

**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): January 13, 2021

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**

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	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 7.01 Regulation FD Disclosure.

On January 13, 2021, Idera Pharmaceuticals, Inc. (the “Company,” “we,” “us,” and “our”) uploaded a presentation to its website, www.iderapharma.com, discussing the state of the Company. We may rely on all or part of this presentation any time we are discussing the current state of the Company in communications with investors or at conferences. 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 (“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 information in this Current Report on Form 8-K 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.

Item 9.01. Financial Statements and Exhibits.

(d)

<u>Exhibit No.</u>	<u>Exhibit Name</u>
99.1	Investor Presentation dated January 13, 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.

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

Dated: January 13, 2021



Our Time is Now

January 2021



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 Idera Pharmaceuticals, Inc.'s (the "Company" or "Idera") 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, objectives of management, stockholder value, value growth, commercial and expansion opportunities, market demand, sales projections, possible indications, 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 the Company will have any unforeseen cash needs; whether the Company will receive all potential proceeds from existing private placements; 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 on a timely basis or at all and receive approval from the U.S. Food and Drug Administration or equivalent foreign regulatory agencies; and if the Company's products receive approval, whether they will be successfully distributed and marketed.

All forward-looking statements included in this presentation are made as of the date hereof and are expressly qualified in their entirety by this cautionary notice and additional risks and uncertainties, including, without limitation, those risks and uncertainties described in the Company's Annual Report on Form 10-K for the year ended December 31, 2019, 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.

Tilsotolimod: Injecting Innovation into Cancer Immunotherapy

Our time is now

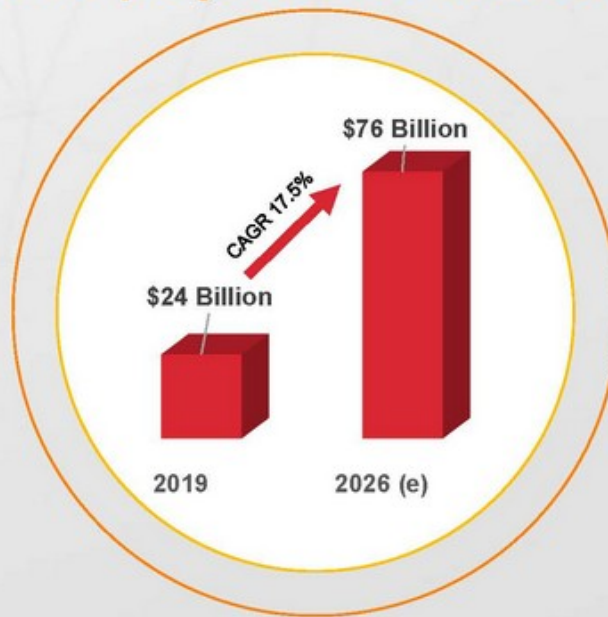
- Significant Patient Need
- Competitive Attributes
- Advanced Melanoma
- Moving Beyond Melanoma
- Strong Exclusivity and Financial Readiness



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As cancer incidence continues to rise, spending on global PD-(L)1 therapies are projected to more than triple

- **Increased diagnoses**
 - Rising incidence of cancer
 - Greater disease awareness
 - Timely detection
- **New approved uses of existing PD-(L)1 therapies**
- **New compounds**
- **Use in earlier lines of therapy**



Significant unmet need remains

- Patients with advanced cancer typically have a **poor prognosis**
- As many as **87% of patients progress** due to primary or acquired resistance to anti-PD-(L)1s¹
- If shown to be an effective therapy post anti-PD-1, **tilsotolimod could provide hope to many cancer patients**



¹Haslam and Prasad, *JAMA Network Open*. 2019;2(5):e192535.

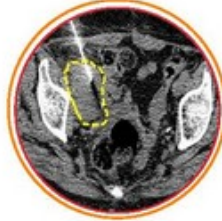


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Key Attributes of Tilsotolimod

vs other therapies following anti-PD-1

- May help overcome resistance to anti-CTLA-4s
- Encouraging safety profile
- Non-viral
- Can be administered into deep lesions or viscera
- Single site of injection
- No device needed
- Total treatment duration of 6 months*



(with radiology guidance)

* For tilsotolimod + ipilimumab combination in ILLUMINATE-301



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Tilsotolimod is the most advanced TLR9 agonist in development.

