

IDEAYA Reports Darovasertib (IDE196) Monotherapy Overall Survival Data and Observes Early Partial Responses in Binimetinib Combination in Metastatic Uveal Melanoma

- Darovasertib monotherapy results in 57% 1-year Overall Survival (OS) Rate in predominantly 2L / 3L and heavily pre-treated (out to 7L / 8L) MUM patients, where historical 1-year OS Rate has been reported at 37%
- Darovasertib monotherapy median Overall Survival in MUM is 13.2 months, where historical median OS has been reported at approximately 7 months
- Darovasertib and binimetinib combination reports 2 partial responses (PR), including one confirmed partial response, out of nine evaluable patients with at least 2 post-baseline scans (22%) in MUM; 1 PR patient (-40.5%) is awaiting a confirmatory scan
- Company to host Darovasertib Investor Day today at 8:00 a.m. ET, with Dr. Meredith McKean (Sarah Cannon Research Institute at Tennessee Oncology) and Dr. Richard Carvajal (Columbia University Irving Medical Center)

SOUTH SAN FRANCISCO, Calif., April 16, 2021 [/PRNewswire/](#) -- IDEAYA Biosciences, Inc. (NASDAQ: IDYA), a synthetic lethality-focused precision medicine oncology company committed to the discovery and development of targeted therapeutics, announced clinical data from the ongoing Phase 1/2 trial evaluating darovasertib (IDE196) monotherapy and binimetinib combination therapy in patients with solid tumors, including Metastatic Uveal Melanoma (MUM) and Skin Melanoma (ClinicalTrials.gov Identifier: NCT03947385).

"The darovasertib single-agent one-year survival data in MUM is encouraging and compares favorably to historical survival rates in this indication, where a therapy has yet to be approved," said Meredith McKean, MD, MPH, Associate Director, Melanoma and Skin Cancer Research, Sarah Cannon Research Institute at Tennessee Oncology, Nashville, TN. "The early partial responses observed in the darovasertib and binimetinib combination in MUM are exciting where historical response rates have been from zero to low to mid-single-digit percent, and we look forward to seeing the data set mature," said Richard Carvajal, MD, Co-Leader, Precision Oncology and Systems Biology Program, Director of Experimental Therapeutics and Director of the Melanoma Service, Columbia University Irving Medical Center.

Darovasertib Monotherapy Clinical Efficacy in Solid Tumors

There have been 81 darovasertib monotherapy BID MUM and 7 Skin Melanoma patients enrolled across the IDEAYA and Novartis Phase 1/2 clinical trials at the time of data and analyses cutoff on April 13th, 2021, with an aggregate of 88 patients evaluable for safety and 81 evaluable for efficacy based on RECIST 1.1. Reported data is preliminary and based on an unlocked database. Evaluation and follow-up of the monotherapy arm of the clinical trial continues.

Darovasertib Monotherapy Preliminary Results Summary

- 57% 1-Year Overall Survival (OS) Rate was observed in predominantly second line, third line and heavily pre-treated (out to 7 and 8 lines of prior treatment) Metastatic Uveal Melanoma (MUM) patients with 95% CI (44%, 69%); Historical 1-Year OS Rate in similar MUM populations has been reported at 37% (Source: Rantala 2019, Immunocore March 2021 presentation, Synthetic Control Arm, 2+ L)
- Median OS of 13.2 months was observed in predominantly second line, third line and heavily pre-treated (out to 7 and 8 lines of prior treatment) MUM patients with 95% CI (10.7 months, Not Reached); Historical median OS in similar MUM populations has been reported at approximately 7 months (Source: Rantala 2019, Immunocore March 2021, Synthetic Control Arm, 2+ L)
- 61% (n=46) of MUM patients out of 75 evaluable had tumor reduction per RECIST 1.1. evaluation, including 15 patients (20%) with $\geq 30\%$ target lesion reduction and one confirmed complete response. In the Skin Melanoma cohort, 80% (n=4) of evaluable patients (n=5) had tumor reduction per RECIST 1.1. evaluation, including one confirmed partial response

Darovasertib Monotherapy Clinical Safety

Overall safety profile of darovasertib monotherapy is consistent with prior reports (Ref. 2019 AACR) and includes primarily common low grade but manageable GI toxicities and hypotension.

