IDEAYA Biosciences Reports Positive Median Overall Survival Data from Phase 2 Trial of the Darovasertib and Crizotinib Combination in First-line Metastatic Uveal Melanoma at the 2025 Society for Melanoma Research Congress

- Combination demonstrated median overall survival (OS) of 21.1 months, compared to reported historical mOS of approximately 12 months in published meta-analysis of metastatic uveal melanoma in the first-line setting
- Median progression free survival (PFS) of 7.0 months
- Confirmed overall response rate (ORR) by RECIST 1.1 of 34%, median duration of response (mDOR) of 9 months and disease control rate (DCR) of 90%

SOUTH SAN FRANCISCO, Calif., Oct. 20, 2025 /PRNewswire/ -- IDEAYA Biosciences, Inc. (NASDAQ: IDYA), a leading precision medicine oncology company, announced the first reported median overall survival (OS) results from their Phase 1/2 clinical trial (OptimUM-01) evaluating darovasertib, the company's investigational oral protein kinase C (PKC) inhibitor, in combination with Pfizer's crizotinib[1], a c-MET inhibitor, as a first-line treatment for patients with metastatic uveal melanoma (mUM). The data will be presented on Sunday, October 26, 2025 by Dr. Justin Moser at the 2025 Society for Melanoma Research Congress (SMR) taking place in Amsterdam, Netherlands.

The presentation at SMR will include data from 44 first-line (1L) mUM patients, including both HLA*A2:01-negative and HLA*A2:01-positive patients, in the single-arm Phase 1/2 OptimUM-01 trial with a median follow-up time of 25 months as of a cut-off date of May 28, 2025. Across all 44 patients treated with the darovasertib and crizotinib combination, a median OS of 21.1 months and a median PFS of 7.0 months was observed. In 41 efficacy-evaluable patients, the confirmed ORR by RECIST 1.1 was 34% (14/41) with a 9.0 month mDOR. A DCR of 90% (37/41) was also observed, with 85% (35/41) of patients achieving 'any reduction' in target lesions. The combination continued to have manageable tolerability, with the most common treatment-related adverse events (TRAEs >30%) of diarrhea, nausea, edema, vomiting, dermatitis, hypoalbuminemia, and fatigue. No Grade 3 or greater TRAEs >5% were observed. The proportion of patients enrolled in the OptimUM-01 study that had baseline ECOG performance status scores (PS) of 0 and 1 was 61% (27/44) and 39% (17/44), respectively. The proportion of patients with ECOG PS 1 in the OptimUM-01 study is approximately two times higher than an earlier published registrational study in mUM.

"These first reported overall survival data and broader clinical efficacy observed with a manageable safety profile underscores the potential of the darovasertib and crizotinib combination in the first-line treatment landscape for patients with metastatic uveal melanoma," said Darrin Beaupre, M.D., Ph.D., Chief Medical Officer of IDEAYA Biosciences.

"We are encouraged by the clinically meaningful median overall survival, overall response rate, median duration of response, and median progression free survival reported in this first-line metastatic uveal melanoma population and look forward to advancing this combination in the ongoing registrational OptimUM-02 trial," said Meredith McKean, M.D., MPH, Director of Melanoma and Skin Cancer Research for Sarah Cannon Research Institute and principal investigator on the trial.

Metastatic uveal melanoma is a rare and aggressive form of ocular cancer with poor prognosis, where historical median OS reported in published meta-analysis from patients in the treatment naïve setting is approximately 12 months (ES Rantala et al, Melanoma Research, 2019; L Khoja et al, Annals of Oncology, 2019). IDEAYA is conducting a registration-enabling Phase 2/3 trial (OptimUM-02) of the darovasertib and crizotinib combination in

1L HLA*A2:01-negative mUM and is targeting to report median PFS data from this trial by year-end 2025 to Q1 2026 to support a potential U.S. accelerated approval filing.

A presentation summary of the SMR data will be available on the Investor Relations tab of IDEAYA's corporate website after the presentation.

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[1] Pursuant to the Clinical Trial Collaboration and Supply Agreement with Pfizer to evaluate darovasertib and crizotinib as a combination therapy in mUM, Pfizer provided the company with a defined quantity of crizotinib at no cost, as well as an additional defined quantity of crizotinib at a lump-sum cost.

About IDEAYA Biosciences

IDEAYA is a precision medicine oncology company committed to the discovery, development, and commercialization of transformative therapies for cancer. Our approach integrates expertise in small-molecule drug discovery, structural biology and bioinformatics with robust internal capabilities in identifying and validating translational biomarkers to develop tailored, potentially first-in-class targeted therapies aligned to the genetic drivers of disease. We have built a deep pipeline of product candidates focused on synthetic lethality and antibody-drug conjugates, or ADCs, for molecularly defined solid tumor indications. Our mission is to bring forth the next wave of precision oncology therapies that are more selective, more effective, and deeply personalized with the goal of altering the course of disease and improving clinical outcomes for patients with cancer.

Forward-Looking Statements

This press release contains forward-looking statements, including, but not limited to, statements related to (i) the potential therapeutic benefits of darovasertib, including in combination with crizotinib; (ii) the safety profile of darovasertib; (iii) the timing of reporting median PFS data from Phase 2/3 OptimUM-02 trial; and (iv) the potential for accelerated approval in 1L HLA*A2 negative mUM. Such forward-looking statements involve substantial risks and uncertainties that could cause IDEAYA's preclinical and clinical development programs, commercialization of products, 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' in early or late 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 the manufacturing or commercialization of drug products, the outcome of pricing, coverage and reimbursement negotiations with third-party payors for IDEAYA's products, IDEAYA's ability to successfully establish, protect and defend its intellectual property, and other matters that could affect the sufficiency of existing cash to fund operations. Neither Breakthrough Therapy nor Orphan Drug designations, nor any clinical study results, whether preliminary or final, necessarily translate into a successful outcome in another study or approval of the drug. 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 Annual Report on Form 10-K dated February 18, 2025, and any current and periodic reports filed with the U.S. Securities and Exchange Commission.

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