

IDEAYA Biosciences and Servier Announce Data From Three Clinical Trials at ESMO 2026 Supporting the Potential of Darovasertib to Become a Foundational New Therapy for Patients Across the Treatment Journey of Uveal Melanoma

- *OptimUM-01 and OptimUM-02 data supports the broad potential of darovasertib plus crizotinib to drive meaningful clinical benefits for patients with metastatic uveal melanoma, irrespective of HLA-A*02:01 allele status or line of therapy*
- *OptimUM-01 data demonstrates encouraging clinical activity from darovasertib combined with crizotinib in both treatment-naïve (7.4 month PFS, 27.1 month mOS, n=13) and heavily pretreated HLA-A*02:01-positive metastatic uveal melanoma, including in 2L patients following tebentafusp*
- *Treatment-naïve patients in OptimUM-01 and OptimUM-02 demonstrate comparable ORR, PFS and DOR in HLA-A*02:01-positive and -negative patients and consistent improvements in ORR and PFS versus investigator's choice of therapy across a range of clinically relevant subgroups*
- *OptimUM-09 continues to demonstrate robust tumor shrinkage in >80% of primary uveal melanoma patients treated with neoadjuvant darovasertib, resulting in a 57% eye preservation rate and 66% of patients achieving a reduced projected dose of radiation to critical eye structures in the enucleation and plaque brachytherapy cohorts, respectively*

SOUTH SAN FRANCISCO, Calif., Oct. 19, 2026 /[PRNewswire](#)/ -- IDEAYA Biosciences, Inc. (Nasdaq: IDYA), a leading precision medicine oncology company, today announced updated clinical data from three ongoing studies evaluating darovasertib in metastatic and primary uveal melanoma (UM) that will be presented at the European Society for Medical Oncology (ESMO) Congress 2026, taking place on October 23–27 in Madrid, Spain. The updates will include Phase 2 expansion data from OptimUM-01 in HLA-A*02:01-positive patients with metastatic uveal melanoma (mUM), subgroup analyses from the registrational Phase 2/3 OptimUM-02 trial in first line (1L) HLA-A*02:01-negative mUM and follow-up data from the Phase 2 OptimUM-09 trial evaluating neoadjuvant darovasertib in patients with primary UM.

"These three clinical updates at ESMO continue to support our belief in the potential for darovasertib to address important unmet needs across the uveal melanoma treatment journey," said Yujiro S. Hata, Chief Executive Officer of IDEAYA Biosciences. "In the metastatic setting we believe the data from OptimUM-01 and OptimUM-02 offer strong and consistent evidence for the potential of darovasertib to address the needs of a broad patient population, irrespective of HLA-allele status. In primary disease, longer follow up data from OptimUM-09 continues to highlight the potential of neoadjuvant darovasertib to shrink tumors before primary local treatment to help more patients preserve their eyes and avoid the risk of long-term vision loss. Together, these data advance our vision of establishing darovasertib as a foundational therapy for uveal melanoma."

OptimUM-01 Activity in HLA-A*02:01-Positive Metastatic Uveal Melanoma

OptimUM-01 is a Phase 1/2 single-arm, multi-center, open label dose escalation and expansion study evaluating darovasertib in combination with crizotinib (the darovasertib combination) in patients with solid tumors harboring GNAQ/11 mutations. The ESMO update focuses on the Phase 2 expansion results from OptimUM-01 in HLA-A*02:01-positive mUM patients as of a cutoff date of March 23, 2026. A total of 101 patients were evaluated with median follow up of 10.4 months, including 13 treatment naïve patients and 15 patients that received prior tebentafusp as their only systemic treatment prior to the darovasertib combination. Notably, approximately 66% of

the patients had received two or more prior lines of therapy. As summarized in the table below, the combination demonstrated an encouraging profile across key measures of efficacy, including overall response rate (ORR), disease control rate (DCR), duration of response (DOR), progression free survival (PFS) and overall survival (OS).

