IDEAYA Biosciences to Initiate New Drug Application Submission from the Darovasertib OptimUM-02 Trial under the Oncology Center of Excellence Real-time Oncology Review (RTOR) Program

- Phase 2/3 registrational trial (OptimUM-02) of darovasertib combination met its primary endpoint and will be presented in a late-breaking oral presentation at ASCO 2026
- IDEAYA to initiate the RTOR submission process with the first pre-submission in May, with completion of the NDA filing expected in H2 '26

SOUTH SAN FRANCISCO, Calif., April 30, 2026 /PRNewswire/ -- IDEAYA Biosciences, Inc. (NASDAQ: IDYA), a precision medicine oncology company, today announced that the U.S. Food and Drug Administration (FDA) has agreed to review its New Drug Application (NDA) for darovasertib in combination with crizotinib (darovasertib combination) for patients with first line (1L) HLA*A2-negative metastatic uveal melanoma (mUM) under the Oncology Center of Excellence (OCE) Real-Time Oncology Review (RTOR) program.

"We are grateful for the continued partnership with the FDA and being accepted in the Oncology Center of Excellence Real-Time Oncology Review program based on the topline results from the OptimUM-02 trial. This is an important achievement for IDEAYA and the people living with mUM who today have very few treatment options. We believe the topline results from OptimUM-02 provide further evidence to support the potential benefit of the darovasertib combination in patients with first-line HLA*A2-negative mUM, and we look forward to working closely with the FDA through the RTOR process to make this promising new potential treatment available to patients as quickly as possible," said Yujiro S. Hata, President and Chief Executive Officer of IDEAYA Biosciences.

On April 13th, IDEAYA reported positive topline data from the Phase 2/3 OptimUM-02 trial of darovasertib in combination with crizotinib in 1L HLA*A2-negative mUM. The trial met its primary endpoint, with the combination reducing the risk of disease progression by 58% (Hazard Ratio of 0.42; 95% CI: 0.30, 0.59; p-value: <0.0001) and achieving a statistically significant improvement in median progression-free survival (PFS) of 6.9 months versus 3.1 months in the investigator choice of therapy (ICT) arm as assessed by blinded independent central review (BICR). On secondary endpoints, an overall response rate (ORR) of 37.1%, including 5 complete responses, was observed in patients treated with the darovasertib combination versus 5.8% in the ICT arm (p-value: <0.0001) with a median duration of response (DOR) of 6.8 months. Overall survival (OS) data were not yet mature, however the darovasertib combination did show an early trend in OS improvement versus the ICT arm. The combination was generally well-tolerated with a manageable safety profile consistent with previously reported results and known side-effects of each drug.

The FDA's OCE RTOR program allows an applicant to pre-submit components of its NDA to allow the FDA to review clinical trial data before the complete filing is submitted and aims to provide a more efficient review process to ensure safe and effective treatments are available to patients as early as possible. IDEAYA plans to initiate the RTOR submission process with the first pre-submission targeted for May, with completion of the NDA filing expected in the second half of 2026.

Full results from the OptimUM-02 trial will be presented in a late-breaking oral presentation at the 2026 American Society of Clinical Oncology (ASCO) annual meeting, taking place in Chicago, Illinois. IDEAYA is also conducting clinical trials of darovasertib in HLA*A2-positive mUM as well as in the neoadjuvant and adjuvant settings of primary uveal melanoma.

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. IDEAYA's corporate presentation is available on its website: https://ir.ideayabio.com/

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the federal securities laws, including statements regarding IDEAYA Biosciences' plans to initiate and complete a New Drug Application (NDA) submission for darovasertib under the FDA's Real-Time Oncology Review (RTOR) program; the timing of such submission; the potential for RTOR to enable a more efficient review process; the anticipated presentation of clinical data; the potential therapeutic benefit, safety, and tolerability of darovasertib in combination with crizotinib; the potential for regulatory approval; and the ability of darovasertib to address unmet medical needs in patients with metastatic uveal melanoma. These forward-looking statements are based on IDEAYA's current expectations and beliefs and are subject to a number of risks, uncertainties, and assumptions that could cause actual results to differ materially from those described in the forward-looking statements. Such risks and uncertainties include, but are not limited to: risks related to the timing and success of the NDA submission and acceptance; the FDA's review process and decisions, including whether RTOR will result in a more efficient review timeline; the completeness and quality of the data submitted; the ability to successfully present and interpret clinical data; the risk that topline or interim data may not be predictive of final results; the potential for delays in clinical development or regulatory interactions; the risk that darovasertib in combination with crizotinib may not demonstrate sufficient safety or efficacy in further analyses; and other risks described in IDEAYA's filings with the U.S. Securities and Exchange Commission (SEC), including its most recent Annual Report on Form 10-K and subsequent Quarterly Reports on Form 10-Q.

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