IDEAYA Announces Results for Darovasertib Phase 2 IST in Neoadjuvant Uveal Melanoma at ASCO and Clinical Update for Phase 2 Company-Sponsored Neoadjuvant Study

- 75% eye preservation rate (9 of 12 enucleation patients)
- ~67% (8 of 12 enucleation patients) observed greater than 30% tumor shrinkage and median tumor shrinkage of 47% by volume change after 6 months
- Company-sponsored Phase 2 Neoadjuvant UM: Over 40 patients enrolled, and for the 8 patients with ≥4-months of darovasertib observed median tumor shrinkage of 72% by volume change and eye preserved for the majority of enucleation patients
- Targeting Type C meeting with the FDA in H2 2024 for guidance on potential registrational trial for darovasertib in neoadjuvant UM setting
- Projected global annual incidence of primary UM is ~8,000 to ~10,000 patients

SOUTH SAN FRANCISCO, Calif., June 3, 2024 /PRNewswire/ -- IDEAYA Biosciences, Inc. (Nasdaq: IDYA), a precision medicine oncology company committed to the discovery and development of targeted therapeutics, today announced updated clinical results from the ongoing investigator-sponsored Phase 2 trial of darovasertib, a first-in-class oral, small molecular inhibitor of protein kinase C (PKC), as neoadjuvant/adjuvant treatment in uveal melanoma (UM) and clinical update for Phase 2 company-sponsored neoadjuvant UM study. The clinical data from the ongoing investigator-sponsored Phase 2 trial were included in an oral presentation at the American Society of Clinical Oncology (ASCO) 2024 Annual Meeting.

"The clinical data presented at ASCO provides further validation for the potential of darovasertib in the neoadjuvant UM setting to preserve the eye and to shrink ocular tumors for UM patients," said Yujiro S. Hata, President and Chief Executive Officer, IDEAYA Biosciences. "We believe neoadjuvant and adjuvant UM represent high unmet medical needs and indication expansion opportunities that are potential first-line treatment opportunities across the patient journey and irrespective of HLA-A2 status that will significantly expand the addressable patient population for darovasertib beyond the metastatic setting."

"The clinical data presented at ASCO highlights the potential of darovasertib as a neoadjuvant treatment to provide meaningful tumor shrinkage in patients with ocular tumors and spare patients from enucleation, with a manageable AE profile," added Darrin Beaupre, M.D., Ph.D., Chief Medical Officer, IDEAYA Biosciences. "We are targeting a Type C meeting with the FDA in H2 2024 for guidance on a potential registrational trial in neoadjuvant UM, and we are encouraged by the rapid enrollment, and preliminary clinical efficacy and safety observed from IDEAYA's company-sponsored Phase 2 neoadjuvant UM trial."

Anthony Joshua, MBBS, PhD, FRACP, Head Department of Medical Oncology, Kinghorn Cancer Centre, St. Vincent's Hospital in Sydney, and the lead principal investigator of the Phase 2 study, presented clinical results from the Phase 2 Neoadjuvant / Adjuvant trial of Darovasertib in Ocular Melanoma (NADOM) at ASCO. Fifteen patients planned for enucleation with localized UM were treated with darovasertib 300mg twice daily. An initial safety cohort of three patients were treated for one month, and the remaining 12 patients were treated in an expansion cohort for up to six months as neoadjuvant treatment prior to their primary intervention (enucleation, plaque brachytherapy or external beam radiotherapy (EBRT)) across three Australian centers.

As of the database lock on May 14, 2024, 13 patients had completed neoadjuvant treatment, 11 patients received adjuvant darovasertib after primary treatment of their UM, with five patients completing the planned six months of therapy. As of May 14, 2024, 75% (9 out of 12 enucleation patients) had confirmed Eye Saved (i.e., converted to plaque brachytherapy or EBRT) and approximately 67% (8 out of 12 enucleation patients) observed greater than

30% tumor shrinkage (maximum volume change) after 6 months. Median tumor shrinkage (maximum volume change) in 12 enucleation patients was approximately 47% after 6 months.

The darovasertib monotherapy neoadjuvant treatment had a manageable adverse event (AE) profile with no drug-related serious adverse events observed. Drug-related AEs were predominantly Grade 1 or Grade 2 and 20% of patients reported at least one drug-related Grade 3 adverse event.

The Company is targeting a Type C meeting with the FDA to discuss a potential registrational trial for darovasertib in the neoadjuvant UM setting and a clinical efficacy update from its Phase 2 company-sponsored darovasertib neoadjuvant UM trial in H2 2024. As of May 24, 2024 cut-off date, the Phase 2 company-sponsored darovasertib neoadjuvant UM trial has activated over 14 sites globally and enrolled over 40 patients. As of the cut-off date, 8 patients (6 enucleation and 2 plaque eligible) have been on darovasertib treatment for 4-months or more and observed median tumor shrinkage (maximum height/base/volume change) of approximately 40%/25%/72% and the majority of the 6 enucleation patients had reported Eye Saved (i.e., converted to plaque brachytherapy or EBRT eligible).

In the 8 patients with 4-months or more of darovasertib treatment as of May 24, 2024, darovasertib had a manageable AE profile with no drug-related serious adverse events observed, and drug-related AEs were predominantly Grade 1 or Grade 2 and approximately 13% of patients reported at least one drug-related Grade 3 AE.

The darovasertib program has ongoing enrollment of a potential registrational Phase 2/3 trial in first-line HLA-A2-negative metastatic UM (MUM), and Phase 2 trials in HLA-A2 positive MUM and neoadjuvant and adjuvant UM. Darovasertib received FDA Fast Track designation in MUM and FDA Orphan Drug designation for the treatment of Uveal Melanoma, including MUM. We project the global annual incidence of primary uveal melanoma is approximately 8,000 to 10,000 patients, with the majority of patients in the U.S. and Europe.

A copy of the ASCO oral presentation and clinical data update from the Phase 2 company-sponsored darovasertib neoadjuvant UM trial summarized in the Corporate Presentation will be available on the Investor Relations section of the website at approximately 8:05am EST on Monday, June 3rd, 2024.

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 timing of FDA regulatory guidance, (ii) the potential therapeutic benefits of IDEAYA therapeutics, (iii) the translation of preliminary clinical trial results into future clinical trial results, and (iv) the estimate of patient populations. 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 20, 2024 and any current and periodic reports filed with the U.S. Securities and Exchange Commission.

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https://media.ideayabio.com/2024-06-03-IDEAYA-Announces-Results-for-Darovasertib-Phase-2-IST-in-Neoadjuvant-Uveal-Melanoma-at-ASCO-and-Clinical-Update-for-Phase-2-Company-Sponsored-Neoadjuvant-Study