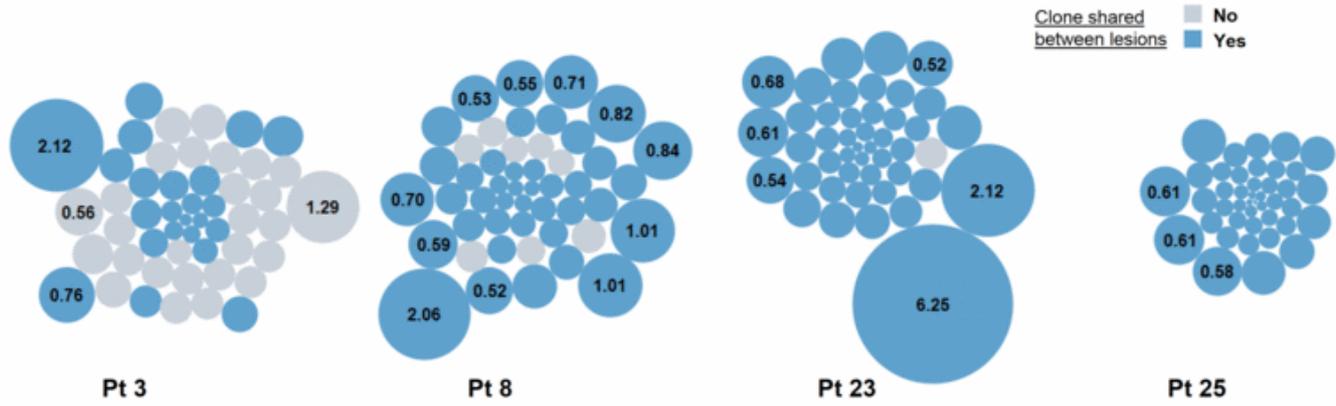
n=15

Source: SITC 2017

© 2019 Idera

Expanding Clones in the Distant Lesion are Shared with the Injected Lesion

Top 50 clones in the distant lesion at C3W8 of responding patients



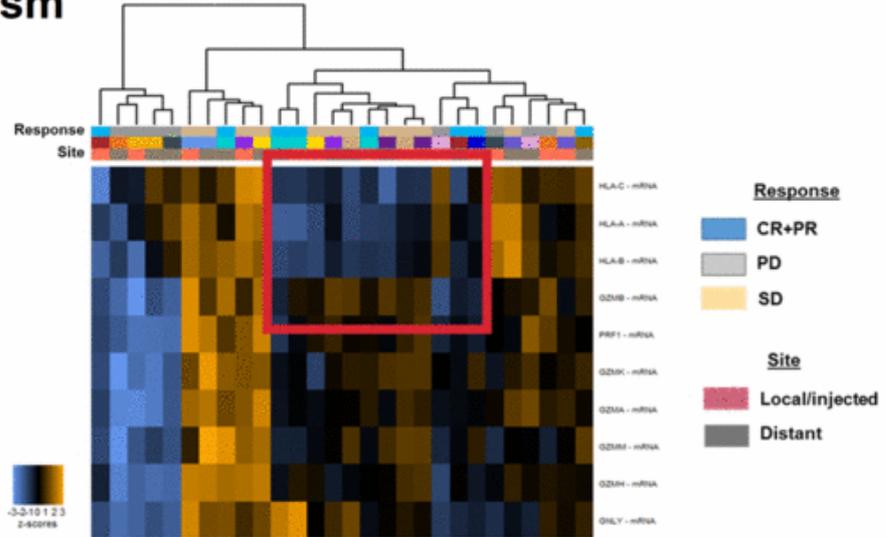
Number = clonal specific change in frequency (C3W8 – predose)
 Circle size reflects the frequency of the clone relative to the other clones present

Source: SITC 2017

Demonstrated Potential of Tisotolimod to Overcome CTLA-4 (Cytotoxic T-Lymphocyte Antigen) Resistance Mechanism

Responses seen in HLA-ABC* low tumors at baseline (red box)

* HLA-ABC: human leucocyte antigen; ABC refers to three genes part of MHC class 1



ILLUMINATE 204 Summary

Final data planned for major medical meeting 1H 2020

- Established the recommended Phase 2 dose (RP2D) of 8mg tilsotolimod
- Provided proof of mechanism for tilsotolimod based on translational work from Phase 1
 - Rapid, within 24 hours, induction of IFN α
 - Responses in tumors not expected to respond to ipilimumab alone based on HLA-ABC low baseline expression
- Clinical responses rates (ORR/DCR) greater than historical control and median overall survival (OS) not yet reached



