IDEAYA Biosciences and Servier Announce Positive Topline Results from Phase 2/3 Registrational Trial (OptimUM-02) of Darovasertib in Combination with Crizotinib in First-line HLA-A*02:01-Negative Metastatic Uveal Melanoma

- Trial met the primary endpoint showing statistically significant improvement in median PFS by BICR, with 6.9 months for the darovasertib combination versus 3.1 months for ICT (HR: 0.42; 95% CI: 0.30, 0.59; p-value: <0.0001)
- Secondary endpoint of ORR by BICR was 37.1% for the darovasertib combination versus 5.8% for ICT (p-value: <0.0001), including 5 complete responses in the darovasertib combination arm
- Darovasertib combination showed an early trend in improvement for OS versus ICT
- Well-tolerated, with manageable safety profile consistent with previously reported AEs
- NDA submission planned for H2'26 to support U.S. accelerated approval filing. Full data from OptimUM-02 to be presented at major medical conference in 2026
- IDEAYA to host webcast today at 8:00 AM ET to discuss study results and next steps

SOUTH SAN FRANCISCO, Calif., April 13, 2026 /PRNewswire/ -- IDEAYA Biosciences, Inc. (NASDAQ: IDYA), a precision medicine oncology company, and Servier, an independent international pharmaceutical group governed by a foundation, today announced positive topline results from their Phase 2/3 registrational trial, OptimUM-02, evaluating darovasertib in combination with crizotinib (darovasertib combination) in patients with first-line (1L) HLA-A*A2:01-negative metastatic uveal melanoma (mUM). The darovasertib combination met the trial's primary endpoint of a statistically significant improvement in median progression-free survival (PFS) relative to the investigator choice of therapy (ICT) arm as assessed by blinded independent central review (BICR). The secondary endpoints in the study include overall response rate (ORR) and duration of response (DOR).

"OptimUM-02 is the first randomized study to demonstrate a statistically significant and clinically meaningful benefit in PFS in the clinical setting of first-line HLA-A*02:01-negative metastatic uveal melanoma. For patients with uveal melanoma, these results potentially offer a new treatment option that delivers a significant clinical advancement in both PFS and ORR versus currently available therapies," said Yujiro S. Hata, President and Chief Executive Officer, IDEAYA Biosciences.

"This is a very encouraging milestone demonstrating the potential of this combination in the first-line treatment landscape for patients with metastatic uveal melanoma. Our collaboration with IDEAYA reflects a shared commitment to advancing research and bringing a potential first-in-class treatment to patients," said Claude Bertrand, Executive Vice President Research and Development, Servier.

"Metastatic uveal melanoma is an area of high unmet medical need with poor prognosis and short overall survival, and there are currently no approved therapies for HLA-A*02:01-negative mUM patients. The data from the OptimUM-02 study provides potential practice changing results for the treatment of first-line metastatic uveal melanoma," said Dr. Meredith McKean, Sarah Cannon Research Institute.

OptimUM-02 Study Highlights

OptimUM-02 is a global, randomized Phase 2/3 trial in 1L HLA-A*A2:01-negative MUM evaluating darovasertib combination arm of 210 patients versus the ICT arm reflective of real-world clinical practice that consists of 103 patients. The ICT arm was composed of 76% (n=78) ipilimumab plus nivolumab (anti-CTLA-4/PD-1) and 24% (n=25) pembrolizumab (anti-PD-1). The primary endpoint is median PFS as assessed by BICR, which will be used to support an initial NDA submission in the United States. Topline results were from a total of 313 patients enrolled in the Phase 2b/3 portion of the trial as of the cut-off date of January 23, 2026. The PFS analysis was

based on a total of 159 events.

Patients treated with the darovasertib combination reduced their risk of disease progression as assessed by BICR by 58% (Hazard Ratio of 0.42; 95% CI: 0.30, 0.59; p-value: <0.0001) and achieved a statistically significant improvement in median PFS of 6.9 months versus 3.1 months in the ICT arm. The overall response rate (ORR) by BICR in the darovasertib combination and ICT arm was 37.1% and 5.8% (p-value: <0.0001), respectively. There were 5 complete responses by BICR observed in the darovasertib combination arm, and no complete responses observed in the ICT arm. The median duration of response (DOR) in the darovasertib combination arm was 6.8 months.