Phase 3 data is imminent

- ✓ Late Q1 2021

Activates both TNF α and B cells

- ✓ TNF α \rightarrow activation and proliferation of naïve and effector T cells
- ✓ Checkpoint inhibitors require **T-cells & B-cells** to effectively fight cancer

Purposeful Structure

- ✓ Potency via 2 accessible 5'-ends, which are needed for **immune activation**
- ✓ Avoids increased manufacturing complexity for virus-like particle encapsulation





Advanced Melanoma

- Patient Need
- Illuminate 301
- Market Potential
- Next Steps



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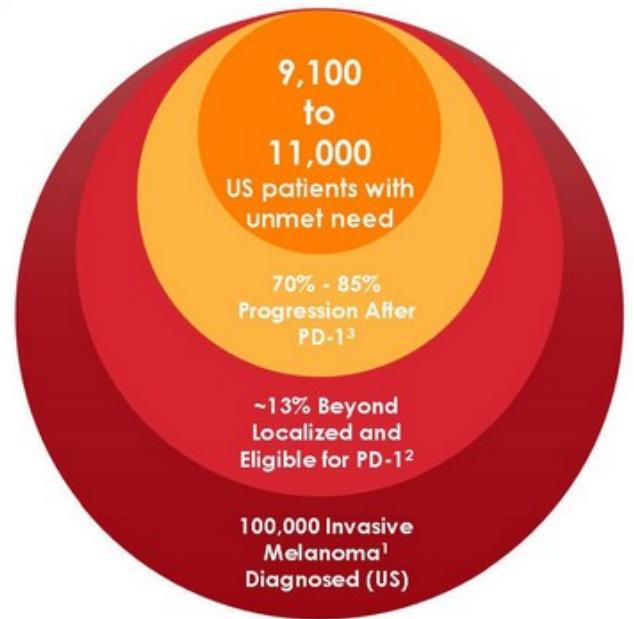
Most Melanoma Patients Progress After PD-1

This may be the result of the absence of T-cells and/or acquired immune resistance, limiting the ability of the immune system to target the tumor

1. American Cancer Society. www.cancer.org/cancer/melanoma-skin-cancer/about/key-statistics.html. Accessed January 7, 2021. 2. Watson et al. *J. Am. Acad. Dermatol.* 2011;65(5):563. Mooradian and Sullivan. *Cancer Network* 2019;32(4).



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Ipilimumab alone does not seem to sufficiently address the unmet need in anti-PD-1 refractory patients.

Historical data of 321 patients suggest ipilimumab monotherapy ORR of 9.5% and DCR of 28.7%*

* ORR: Overall Response Rate; DCR: Disease Control Rate.

Weighted average of above 6 studies. 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%); Jacobsone-Ulrich et al. *Melanoma Res.* 2016;26(2): 153-156 (ORR=50%); Saijo, et al. *Tohoku J. Exp. Med.*, 2019;248:37-43 (ORR=0%).



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N	ORR	DCR	Reference
97	13%	45%	Long et al (2016, Nov). Outcomes in patients treated with ipilimumab after pembrolizumab in KEYNOTE-006. Presented at the Society for Melanoma Research 2016 Congress, Boston, MA.
60	4%	16%	Fujisawa et al. Retrospective study of advanced melanoma patients treated with ipilimumab after nivolumab: Analysis of 60 Japanese patients. <i>J. Dermatol. Sci.</i> 2018;89(1):60-66.
47	4%	17%	Weichenthal et al. Salvage therapy after failure from anti PD-1 single agent treatment, A Study by the German ADOReg melanoma registry. <i>J. Clin. Oncol.</i> 2019;37:15_suppl.9505.
47	16%	42%	Zimmer et al. Ipilimumab alone or in combination with nivolumab after progression on anti PD-1 therapy in advanced melanoma. <i>Eur. J. Cancer.</i> 2017;75:47-55.
40	10%	18%	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. <i>Br. J. Cancer.</i> 2016;114(10):1084-1089.
30	7%	13%	Muto et al. Investigation of clinical factors associated with longer overall survival in advanced melanoma patients treated with sequential ipilimumab. <i>J. Dermatology.</i> 2019;46:498-506.

