

## **IDEAYA Biosciences and Servier Provide Complete Data from Phase 2/3 Registrational OptimUM-02 Trial of the Darovasertib Combination in First Line HLA\*A2:01 Negative Metastatic Uveal Melanoma in a Late-Breaking Oral Presentation at ASCO**

- Darovasertib combination resulted in a statistically significant and clinically meaningful improvement in median PFS vs. investigator's choice of therapy (ICT) – 6.9 months vs. 3.1 months, HR: 0.42, 58% reduction in risk of disease progression
- Significantly improved ORR (37.1% vs 5.8%) and DCR (73.3% vs. 31.1%) by BICR vs. ICT, where ~77% were treated with ipilimumab + nivolumab
- OS not yet mature but early trend favoring the darovasertib combination; targeting to provide the next update as part of the pre-specified interim analysis
- Manageable safety profile consistent with prior results, with a low rate of TR-SAE (9.2%) and discontinuations due to TRAEs for darovasertib (2.5%) and crizotinib (10%)
- NDA submission in process under RTOR program; expect to complete filing in H2 2026

SOUTH SAN FRANCISCO, Calif., June 1, 2026 /PRNewswire/ -- IDEAYA Biosciences, Inc. (Nasdaq: IDYA), a leading precision medicine oncology company, and Servier, an independent international pharmaceutical group governed by a foundation, today presented complete data from the primary analysis of their registrational Phase 2/3 OptimUM-02 trial of darovasertib in combination with crizotinib (darovasertib combination) in first line (1L) HLA\*A2:01 negative metastatic uveal melanoma (mUM) at the 2026 American Society of Clinical Oncology (ASCO) Annual Meeting taking place in Chicago, Illinois. The data were provided in a late-breaking oral presentation by Dr. Marlana Orloff, M.D., Professor of Medical Oncology at Thomas Jefferson University Hospital and lead investigator on the trial. A copy of the presentation will be available on IDEAYA's corporate website.

"The data from OptimUM-02 represent an exciting step forward in the treatment landscape for metastatic uveal melanoma, particularly for patients with HLA\*A2:01 negative disease who have no approved treatment options," said Dr. Orloff. "The darovasertib combination drove consistent, robust and clinically meaningful improvements in response rate and progression free survival relative to checkpoint inhibitors that are commonly used today and supports its potential as a new therapeutic standard for patients with this devastating disease."

OptimUM-02 is a global, registrational Phase 2/3 trial evaluating a total of 313 patients with 1L HLA\*A2:01 negative mUM, randomized 2:1 to the darovasertib combination or an investigator's choice of therapy (ICT) arm reflective of real-world clinical practice that included ipilimumab plus nivolumab (anti-CTLA-4/PD-1) or pembrolizumab (anti-PD-1). The primary endpoint to support accelerated approval is median progression-free survival (PFS) as assessed by blinded independent central review (BICR). Secondary endpoints include safety and investigator assessed PFS, overall response rate (ORR), disease control rate (DCR) and duration of response. Data presented at ASCO were as of a cutoff date of January 23, 2026 and included additional detail on baseline characteristics as well as safety, secondary endpoints and median PFS across patient subgroups.

### **Key Findings from OptimUM-02**

- Primary endpoint (Phase 2 portion): progression free survival by BICR
  - The trial met the primary endpoint, with patients treated with the darovasertib combination demonstrating a statistically significant improvement in median PFS of 6.9 months versus 3.1 months in the ICT arm by BICR (HR: 0.42; 95% CI: 0.30, 0.59; p-value: <0.0001).
  - Patients treated with the darovasertib combination also had a statistically significant improvement in

median PFS of 6.7 months versus 2.7 months for ICT by investigator assessment (HR: 0.36; 95% CI: 0.26, 0.50, p-value: <0.0001).

