IDEAYA Biosciences Completes Targeted Full Enrollment in Randomized Pivotal Phase 2/3 Trial (OptimUM-02) of Darovasertib in Combination with Crizotinib in First-line HLA*A2-Negative Metastatic Uveal Melanoma

- Targeted enrollment of 435 patients to enable potential full approval filing has been completed in OptimUM-02 trial
- Topline data, including median PFS, are expected in 1Q 2026 to support a potential accelerated approval filing in the United States

SOUTH SAN FRANCISCO, Calif., Dec. 11, 2025 /PRNewswire/ -- IDEAYA Biosciences, Inc. (NASDAQ: IDYA), a leading precision medicine oncology company, today announced it has completed its targeted full enrollment of 435 patients in the registration-enabling Phase 2/3 trial (OptimUM-02) evaluating darovasertib, the company's investigational oral protein kinase C (PKC) inhibitor, in combination with Pfizer's crizotinib, an oral c-MET inhibitor, in first line (1L) HLA*A2-negative metastatic uveal melanoma (mUM). IDEAYA expects to report median progression-free survival (PFS) data from this trial in the first quarter 2026 to support a potential accelerated approval filing in the United States. Median overall survival (mOS) data from OptimUM-02, once available, will be used to support a potential full approval filing. Metastatic uveal melanoma is a rare, aggressive form of ocular cancer with limited treatment options and historically poor survival outcomes.

"We are very pleased to announce that we have achieved the target enrollment to enable potential full approval filing in our Phase 2/3 registration-enabling trial of darovasertib in combination with crizotinib in first-line HLA*A2-negative metastatic uveal melanoma. This milestone reflects both the clear unmet need in metastatic uveal melanoma, as well as the strong clinical interest in our darovasertib program. Moreover, the promising overall survival data and broader clinical efficacy demonstrated in the recently reported median overall survival results from the Phase 1/2 clinical trial (OptimUM-01) of this combination in metastatic uveal melanoma are indicative of the clinical potential of darovasertib to meaningfully impact patients with this devastating disease. With target full enrollment now complete, we look forward to the availability of median PFS data we project from OptimUM-02 in the first quarter of next year, and, if approved, making darovasertib in combination with crizotinib available to patients with HLA*A2-negative metastatic uveal melanoma as a first-line treatment as expeditiously as possible," said Yujiro S. Hata, President and Chief Executive Officer, IDEAYA Biosciences.

OptimUM-02 is a multi-arm, multi-stage, open-label Phase 2/3 trial with patients randomized to receive either the darovasertib and crizotinib combination or investigator's choice of treatment (pembrolizumab, ipilimumab + nivolumab, or dacarbazine). The primary endpoints are median PFS and median OS, which will be used to support a potential accelerated approval and full approval in the United States, respectively. In October 2025, IDEAYA presented data from its single-arm, Phase 2 trial (OptimUM-01) of the darovasertib and crizotinib combination at the Society for Melanoma Research (SMR) Congress that demonstrated a 21.1 month median OS and 7.0 months median PFS in 1L mUM, including both HLA*A2-negative and HLA*A2-positive patients.

Darovasertib has received U.S. Food and Drug Administration (FDA) Breakthrough Therapy Designation as neoadjuvant therapy in enucleation recommended primary uveal melanoma (UM) and Fast Track designation for darovasertib in combination with crizotinib in adult patients with metastatic UM. Darovasertib has also been designated as an Orphan Drug by the U.S. FDA in UM, including in metastatic UM. IDEAYA is currently enrolling patients in a pivotal Phase 3 trial of single-agent darovasertib in the neoadjuvant setting of primary UM (OptimUM-10).

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 timing and content of clinical trial programs and updates, including enrollment achievements, regulatory updates, clinical trial data readouts; (ii) the potential for an accelerated and full approval for darovasertib; (iii) the potential therapeutic benefit of darovasertib, including in combination with crizotinib; and (iv) the timing of development and regulatory milestones. Clinical trial results, preliminary or otherwise, are not necessarily predictive of future clinical trial results and/or approval. Neither Breakthrough Therapy nor Orphan Drug Designation necessarily translates into approval of the drug. 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 and commercializing drug 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. 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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