The overall survival (OS) data is not mature. However, in the OptimUM-02 study, there is an early trend in improvement in OS with the darovasertib combination arm versus the ICT arm.

Darovasertib combination was generally well-tolerated with a manageable safety profile consistent with prior reported results and known side-effects of each drug. The most common Grade 3+ treatment emergent adverse events included diarrhea, syncope, and hypotension. The treatment-related serious adverse events rate in the darovasertib combination was in the single-digit percent range.

Based on these data, the company will target to submit a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) in the second half of 2026. IDEAYA plans to provide additional details from OptimUM-02 at a major medical conference in 2026.

Conference Call and Q&A Webcast Information

Members of IDEAYA's management and distinguished key opinion leader Dr. Meredith McKean, M.D., MPH, Sarah Cannon Research Institute, will host a conference call and live question and answer (Q&A) webcast for covering research analysts to discuss the study results and next steps today, April 13, 2026, at 8:00 AM ET. The IDEAYA management participants will be Yujiro Hata, Chief Executive Officer and President, Darrin Beaupre, M.D., Ph.D., Chief Medical Officer, and Joshua Bleharski, Ph.D., Chief Financial Officer. The webcast can be accessed using this link or by visiting the Events section of the IDEAYA website (please allow time for registration). A replay will be available on the company's website for 30 days following the live event.

About Uveal Melanoma

Uveal melanoma (UM) is a rare, aggressive form of ocular cancer in which approximately 95% of patients have activating mutations in GNAQ/11 GTPase proteins that drive downstream PKC signaling and tumor growth. The annual incidence of primary UM is >10,000 patients globally (including North America, Europe and Australia) and >3,000 patients in the United States, with approximately 50% of patients progressing to metastatic disease (mUM). We estimate the majority (50-70%) of mUM patients are of the HLA-A*02:01-negative serotype. Currently, there are no FDA-approved systemic therapies for primary UM and no FDA-approved therapies for patients with HLA-A*02:01-negative mUM.

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/

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 deliver 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

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Forward-Looking Statements

This press release contains forward-looking statements, including, but not limited to, statements related to the clinical significance and potential therapeutic benefit of darovasertib in combination with crizotinib; the interpretation of the topline results from the OptimUM-02 trial; the potential for the combination to become a new standard of care for first-line HLA-A*02:01-negative metastatic uveal melanoma; the sufficiency of the trial results to support regulatory submissions; the preliminary trends in overall survival data; the safety and tolerability profile of darovasertib combination; the timing and plans for submission of a New Drug Application (NDA) in the second half of 2026; the potential for accelerated approval in the United States; the timing and content of future data presentations; the development, regulatory and commercial plans for darovasertib; and the potential market opportunity for the combination therapy. Such forward-looking statements are based on management's current expectations, assumptions and beliefs and involve substantial risks and uncertainties that could cause actual results, including, but not limited to, those related to IDEAYA's clinical programs, commercial activities, and performance and/or achievements, to differ significantly and/or materially 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 the process of designing and conducting preclinical and clinical trials, enrollment rates, safety outcomes, efficacy results, regulatory interactions and decisions, and the ability to translate preclinical findings into clinical benefit, manufacturing and supply risks, competition, changes in standard of care, the timing and success of commercialization efforts, the outcome of collaborations and licensing arrangements, IDEAYA's ability to successfully establish, protect and defend its intellectual property, and other matters that could affect the sufficiency of financial resources to fund operations. IDEAYA undertakes no obligation to update or revise any forward-looking statements. A further description of 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, are in IDEAYA's filings with the Securities and Exchange Commission, including IDEAYA's most recent Annual Report on Form 10-K for the year ended December 31, 2025 filed on February 17, 2026 and any current and periodic reports filed with the U.S. Securities and Exchange Commission.

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