Tilsotolimod Expansion Strategy

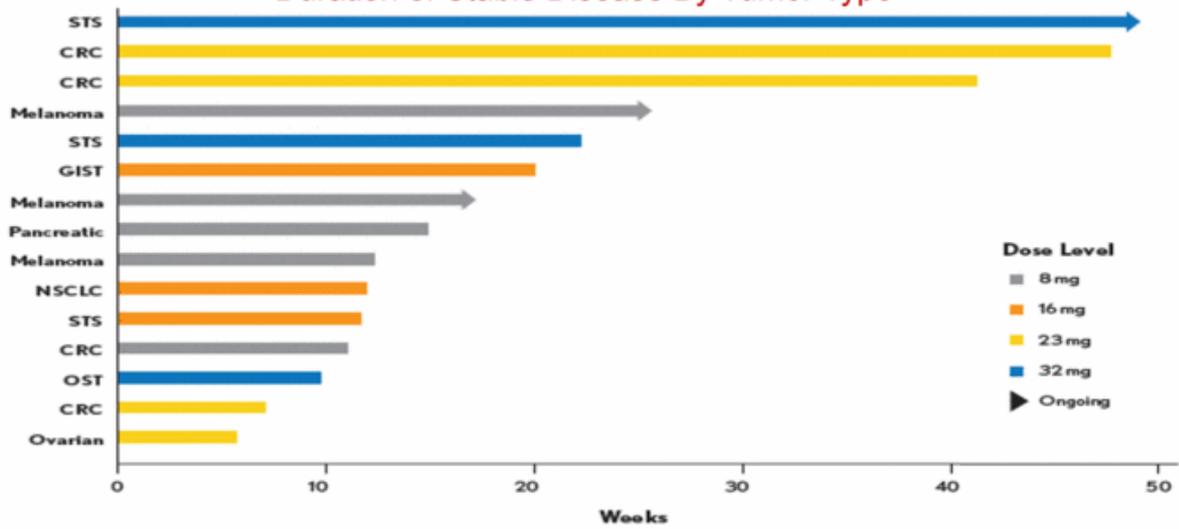


A Phase 1B Study of Intratumoral Tilsotolimod (IMO-2125) in Patients with Refractory Solid Tumors (Data as of July 1, 2019)

- Dose-escalation cohort objectives
 - Primary: safety
 - Secondary: establish RP2D; assess clinical activity and pharmacokinetics
 - Exploratory: evaluate immunologic activity
- Dose-expansion cohort objectives
 - Primary: clinical activity of overall response rate via RECIST v1.1
 - Secondary: safety, other measures of clinical benefit, and pharmacokinetics
 - Exploratory: evaluate biomarkers for immunologic assessment and assess antidrug antibody formation

ILLUMINATE-101 Efficacy

Duration of Stable Disease By Tumor Type



CRC, colorectal cancer; GIST, gastrointestinal stromal tumor; NSCLC, non-small cell lung cancer; OST, osteosarcoma; STS, soft tissue sarcoma.

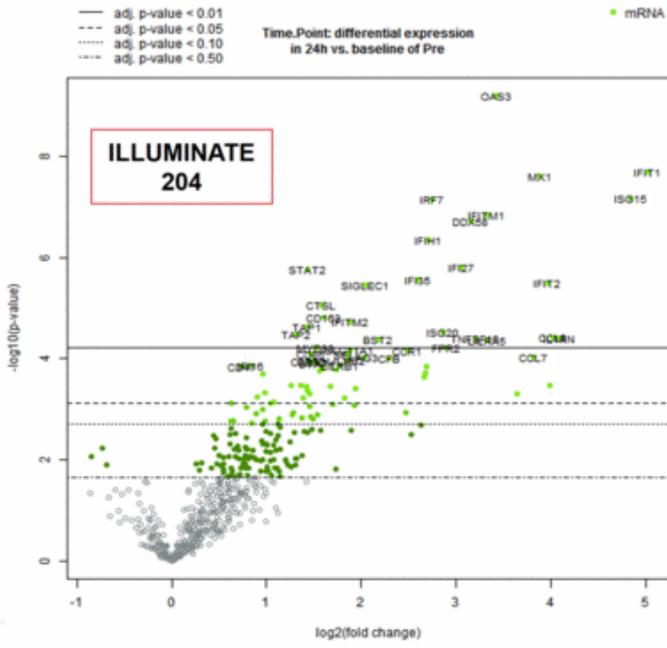
- Intratumoral injection of single-agent tilsotolimod is generally well-tolerated; preliminary evidence of clinical activity across multiple solid tumors include those traditionally unresponsive to immunotherapy
- Uninjected lesions respond similarly to injected lesions, suggesting a potential abscopal-like effect
- Tilsotolimod rapidly increases dendritic cell activation, upregulation of MHC class II, and upregulation of IFN- α signaling, is suggesting improved antigen presentation
- Tilsotolimod-induced upregulation of antigen presentation is observed across multiple tumor types; changes are consistent with those observed in a previous phase 1/2 clinical trial of patients with metastatic melanoma