	Treatment-naïve (1L) (N=13)	Prior tebentafusp (2L) (N=15)	Overall (N=101)
ORR* % (n/N) 95% CI	36.4% (4/11) 10.9-69.2	35.7% (5/14) 12.8-64.9	22.1% (19/86) 13.9-32.3
DCR* % (n/N)	90.9% (10/11)	85.7% (12/14)	80.2% (69/86)
Median DOR*	10.2 mos	5.6 mos	7.4 mos
Median PFS† 95% CI	7.4 mos 3.6-19.6	5.7 mos 3.65-NE	5.4 mos 3.7-6.8
Median OS† 95% CI	27.1 mos 8.94-NE	12.1 mos 9.79-NE	13.4 mos 9.8-26.3

CI = confidence interval, NE = not estimable

* Response assessments utilized efficacy-evaluable population, which includes all patients ≥3 post-baseline assessments or who discontinued treatment; † PFS and OS assessments were based on the total enrolled population, which includes all patients receiving ≥1 dose of treatment

Based on data from large meta-analyses published by Khoja and Rantala it has been shown that mUM has an especially poor prognosis, with a reported median PFS of 2.8 months and median OS of ~12 months in the treatment-naïve setting. In the 2L setting, median PFS remains at ~2-3 months but median OS drops to ~8 months with a 1-year OS rate of ~37%. As shown in the table above the data from OptimUM-01 compares favorably to these historical PFS and OS benchmarks, as well as to historical ORR which is typically ~5%. Safety was manageable and generally consistent with previously reported results, with the most common treatment-related adverse events of diarrhea (82%), nausea (76%), peripheral edema (70%), and vomiting (57%). Related adverse events leading to treatment discontinuation occurred in 9 (8.9%) participants.

OptimUM-02 Subgroup Analyses in 1L HLA-A*02:01-Negative Metastatic Uveal Melanoma

OptimUM-02 is a Phase 2/3, open label trial evaluating the darovasertib combination in patients with HLA-A*02:01-negative mUM. In June 2026, IDEAYA reported positive results from OptimUM-02 at the American Society of Clinical Oncology (ASCO) demonstrating that 1L HLA A*02:01 -negative mUM patients treated with the darovasertib combination had a median PFS of 6.9 months by blinded independent central review (BICR) and 6.7 months by investigator assessment, compared to 3.1 months and 2.7 months in the investigator's choice of therapy (ICT) control arm, respectively. The ESMO data builds on these results, showing consistent improvements in ORR and PFS compared to ICT across multiple clinically relevant subgroups, including baseline

lactate dehydrogenase (LDH) levels, ECOG performance status, largest target lesion size and choice of ICT used in the control arm. As expected, patients with higher tumor burden (lesion size ≥ 8 cm, LDH $\geq 2X$ ULN) had a worse prognosis, however outcomes were still better with the darovasertib combination compared to ICT.

"I am highly encouraged by the OptimUM-01 and OptimUM-02 data being presented at ESMO 2026, which highlights the continued progress being made for patients with metastatic uveal melanoma. The randomized OptimUM-02 results demonstrate the potential for darovasertib plus crizotinib to establish a new first line standard for patients with HLA-A*02:01-negative disease, while the OptimUM-01 findings reinforce its potential to become a new standard of care for the broader population of patients irrespective of HLA-A*02:01 status and line of therapy. Together, these data represent a meaningful advancement toward addressing the diverse and significant needs of the metastatic uveal melanoma patient community," said Dr. Meredith McKean, M.D., MPH, Director of Melanoma and Skin Cancer Research at Sarah Cannon Research Institute.

OptimUM-09 Follow-Up in Neoadjuvant Primary Uveal Melanoma

OptimUM-09 is a Phase 2 trial evaluating single-agent darovasertib before local treatment in patients with primary uveal melanoma requiring enucleation, or surgical removal of the eye (Cohort 1), or plaque brachytherapy (Cohort 2). The primary endpoints for these cohorts are eye preservation rate and planned radiation dose reduction, respectively. The data in the ESMO abstract was from 116 patients treated with neoadjuvant darovasertib, including 66 patients in Cohort 1 and 50 patients in Cohort 2, as of a cutoff date of February 23, 2026, and is described below. However, the updated data to be presented at ESMO is from a total of 119 patients as of a cutoff date of June 15, 2026. Nonetheless, the data is largely consistent and continues to support the previously reported results from the trial, including at ESMO in 2025.

