



Idera Pharmaceuticals Presents Positive Phase 1 Data for Intratumoral IMO-2125 in Combination with Ipilimumab Demonstrating an Overall Response Rate (ORR) of 44% in Melanoma Patients Refractory to Anti-PD1 Therapy

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- **Data from Ongoing Phase 1/2 Study Presented at the 2017 European Society for Medical Oncology (ESMO) Congress -**
- **4 of 9 (44%) Achieved RECIST v1.1 Responses, including one Durable Complete Response (CR), with 6 of 9 (67%) Anti-PD-1 Refractory Patients Experiencing Disease Control (CR, PR, or SD \geq 12 weeks) -**
- **Company Plans to Initiate Phase 3 Trial in First Quarter 2018 -**
- **Investor Webcast Tomorrow, September 11, 2017 at 9:00 AM ET -**

CAMBRIDGE, Mass. and EXTON, Pa., Sept. 10, 2017 /PRNewswire/ -- Idera Pharmaceuticals, Inc. (NASDAQ: IDRA), a clinical-stage biopharmaceutical company developing toll-like receptor and RNA therapeutics for patients with rare cancers and rare diseases, today announced final results from the dose-selection phase of an ongoing Phase 1/2 trial investigating IMO-2125, Idera's intratumorally-delivered Toll-like Receptor (TLR) 9 agonist, in combination with ipilimumab (Yervoy®), manufactured by Bristol-Myers Squibb. These data were presented at the 2017 European Society for Medical Oncology Congress (ESMO) in Madrid, Spain.



The IMO-2125-ipilimumab dose-selection phase included 18 patients, all but one of whom had progressed on nivolumab or pembrolizumab. Patients were treated with up to 6 doses of intratumoral IMO-2125 at doses ranging from 4 to 32 mg, along with standard dosing of ipilimumab. No dose-limiting toxicities were seen and the maximum tolerated dose (MTD) was not reached. No previously unreported immune-related toxicities were observed. The 8 mg IMO-2125 dose was selected for further development in combination with ipilimumab based upon acceptable safety, clinical activity, and evidence for target engagement on serial biopsies of the injected tumor and a distant (non-injected) metastasis.

Key Findings

- Nine patients were treated at the Recommended Phase 2 Dose (RP2D) of 8 mg IMO-2125 (in combination with ipilimumab)
- Confirmed RECIST v1.1 responses (including 1 Complete Response (CR) \geq 1 year) were observed in 4 of these 9 subjects (44%);
- Overall 6 patients out of 9 treated at the RP2D (67%) experienced disease control (CR, PR, or durable SD);
- A RECIST v1.1 PR of > 1 year duration is ongoing in a patient treated with IMO-2125 4 mg (in combination with ipilimumab);
- IMO-2125 in combination with ipilimumab is tolerable at all dose levels studied
- IMO-2125 was safely administered via deep injection (using interventional radiology guidance) in patients lacking superficially accessible disease for injection
- Dose escalation with IMO-2125 and pembrolizumab is ongoing; one patient has an ongoing PR by RECIST (v1.1), and;

- An abstract highlighting translational findings from the trial has been accepted as an oral presentation for the upcoming Society for Immunotherapy of Cancer (SITC) meeting in November.

"The majority of patients with solid tumors do not respond to anti-PD-1 therapy and the published response rate to ipilimumab alone in anti-PD-1 refractory melanoma is only 10-13%; to be seeing 6 out of 9 patients experiencing clear disease control is extremely exciting," stated Adi Diab, M.D., Lead Trial Investigator, Assistant Professor, Department of Melanoma Medical Oncology, Division of Cancer Medicine, University of Texas, MD Anderson Cancer Center.