Tilsotolimod, in combination with ipilimumab, may address that unmet need



Ipilimumab-naïve patients with anti-PD-1 refractory advanced melanoma

1:1
N = 454

Arm A

•Ipilimumab 3 mg/kg
Treatment Duration: 10 weeks

No Crossover

Arm B

•Ipilimumab 3 mg/kg
+
•Intratumoral tilsotolimod 8 mg
Treatment duration: 24 weeks

Primary endpoint family

- ORR by independent review per RECIST v1.1
- OS

Key secondary endpoints

- Durable response rate (DRR)
- Duration of response (DOR)
- Time to response
- Progression-free survival (PFS)
- PFS and OS at 1 & 2 years
- Patient-reported outcomes
- Safety

BMS is providing Idera the ipilimumab for ILLUMINATE-301 free of charge



ILLUMINATE-301

Success factors

Accelerated Approval
would be sought based
on the totality of the
topline data available
in late Q1 2021 →

Study to continue
to OS outcome

- **Statistically and clinically meaningful improvement in response rate**
 - For example: ORR of 20% in combination arm vs 10% in ipilimumab-alone arm
- **Positive supporting data**
 - Duration of response (DOR)
 - Disease control rate (DCR)
- **Encouraging safety profile**

Reasons to Believe

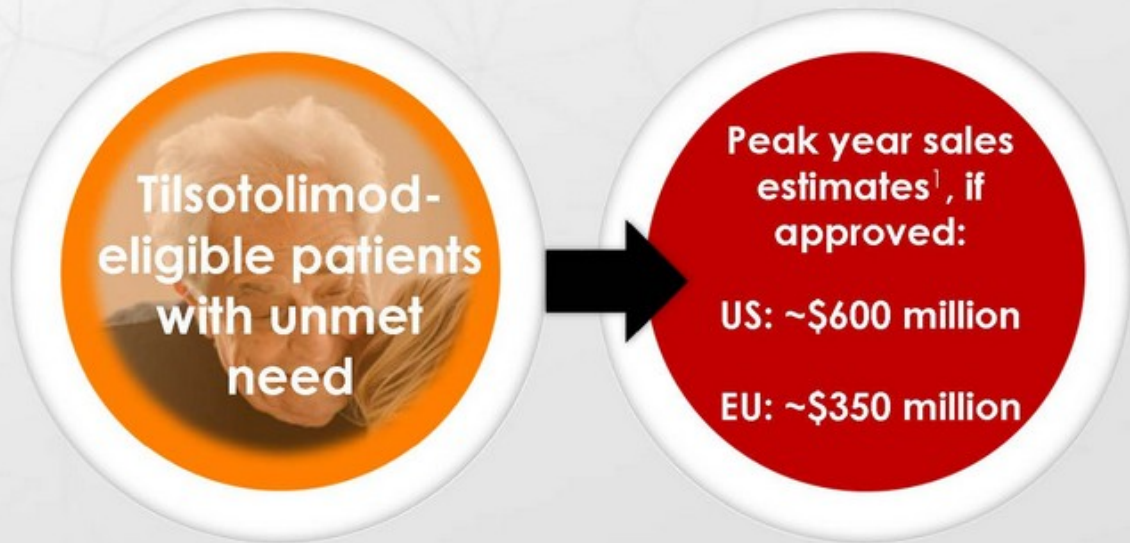
Data from ILLUMINATE-204 show potential for clinically meaningful benefit

	Data from Tisotolimod (8 mg) + Ipilimumab in ILLUMINATE-204, % (n) (n=49) ¹	Historical Data of Ipilimumab Monotherapy: (n=321) ²
Overall Response Rate (CR or PR)	22.4% (11) (95% CI: 11.8-36.6%) Median Duration of Response (DOR) of 11.4 months (95% CI: 3.3 - NR)	9.5%
Disease Control Rate (CR, PR, or SD)	71.4% (35) (95% CI: 56.7-83.4%)	28.7%
Safety	Encouraging Safety Profile	
Median Overall Survival	21.0 months (95% CI: 9.8-NR)	



