IDEAYA Biosciences and Servier Announce First Patient Dosed in OptimUM-11 Global Phase 3 Registrational Trial of Darovasertib and Crizotinib as Adjuvant Therapy for Subjects with Uveal Melanoma

- Global Phase 3 trial will evaluate the darovasertib and crizotinib combination in primary uveal melanoma patients with increased risk of metastasis following completion of local therapy
- OptimUM-11 expands development of darovasertib across the uveal melanoma patient journey into the adjuvant setting, where there is a significant unmet need for systemic treatment options designed to reduce the risk of metastatic recurrence

SOUTH SAN FRANCISCO, Calif., Sept. 9, 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 announced that the first patient has been dosed in OptimUM-11, a global Phase 3 registrational trial evaluating darovasertib, a first-in-class oral protein kinase C (PKC) inhibitor, in combination with crizotinib, an oral cMET inhibitor, as adjuvant therapy for patients with primary uveal melanoma who have completed local therapy and have an increased risk of developing metastatic disease. Currently, there are no approved adjuvant treatment options for patients with primary uveal melanoma.

"Dosing the first patient in OptimUM-11 represents an important milestone in our strategy to advance darovasertib across the uveal melanoma patient journey," said Darrin M. Beaupre, M.D., Ph.D., Chief Medical Officer of IDEAYA Biosciences. "Patients with primary uveal melanoma are commonly at risk for metastatic recurrence following treatment of their primary tumor, highlighting the need for an effective systemic therapy in the adjuvant setting to delay or prevent disease progression. We believe the darovasertib combination has the potential to address the principal pathways associated with the initiation and metastatic progression of uveal melanoma, and we look forward to working with our partner Servier and the global investigator community to advance this registrational trial."

"Preventing or delaying metastatic recurrence could fundamentally change the treatment journey for patients with high-risk primary uveal melanoma," said Arnaud Lallouette, Executive Vice President Global Medical & Patient Affairs at Servier. "Through OptimUM-11, Servier and IDEAYA are jointly advancing a global registrational study of the darovasertib combination with the goal of establishing a new adjuvant treatment option for patients worldwide."

OptimUM-11 is being conducted by IDEAYA in collaboration with its partner, Servier, to evaluate darovasertib in combination with crizotinib as an adjuvant therapy for patients with primary uveal melanoma. The trial is expected to enroll approximately 450 patients who have completed primary local therapy and have an increased risk of metastasis. Patients will be eligible irrespective of HLA status and will be randomized 1:1 to receive darovasertib in combination with crizotinib for 12 months or observation. The primary endpoint of the trial is relapse-free survival. IDEAYA retains regulatory and commercial rights to darovasertib in the United States, while Servier holds all such rights outside the United States. The companies will share the associated development costs of the trial.

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 patients with metastatic disease (OptimUM-01 and OptimUM-02), as well as in primary uveal melanoma as a

neoadjuvant (OptimUM-09 and OptimUM-10) and adjuvant (OptimUM-11) therapy.

IDEAYA has initiated submission of a new drug application (NDA) for darovasertib in combination with crizotinib for patients with first line metastatic uveal melanoma (mUM) 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 mUM, 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.

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 Follow us on social media: LinkedIn, Facebook, X, Instagram

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and other applicable securities laws. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including, but not limited to, statements regarding the design, conduct, enrollment, timing, progress, completion and results of the OptimUM-11 clinical trial; the potential safety, efficacy, tolerability and therapeutic benefits of darovasertib in combination with crizotinib; the potential for the darovasertib combination to improve relapse-free survival or delay or prevent

metastatic recurrence in patients with primary uveal melanoma; the potential of darovasertib to become an important treatment option across the uveal melanoma patient journey; the timing, progress and outcome of regulatory activities; and the performance, expected activities and potential benefits of IDEAYA's collaboration with Servier. Such forward-looking statements are based on IDEAYA's management's current expectations, assumptions and beliefs and involve risks, uncertainties, and other factors that could cause actual results, including those related to IDEAYA's clinical programs, regulatory activities, commercial activities and performance or achievements, to differ significantly or materially from those expressed or implied by the forward-looking statements.

Such risks and uncertainties include, among others, risks relating to the timing, design, initiation, conduct and completion of clinical trials; the ability to activate clinical trial sites and enroll, retain and dose patients; the possibility that clinical trial results may not demonstrate the safety, tolerability, efficacy or therapeutic benefits anticipated by IDEAYA; the possibility that results from OptimUM-11 may not support regulatory submissions or approvals; the timing and outcome of interactions with the FDA and other regulatory authorities; uncertainties regarding the regulatory review process, including participation in the RTOR program; the ability to obtain and maintain regulatory approvals; manufacturing and drug-supply risks; reliance on clinical investigators, contract research organizations, manufacturers, suppliers and collaboration partners, including Servier; the ability of IDEAYA and Servier to perform their respective obligations and realize the anticipated benefits of their collaboration; competition and changes in the standard of care; the ability to successfully develop and commercialize product candidates; IDEAYA's ability to establish, protect and defend its intellectual property; and other matters that could affect the sufficiency of financial resources to fund operations. For a further description of risks and uncertainties that could cause actual results to differ from those expressed in or implied by these forward-looking statements, as well as risks relating to IDEAYA's business generally, is included in IDEAYA's filings with the Securities and Exchange Commission, including its most recent Annual Report on Form 10-K, filed on February 17, 2026, subsequent Quarterly Reports on Form 10-Q and Current Reports on Form 8-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 contained herein to reflect any change in expectations, new information, subsequent events or circumstances, or otherwise, except as required by law.

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