Treatment with neoadjuvant darovasertib led to robust tumor shrinkage in both cohorts, with approximately 80% of patients demonstrating tumor shrinkage from baseline. Tumor shrinkage of $\geq 20\%$ was observed in 57.8% (67/116) of patients, including 51.5% (34/66) in Cohort 1 and 66% (33/50) in Cohort 2; notably, data presented from OptimUM-09 at ESMO in 2025 showed that patients who achieved a $\geq 20\%$ level of tumor shrinkage had a higher rate of eye preservation and improved visual outcomes compared to those below that threshold. Here, a 57% eye preservation rate was observed in the enucleation cohort, and 66% of patients in the plaque brachytherapy cohort had a reduction in planned radiation dose to critical eye structures, with early outcomes data suggesting no detriment from delayed primary local therapy compared to historical recurrence rates. Across both cohorts, 86.3% of patients were free from metastasis at 15 months (Cohort 1: 79.7%, Cohort 2: 94.4%) and all but one relapsed subject had high or intermediate risk for metastasis. Darovasertib continued to demonstrate a manageable safety profile, with the most common treatment-related adverse events including diarrhea (64%), nausea (58%), fatigue (33%), and vomiting (28%). Treatment-related serious adverse events occurred in 6.0% of patients, most commonly as hypotension (3.4%). Drug interruption, modification, or discontinuation due to any AEs occurred in 0%, 10%, and 9%, respectively.

"For patients with primary uveal melanoma, shrinking the tumor before local treatment with neoadjuvant darovasertib could fundamentally change their quality of life by increasing their odds of eye preservation and protecting their long-term quality of vision. The additional follow-up data from OptimUM-09 presented at ESMO represents a meaningful potential advance for patients in the primary disease setting, where there are no approved systemic treatment options," said Dr. Marcus O. Butler, M.D., Associate Professor, Princess Margaret Cancer Center.

ESMO Presentation Details

All presentations will take place on Saturday, October 24th, 2026, 12:00-12:45pm (CEST):

2086P (Poster Presentation)

Title: Darovasertib and Crizotinib for HLA-A*02–Positive Metastatic Uveal Melanoma: Results from the Phase 2 OptimUM-01 Study

Presenting Author - Meredith McKean, MD, MPH, Sarah Cannon Research Institute, Nashville, Tennessee, United States

2104P (Poster Presentation)

Title: Darovasertib with Crizotinib vs Investigator's Choice as First-Line Treatment for Patients with HLA-A2 Negative Metastatic Uveal Melanoma (OptimUM-02): A Subgroup Analysis

Presenting Author - Sophie Piperno-Neumann, MD, PhD, Institute Curie Research University, Paris, France

2092P (Poster Presentation)

Title: Neoadjuvant Darovasertib in Primary Uveal Melanoma: Follow-Up Data from the Phase 2 OptimUM-09 Study

Presenting Author - Mark Shackleton, MBBS, PhD, FRACP, Department of Oncology, Alfred Hospital, and Department of Cancer Medicine, Monash University, Melbourne, Australia

About Darovasertib

Darovasertib is a potential first-in-class oral, small-molecule inhibitor of PKC. Darovasertib was designed to inhibit PKC isoforms downstream of the GNAQ and GNA11 oncogenic driver mutations that are present in nearly all uveal melanoma patients. Darovasertib is being evaluated in multiple clinical trials in uveal melanoma, including in combination with crizotinib, an oral inhibitor of c-MET, in patients with metastatic disease and as an adjuvant therapy in the pre-metastatic setting. IDEAYA is also evaluating single-agent darovasertib as a neoadjuvant therapy in primary uveal melanoma.