1. 49 of 52 subjects had at least 1 post-baseline disease assessment
 2. Weighted average from pooled post-hoc analysis of 6 studies in post-PD-1 patients. References available on Slide 10.
 NR: not reached

Success in ILLUMINATE-301 could yield a significant commercial opportunity in melanoma



Planning for Success

If approved, MODTYLSO (tilsotolimod) will be Idera's first commercial product

**COO
Dan Soland added
to the team**



Responsibility for
Commercial &
CMC

**NDA &
supply chain
readiness well
under way**



Planning for rolling
submission & priority
review

**Commercial team
buildout to begin
in late 2021**



Total commercial team
est. ~50 or fewer



Moving Beyond Melanoma

Tilsotolimod Expansion
Opportunity



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Tilsotolimod may contribute to better patient outcomes

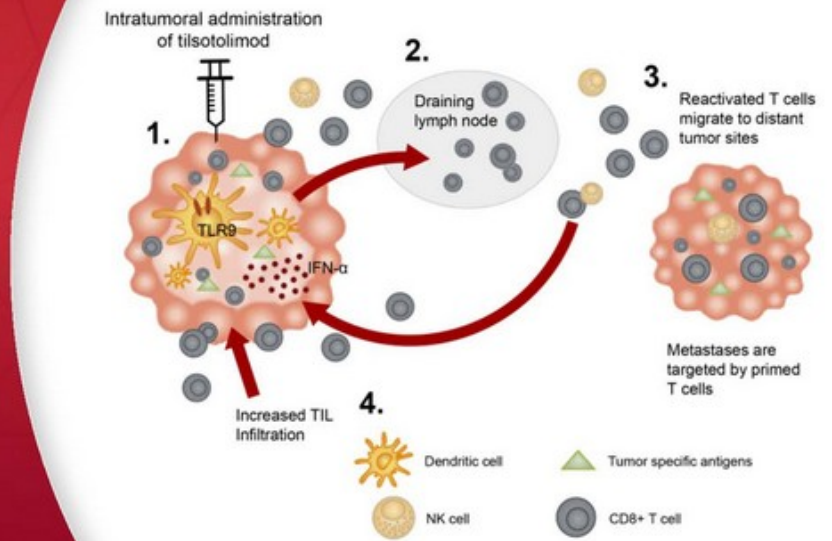
Designed to stimulate the immune system.

- Binds to TLR9
- Alters the tumor microenvironment in both injected and non-injected tumors
- Supports innate and adaptive immunity
- **Results in tumor cell death**

(HAYMAKER et. al., ESMO 2020)



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We believe the well-established mechanism of action may apply in many tumor types

Key evidence supporting the MOA

- Activation of Type I interferon pathway
- Maturation of intratumoral dendritic cells (DC)
- Increased immune infiltration & expansion of major T cell clones
- Tumor regression correlated to presence of Ki67+ T-cells
- Responses observed in tumors with low HLA-ABC baseline expression, which are resistant to ipilimumab alone



illuminate
204

Translational data from Ph 2 trial of tilsotolimod + ipilimumab in patients with anti-PD-1 refractory advanced melanoma*



illuminate
101

Translational data from tilsotolimod monotherapy study in multiple tumor types†

Idera pre-clinical studies



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*Haymaker, ESMO 2020
†Babiker, AACR 2020