- Notably, the darovasertib combination reduced the risk of disease progression by 58% and 64% as assessed by BICR and investigator assessment, respectively.
- Treatment with the darovasertib combination demonstrated a consistent and meaningful improvement in median PFS relative to the ICT arm across a broad range of patient subgroups, including age and gender, type of immune therapy used in ICT, LDH stratification, ECOG status and site of metastasis.
- Secondary endpoints: ORR, DCR, duration of response
  - Patients treated with the darovasertib combination had an ORR of 37.1% (78/210) and 39.5% (83/210) as assessed by BICR and investigator, respectively, compared to 5.8% (6/103) and 1.9% (2/103) in the ICT arm (p-value: <0.0001).
  - The darovasertib combination led to a disease control rate of 73.3% (154/210) and 74.3% (156/210) by BICR and investigator assessment, respectively, compared to 31.1% (32/103) and 27.2% (28/103) in the ICT control arm.
  - The median duration of response was 6.8 months (95% CI: 5.5, 11.3) by BICR and 6.8 months (95% CI: 4.8, 9.7) by investigator assessment based on a median follow-up time of 7.4 months as of the cutoff date.
- Overall survival (Primary endpoint of the Phase 3 portion)
  - As noted in the topline results, data on overall survival (OS) was still immature as of the cutoff date, however, there was an early trend in OS improvement in the darovasertib combination arm relative to the ICT arm.
    - IDEAYA will provide the next OS update as part of the pre-specified interim analysis. Overall survival data, when available, will be used to support a potential full approval in the United States and globally.
- Safety
  - The darovasertib combination was generally well-tolerated with a manageable safety profile consistent with previous results and known side-effects of each agent alone.
  - Median relative dose intensities of darovasertib and crizotinib were 91.0% and 77.1%, respectively, compared to 100% for the ICT arm.
  - Grade 3/4 treatment-related adverse events (TRAEs) occurred in 40.6% (97/239) of patients in the darovasertib combination arm compared to 37.0% (37/100) of patients in the ICT control arm.
    - Treatment-related serious adverse events (TR-SAE) were 9.2% (22/239) and 25.0% (25/100) in the darovasertib combination and ICT arms, respectively.
    - Low discontinuation rate due to TRAEs for darovasertib (2.5%) and crizotinib (10.0%) relative to ICT (19.0%).
  - The most common Grade 3/4 TRAEs included diarrhea (10.0%), syncope (7.1%) and hypotension (3.8%) in the darovasertib combination arm compared to elevated liver enzymes (ALT, 7.0% / AST, 7.0%), diarrhea (6.0%), hepatitis (5.0%) and colitis (4.0%) in the ICT control arm.

In April 2026, IDEAYA announced the U.S. Food and Drug Administration (FDA) has agreed to review their new drug application (NDA) for darovasertib in combination with crizotinib under the Oncology Center of Excellence Real-time Oncology Review (RTOR) program. This program allows applicants to pre-submit components of their 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 completed its first pre-submission in May and expects to complete the NDA filing in the second half of 2026.

## **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.

## **About Servier**

Servier is an independent international pharmaceutical group governed by a foundation. With its governance model, the Group is committed to therapeutic progress to serve patients and integrates the patient voice at every stage of the medicine life cycle.

As a leading global player in cardiology and venous diseases, Servier aims to become a leading innovator in oncology and neurology. The Group intends to offer targeted therapeutic solutions, particularly in rare cancers and neurological diseases, and invests nearly 20% of its brand-name sales in R&D.

Headquartered in France, Servier relies on its more than 20,000 employees and a solid geographic presence with medicines distributed in more than 130 countries. In the 2024/25 financial year, the Group achieved revenues of €6.9 billion.

More information on the Group website: [servier.com](https://www.servier.com)

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## **Forward-Looking Statements**

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements include, but are not limited to, statements regarding: the potential therapeutic benefit, safety, tolerability and clinical activity of darovasertib in combination with crizotinib; the potential significance and implications of data from the Phase 2/3 registrational OptimUM-02 trial; expectations regarding overall survival analyses and timing of interim data updates; IDEAYA's plans and expectations regarding regulatory submissions, including the timing and completion of the NDA submission under the FDA's Real-Time Oncology Review (RTOR) program; the potential for accelerated approval and/or full approval of darovasertib in combination with crizotinib in the United States and globally; and IDEAYA's strategy, business plans and objectives. Such forward-looking statements are based on IDEAYA's current expectations, estimates, assumptions, and beliefs regarding future events and are subject to substantial risks and uncertainties that could cause actual results, outcomes or events to differ materially from those expressed or implied by such statements. These risks and uncertainties include, among others: risks related to the discovery, development and regulatory approval of drug candidates; risks related to the timing, progress and results of clinical trials, including uncertainties regarding enrollment, safety, efficacy and durability of response; risks that clinical trial results may not be replicated in future studies or support regulatory approval; risks related to regulatory interactions, submissions and decisions, including the timing and outcome of NDA review processes; risks related to

manufacturing and supply; risks related to competition and changes in the standard of care; the timing and success of commercialization efforts; the outcome of collaborations and licensing arrangements; IDEAYA's dependence on third parties; risks related to intellectual property protection; and risks related to IDEAYA's ability to obtain, maintain and enforce intellectual property rights for its product candidates. Additional risks and uncertainties that could affect IDEAYA's business and results are described under the caption "Risk Factors" 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 filed with the SEC. Forward-looking statements contained in this press release are made only as of the date hereof, and IDEAYA undertakes no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

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