"Based on these positive and encouraging response data in anti-PD-1 refractory melanoma, where the greatest need exists, we have expanded the target number of patients in the ongoing Phase 2 expansion, including broadening eligibility to patients who have received prior ipilimumab, including the ipilimumab/PD-1 inhibitor combination," stated Joanna Horobin, M.B., Ch.B., Idera's Chief Medical Officer. "We plan to start a Phase 3 trial in patients with PD-1 refractory melanoma in the first quarter of 2018. Preparations are well-underway for this global initiative which is addressing a major unmet need in melanoma. We are very encouraged by the enthusiasm of investigators to participate in the Phase 3 study."

A copy of the poster presentation is currently available on Idera's corporate website at <http://www.iderapharma.com/our-approach/key-publications/>.

About the Phase 1/2 trial of IMO-2125 in combination with ipilimumab (NCT02644967)

Study 2125-204 is a Phase 1/2 open-label study of intratumoral IMO-2125 given in combination with either ipilimumab or pembrolizumab to patients with PD-(L)1 refractory melanoma with a planned enrollment of approximately 90 patients. IMO-2125 is given in escalating dosages from 4 to 32 mg combined with either ipilimumab (3 mg/kg i.v. every 3 weeks for 4 doses) or pembrolizumab (2 mg/kg i.v. every 3 weeks). Study endpoints are safety, tumor response, pharmacodynamics, and pharmacokinetics. Serial biopsies of both the injected and a distant tumor are being performed for translational immunologic studies. Preliminary data, presented at SITC 2016, ASCO-SITC 2017, AACR 2017, and CRI-CIMT-EATI-AACR 2017 are available on Idera's website (<http://www.iderapharma.com/our-approach/key-publications/>).

Investor Event and Webcast

Idera will host a conference call and live webcast on Monday, September 11 at 9:00 A.M. EST to review the data being presented along with discussion of next steps for the IMO-2125 development program. To participate in the conference call, please dial (844) 882-7837 (domestic) and (574) 990-9824 (international). The webcast can be accessed live or in archived form in the "Investors" section of the company's website at www.iderapharma.com. The company plans to post a slide presentation on Monday, September 11, 2017 to the Idera corporate website in the "Investors" section which will be referenced during the conference call.

About IMO-2125

IMO-2125 is a toll-like receptor (TLR) 9 agonist that received orphan drug designation from the US Food and Drug Administration (FDA) in 2017 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 in refractory melanoma patients. Currently approved immuno-oncology treatments for patients with metastatic melanoma, specifically checkpoint inhibitors, work for some but not all, as many patients' immune response is missing or weak and thus they do not benefit from the checkpoint therapy making them so-called "refractory". The combination of ipilimumab and IMO-2125 appears to activate an immune response in these patients who have exhausted all options. Intratumoral injections with IMO-2125 are designed to selectively enable the T-cells to recognize and attack cancers that remained elusive and unrecognized by the immune system exposed to checkpoint inhibitors alone, while limiting toxicity or impact on healthy cells in the body.

About Metastatic Melanoma

Melanoma is a type of skin cancer that begins in a type of skin cell called melanocytes. As is the case in many forms of cancer, melanoma becomes more difficult to treat once the disease has spread beyond the skin to other parts of the body such as the lymphatic system (metastatic disease). Because melanoma occurs in younger individuals, the years of life lost to melanoma are also disproportionately high when compared with other cancers. Although melanoma is a rare form of skin cancer, it comprises over 75% of skin cancer deaths. The American Cancer Society estimates that there were approximately 76,000 new invasive melanoma cases and 10,000 deaths from the disease in the USA in 2016. Additionally, according to the World Health Organization, about 132,000 new cases of melanoma are diagnosed around the world every year.

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 lead 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 continues to invest in research and development, and is committed to working with investigators and partners who share the common goal of addressing the unmet needs of patients suffering from rare, life-threatening diseases. 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, 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, such as 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 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 IMO-2125 will successfully advance through the clinical trial process on a timely basis or at all and receive approval from the United States 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 under the caption "Risk Factors" in the Company's Annual Report on form 10K for the period ended December 31, 2016 and on form 10-Q for the period ended June 30, 2017. 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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