ILLUMINATE 206 Initial Expansion Beyond Melanoma

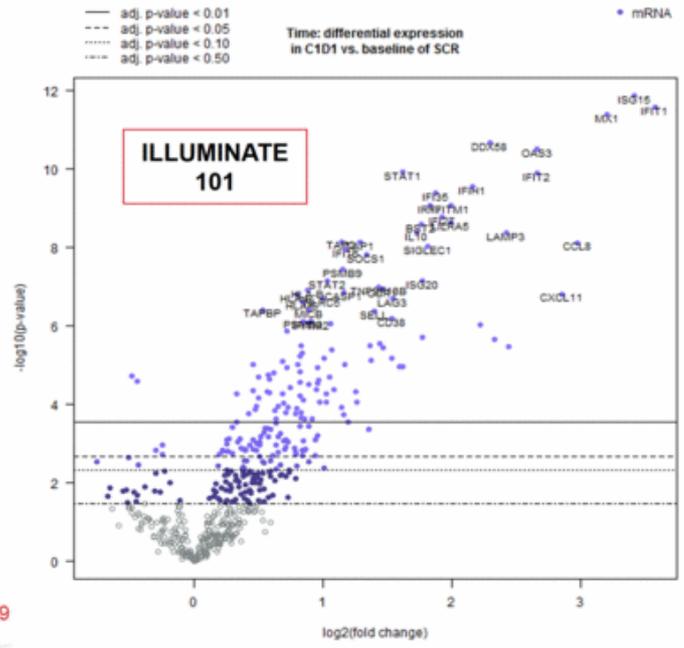
Broad Effort to Determine Appropriate First Tumor Types for Expansion



Tisotolimod Induces Rapid Gene Expression in the Tumor Microenvironment, Regardless of Tumor Type



29



Recently Announced Clinical Collaboration with AbbVie Broadens Expansion Efforts



Idera Pharmaceuticals Announces Immuno-Oncology Clinical Research Collaboration with AbbVie

Exton, PA. September 4, 2019 —Idera Pharmaceuticals, Inc. (NASDAQ: IDRA) announced today that they have entered into an immuno-oncology clinical research collaboration with AbbVie, a global, research-based biopharmaceutical company. The purpose of the collaboration is to conduct a clinical study evaluating whether combinations of an OX40 agonist (ABBV-368), a TLR-9 agonist (tilsotolimod), chemotherapy (nab-paclitaxel) and/or an anti-programmed cell death 1 (PD-1) antagonist (ABBV-181) stimulate the immune system resulting in anti-tumor responses.

This Phase 1b, multi-center, open-label study is designed to determine the safety, tolerability, pharmacokinetics and preliminary efficacy of combinations of ABBV-368 plus tilsotolimod in subjects with recurrent or metastatic head and neck squamous cell carcinoma (HNSCC).

The study will test three separate treatment arms:

- ABBV-368 plus tilsotolimod;
- ABBV-368 plus tilsotolimod and nab-paclitaxel; and
- ABBV-368 plus tilsotolimod, nab-paclitaxel and ABBV-181.

Under the terms of the agreement, Idera will provide clinical trial supply of tilsotolimod to AbbVie and AbbVie will be responsible for conduct of the study.

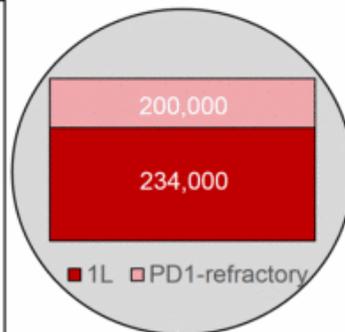


Expanding Potential Growth Opportunities

Emerging I/O addressable tumors

- Moderate response to cornerstone anti-PD1
- Goal to increase number of approved settings

Est. U.S. addressable patient population at 2025^{1,2}



“Cold” tumors unaddressable with current I/O

- Significant opportunity in tumors with:
 - Low mutation load
 - Low dendritic cell infiltration
- Bioinformatics research ongoing to identify attractive tumor targets

¹ Proprietary Idera Commercial Research

² NSCLC, head and neck, colorectal, bladder and gastric

Financials and Capital Structure Updates

- Completed Q2 2019 with \$52.4M cash
- Expected cash runway into Q2 2020
- Approximately 29M shares outstanding
- \$35M Common Stock Purchase Agreement with Lincoln Park Capital
- \$50M ATM in place

Key Milestones

- Completion of ILLUMINATE-301 Enrollment – 1H 2020
- Topline Data from ILLUMINATE-204 – 1H 2020
- Interim Data from ILLUMINATE-206 - 2020
- ORR Data from ILLUMINATE-301 – 1H 2021