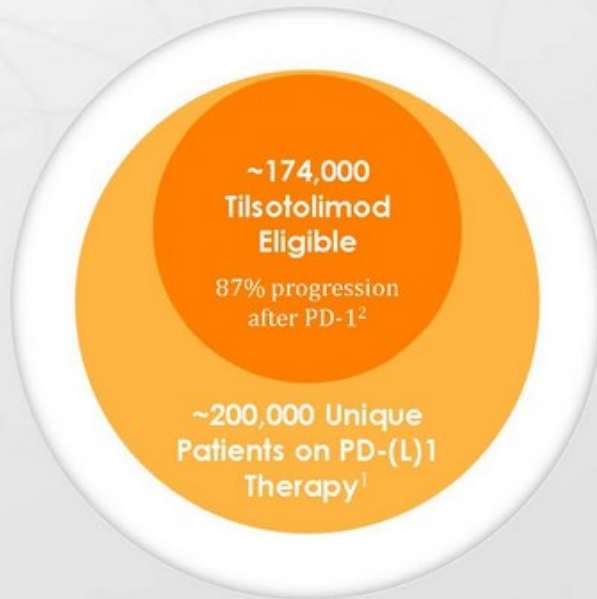
18

Tilsotolimod represents multi-billion-dollar potential to improve patient outcomes following PD-(L)1 therapy

Use in emerging I/O-addressable tumors

Moderate response to cornerstone anti-PD-1

Goal to increase number of approved settings



Use with “cold” tumors not addressable with current I/O

Significant opportunity in tumors with:

Low mutation load

Low dendritic cell infiltration



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¹IQVIA Institute. Global Oncology Trends 2019. Parsippany, NJ.

²Haslam and Prasad. *JAMA Network Open*. 2019;2(5):e192535.

ILLUMINATE-206 Multicohort Protocol Design

Cohorts for each tumor type & combination

First indication:
MSS-CRC

Highly immunosuppressive with no approved I/O options

High Unmet Need

Of total CRC cases, **MSS represents 80-85%** (& a higher proportion of deaths)

~**140,000** new MSS-CRC cases with ~50,000 deaths per year

Significant Commercial Potential

Potential US peak year sales for tilsotolimod in MSS-CRC:

> \$1.6B¹

BMS is providing Idera the ipilimumab and nivolumab for ILLUMINATE-206 free of charge



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¹Based on current company forecast through 2037

21

Next Data Coming in 3Q

Tilsotolimod + nivolumab + ipilimumab in MSS-CRC

- **Encouraged by initial safety profile along with 1 SD per RECIST v1.1**
 - 6 of the progressing patients had stability or reduction in size of injected lesions
 - 6 had stability or reduction in overall size of non-injected lesions
- **Enrolling an additional 10 patients with changes aimed at improving outcomes**
 - Increasing frequency of ipilimumab dosing from Q8W to Q3W
 - Limiting the number of allowed prior lines of treatment to 2 or fewer
- **Data expected Q3 2021**
 - Trial may expand further pending outcomes



Clinical Collaboration with AbbVie

Further broadens commercial potential via other combinations and tumor types



ABBV-368 (OX-40)
+
Tilsotolimod
in Patients with
Recurrent or
Metastatic Head
& Neck Squamous
Cell Carcinoma
(HNSCC)

abbvie

The study will test three separate treatment arms (N = 69, 23 per arm):

- ABBV-368 plus tilsotolimod;
- ABBV-368 plus tilsotolimod and nab-paclitaxel (chemotherapy); and
- ABBV-368 plus tilsotolimod, nab-paclitaxel, and ABBV-181 (anti-PD-1 agonist).



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Strong Exclusivity

Three sources of exclusivity for tilisotolimod in the U.S.



Composition of Matter Patent Exclusivity

Provides exclusivity until 2030 (estimated), inclusive of patent term extension



Method-of-Use Patent

Covers certain melanoma, CRC, & HNSCC treatments in combination with therapies targeting CTLA-4, PD-1, or PD-L1

Est. expiration in Sept. 2037



Orphan Drug Designation

Granted "for treatment of melanoma Stages IIb to IV" by the FDA



Financials

Capital to move tilsotolimod toward commercialization in advanced melanoma



¹ Potential future closings from current private placements at investors' discretion

² Based on estimated, unaudited financial results and management's operating plan as of 12/31/2020

³ Based on potential future closings from current private placements at investors' discretion

Current shares outstanding ~38M as of 12/31/2020



Our time is now

- **Tilsotolimod Opportunity Begins in Melanoma...**
 - Phase 3 trial poised to deliver
 - Data expected late Q1 2021
- **...And is Followed by MSS-CRC**
 - Next Phase 2 data subset expected Q3
- **Financial Flexibility, Exclusivity Protections, and Organizational Readiness to Deliver**



Thank You