IDEAYA is submitting a new drug application (NDA) for darovasertib in combination with crizotinib for patients with first line metastatic uveal melanoma under the oncology center of excellence (OCE) real-time oncology review (RTOR) program and expects to complete the NDA submission in the second half of 2026. The U.S. Food and Drug Administration (FDA) has also granted darovasertib Fast Track designation for the treatment of metastatic uveal melanoma, Orphan Drug designation in primary uveal melanoma and Breakthrough Therapy Designation as a neoadjuvant therapy for patients with primary uveal melanoma for whom enucleation has been recommended. Darovasertib is an investigational product and has not been approved by the FDA or any other regulatory authority.

In 2025, IDEAYA Biosciences and Servier entered into an exclusive licensing agreement whereby Servier obtained the regulatory and commercial rights to darovasertib in all territories outside of the United States. The companies are collaborating on the clinical development of darovasertib and sharing the associated costs.

About Uveal Melanoma

Uveal melanoma is a rare and aggressive cancer arising from melanocytes in the eye and is biologically distinct from cutaneous melanoma. An estimated 10,000-12,000 new cases of primary uveal melanoma are diagnosed globally per year, including more than 3,000 new cases annually in the United States. Primary uveal melanoma is generally treated with local therapy, including plaque brachytherapy, radiation or surgical removal of the eye (enucleation). Despite effective control of the primary tumor, up to 50% of primary uveal melanoma patients eventually progress to metastatic disease. There remains a significant unmet need for systemic therapies capable of delaying or preventing metastatic disease progression following treatment of primary uveal melanoma.

About IDEAYA Biosciences

IDEAYA is a precision medicine oncology company committed to the discovery, development, and commercialization of transformative therapies to address unmet medical needs in cancer. The company

integrates small-molecule drug discovery, structural biology and bioinformatics with extensive capabilities in identifying and validating translational biomarkers to develop potentially first-in-class targeted therapies for selected patient populations. IDEAYA has built a robust pipeline of targeted therapies focused on synthetic lethality and antibody-drug conjugates, or ADCs, including bispecifics, with the goal of 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, including, but not limited to, statements regarding the timing and content of clinical data presentations at ESMO 2026; the potential safety, efficacy and therapeutic benefits of darovasertib, as monotherapy and in combination with crizotinib, in metastatic and primary uveal melanoma; the potential for darovasertib in combination with crizotinib to provide meaningful clinical benefits across HLA-A*02:01 status, lines of therapy and clinically relevant patient subgroups, including following prior tebentafusp treatment; the potential for neoadjuvant darovasertib to shrink tumors, increase eye preservation, reduce radiation exposure to critical eye structures and preserve long-term vision and quality of life; the potential for darovasertib to become a new standard of care or foundational therapy across the uveal melanoma treatment journey; the translation of preliminary, interim or follow-up clinical results into future clinical results and/or regulatory approval; and the timing, progress and outcome of regulatory activities, including completion of the new drug application submission for darovasertib in combination with crizotinib in the second half of 2026 under the FDA's real-time oncology review (RTOR) program.

These forward-looking statements are based on management's current expectations and assumptions and are subject to a number of risks, uncertainties, and other factors 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, progress, and results of clinical trials and preclinical studies; the ability of IDEAYA to obtain and maintain regulatory approvals; uncertainties regarding the regulatory review process, including participation in the RTOR program; the potential for clinical data to differ from preliminary or interim results; the ability to successfully develop, manufacture, and commercialize product candidates; competition from other biotechnology and pharmaceutical companies; the impact of global economic conditions; IDEAYA's ability to successfully establish, protect and defend its intellectual property; and other risks described in IDEAYA's filings with the U.S. Securities and Exchange Commission (SEC), including its most recent Quarterly Report on Form 10-Q and Annual Report on Form 10-K.

Forward-looking statements speak only as of the date of this press release, 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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<https://media.ideayabio.com/2026-10-19-IDEAYA-Biosciences-and-Servier-Announce-Data-From-Three-Clinical-Trials-at-ESMO-2026-Supporting-the-Potential-of-Darovasertib-to-Become-a-Foundational-New-Therapy-for-Patients-Across-the-Treatment-Journey-of-Uveal-Melanoma>