IDEAYA Biosciences Receives US FDA Breakthrough Therapy Designation for Darovasertib Monotherapy in Neoadjuvant Uveal Melanoma

- Designation enables expedited development and priority regulatory review
- BTD application was supported by updated clinical data from Ph2 neoadjuvant UM trial that we are targeting to present at medical conferences in mid-2025 and H2 2025
- Targeting to initiate a Ph3 registrational study in neoadjuvant UM in H1 2025
- Neoadjuvant UM has a projected annual incidence of ~12k patients, and is a high unmet medical with no FDA approved systemic therapies

SOUTH SAN FRANCISCO, Calif., March 31, 2025 /PRNewswire/ -- IDEAYA Biosciences, Inc. (NASDAQ: IDYA), a precision medicine oncology company committed to the discovery and development of targeted therapeutics, today announced that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy designation (BTD) for darovasertib, a potential first-in-class protein kinase C (PKC) inhibitor, for the neoadjuvant treatment of adult patients with primary uveal melanoma (UM) for whom enucleation has been recommended.

"We are pleased to receive FDA Breakthrough Therapy designation as we prepare to advance neoadjuvant darovasertib into a potential Phase 3 registrational trial in patients with primary UM. This designation highlights the potential of monotherapy darovasertib in a patient population with significant unmet medical need where there are currently no FDA-approved systemic therapies," said Dr. Darrin Beaupre, M.D., Ph.D., Chief Medical Officer of IDEAYA Biosciences. "We are targeting to present the updated Phase 2 clinical data in neoadjuvant UM that was provided as part of the BTD application at multiple medical conferences in 2025," said Yujiro S. Hata, President and Chief Executive Officer, IDEAYA Biosciences.

This U.S. FDA BTD designation, follows the Fast Track designation granted by the U.S. FDA for evaluation of darovasertib in combination with crizotinib in adult patients being treated for metastatic uveal melanoma (MUM), where a Phase 2/3 registration-enabling trial of the darovasertib and crizotinib combination in 1L HLA-A2-negative MUM is ongoing. Darovasertib has also been designated as an Orphan Drug by the U.S. FDA in UM, including in MUM, entitling IDEAYA to certain potential tax credits, exemptions from user fees, and statutory marketing exclusivity.

The BTD application was supported by updated interim clinical data from an ongoing Phase 2 open-label trial (NCT05907954) evaluating darovasertib monotherapy in the neoadjuvant setting for localized UM. IDEAYA presented interim clinical data demonstrating an 82% ocular tumor shrinkage rate and a 61% eye preservation rate in UM patients in September 2024 (press release), and neoadjuvant UM data was also presented as an oral presentation at ASCO 2024. Updated clinical data in neoadjuvant UM, including efficacy, safety, radiation reduction, eye preservation, and vision preservation / improvement on treatment, were submitted as part of the BTD application that we plan to present at medical conferences in 2025. Multiple clinical data updates in neoadjuvant UM and MUM, including median overall survival (mOS) from the Phase 2 study (IDE196-001), are targeted to be presented at medical conferences in mid-year 2025 and the second half of 2025. A median progression free survival (mPFS) readout for the Phase 2/3 registration-enabling trial of the darovasertib and crizotinib combination in 1L HLA-A2-negative MUM is targeted by year-end 2025. The Company also intends to initiate a Phase 3 randomized registrational

trial in neoadjuvant UM in the first half of 2025.

A potential Phase 3 registrational study would evaluate neoadjuvant darovasertib in primary UM patients who are eligible for enucleation (Cohort 1) or plaque brachytherapy (Cohort 2). Neoadjuvant UM has a projected annual incidence for North America, Europe, and Australia of approximately 12,000 patients, and is a high unmet medical with no FDA approved systemic therapies.

BTD is designed to expedite the development and regulatory review of promising therapies for serious or life-threatening conditions where preliminary clinical evidence suggests substantial improvement over existing treatments. The designation facilitates more intensive FDA guidance, cross-disciplinary collaboration, and eligibility for rolling submission and priority review.

About IDEAYA Biosciences

IDEAYA is a precision medicine oncology company committed to the discovery and development of targeted therapeutics for patient populations selected using molecular diagnostics. IDEAYA's approach integrates capabilities in identifying and validating translational biomarkers with drug discovery to select patient populations most likely to benefit from its targeted therapies. IDEAYA is applying its research and drug discovery capabilities to synthetic lethality – which represents an emerging class of precision medicine targets.

Forward-Looking Statements

This press release contains forward-looking statements, including, but not limited to, statements related to i) the potential for expedited development and priority regulatory review for darovasertib in neoadjuvant UM; ii) the potential therapeutic benefit of darovasertib; iii) the timing of presentations and readouts of darovasertib clinical trial data; iv) timing of initiating a potential Phase 3 registrational-enabling study of darovasertib in neoadjuvant UM patients and v) projected incidence rates in neoadjuvant UM. Such forward-looking statements involve substantial risks and uncertainties that could cause IDEAYA's preclinical and clinical development programs, future results, performance or achievements to differ significantly 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 IDEAYA's programs' early stage of development, the process of designing and conducting preclinical and clinical trials, the regulatory approval processes, the timing of regulatory filings, the challenges associated with manufacturing drug products, IDEAYA's ability to successfully establish, protect and defend its intellectual property, and other matters that could affect the sufficiency of existing cash to fund operations. IDEAYA undertakes no obligation to update or revise any forward-looking statements. For a further description of the 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, see IDEAYA's Annual Report on Form 10-K dated February 18, 2025 and any current and periodic reports filed with the U.S. Securities and Exchange Commission.

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