Preliminary Darovasertib and Binimetinib Combination Clinical Efficacy in MUM

The combination of darovasertib plus binimetinib is being evaluated pursuant to a clinical trial collaboration and drug supply agreement with Pfizer, which the companies have amended to support a target enrollment of approximately 40 patients in the darovasertib and binimetinib clinical combination arm in MUM. At the time of the data and analyses cutoff on April 13th, 2021, twenty four MUM patients have enrolled in the darovasertib and binimetinib combination study, including 8 patients dosed in the Phase 1/2 dose expansion cohort of the combination study. Reported data is preliminary and based on an unlocked database. Enrollment in the darovasertib and binimetinib combination arm of the clinical trial is ongoing.

Darovasertib and Binimetinib Combination Therapy Preliminary Data Summary

- 2 partial responses observed out of nine MUM patients with at least 2 post-baseline scans (22%) by RECIST 1.1 guidelines, including 1 confirmed partial response and 1 unconfirmed partial response (-40.5%) awaiting a confirmatory scan
- 79% of evaluable MUM patients with at least 1 post-baseline scan show tumor reduction; follow-up for overall response is still immature
- Combination doses for Phase 1/2 dose expansion have been selected based on anticipation of activity and overall tolerability in a larger treatment cohort
- Treatment-related adverse events observed in the darovasertib and binimetinib combination arm in MUM primarily include: nausea, vomiting, diarrhea, rash, edema, AST/ALT increase and CK increase (>10%); and hypotension (<10%)

IDEAYA's clinical development strategy in MUM is focused on darovasertib combinations, including with binimetinib, a MEK inhibitor, and in a separate clinical study with crizotinib, a cMET inhibitor, each pursuant to the clinical trial collaboration and drug supply agreement with Pfizer.

Darovasertib Investor Day Webcast

IDEAYA will host an investor webcast with a presentation at 8:00 a.m. ET today. A link to the webcast and a copy of the presentation is posted on the [Investor Relations Events](#) section of the Company's website at <https://ir.ideayabio.com/events>. The update may also be accessed by dialing 1-866-248-8441 (domestic) or 1-720-452-9102 (international) five minutes prior to the start of the call and providing the passcode 2793795. An archived replay of the webcast will be accessible for 90 days following the event.

Meredith McKean, MD, MPH, Associate Director, Melanoma and Skin Cancer Research, Sarah Cannon Research Institute at Tennessee Oncology, Nashville, TN, and Richard Carvajal, MD, Co-Leader, Precision Oncology and Systems Biology Program, Director of Experimental Therapeutics and Director of the Melanoma Service, Columbia University Irving Medical Center, will participate in the webcast.

About IDEAYA Biosciences

IDEAYA is a synthetic lethality-focused precision medicine oncology company committed to the discovery and development of targeted therapeutics for patient populations selected using molecular diagnostics. IDEAYA's approach integrates capabilities in identifying and validating translational biomarkers with drug discovery to select patient populations most likely to benefit from its targeted therapies. IDEAYA is applying its early research and drug discovery capabilities to synthetic lethality – which represents an emerging class of precision medicine targets.

Forward-Looking Statements

This press release contains forward-looking statements, including, but not limited to, statements related to the darovasertib (IDE196) clinical development strategy. Such forward-looking statements involve substantial risks and uncertainties that could cause IDEAYA's preclinical and clinical development programs, future results, performance or achievements to differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, the uncertainties inherent in the drug development process, including IDEAYA's programs' early stage of development, the process of designing and conducting preclinical and clinical trials, the regulatory approval processes, the timing of regulatory filings, the challenges associated with manufacturing drug products, IDEAYA's ability to successfully establish, protect and defend its intellectual property, the effects on IDEAYA's business of the worldwide COVID-19 pandemic, and other matters that could affect the sufficiency of existing cash to fund operations. IDEAYA undertakes no obligation to update or revise any forward-looking statements. For a further description of the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to the business of IDEAYA in general, see IDEAYA's recent Annual Report on Form 10-K filed on March 23, 2021 and any current and periodic reports filed with the U.S. Securities and Exchange Commission.

SOURCE IDEAYA Biosciences, Inc.

For further information: Investor and Media Contact: IDEAYA Biosciences, Paul Stone, Chief Financial Officer, investor@ideayabio.com

<https://ir.ideayabio.com/2021-04-16-IDEAYA-Reports-Darovasertib-IDE196-Monotherapy-Overall-Survival-Data-and-Observes-Early-Partial-Responses-in-Binimetinib-Combination-in-Metastatic-Uveal-Melanoma>