IDEAYA Announces IDMC Recommendation of Move-Forward Dose in Part 2a of Registration-Enabling Trial of Darovasertib and Crizotinib Combination in 1L HLA-A2-Negative Metastatic Uveal Melanoma

- Independent Data Monitoring Committee (IDMC) recommends move-forward dose in Part 2a of potential registration-enabling trial in 1L HLA-A2-Negative MUM, based on clinical efficacy and safety observed
- Over 185 patients enrolled in potential registration-enabling trial in 1L HLA-A2-Negative MUM, and the darovasertib and crizotinib combination has received U.S. Food and Drug Administration (FDA) Fast Track designation in MUM

SAN FRANCISCO, Dec. 17, 2024 /PRNewswire/ -- IDEAYA Biosciences, Inc. (Nasdaq: IDYA), a precision medicine oncology company committed to the discovery and development of targeted therapeutics, today announced the Independent Data Monitoring Committee (IDMC) recommendation of a move-forward dose and the completion of the Part 2a dose optimization consistent with the U.S. Food and Drug Administration's (FDA) Project Optimus guidelines for the potential registration-enabling Phase 2/3 trial evaluating the combination of darovasertib and crizotinib in the first-line (1L) setting in patients with HLA-A2-negative (HLA-A2(-)) metastatic uveal melanoma (MUM).

"We are pleased with the recommendation of the IDMC and the selection of the move-forward dose for our potential registration-enabling trial evaluating the darovasertib and crizotinib combination in first-line HLA-A2(-) MUM patients. This allows us to complete the Part 2a portion of the study and seamlessly continue to enroll in Part 2b towards a potential accelerated approval based on the primary endpoint of median progression free survival," said Darrin M. Beaupre, M.D., Ph.D., Chief Medical Officer, IDEAYA Biosciences.

"The combination of darovasertib and crizotinib as first-line treatment has shown compelling preliminary clinical results in patients with HLA-A2(-) MUM. The IDMC recommendation of the move-forward dose supports the advancement of this potentially registration-enabling Phase 2/3 trial and is an important step in bringing a new treatment option to patients with MUM. Additionally, the continued rapid enrollment further validates the strong interest from physicians and patients, and highlights the significant unmet need in these patients, who historically have faced a poor prognosis," added Meredith McKean, M.D., MPH, Director, Melanoma and Skin Cancer Research at Sarah Cannon Research Institute, and clinical investigator on the potential registration-enabling clinical trial.

The darovasertib and crizotinib combination in MUM has FDA Fast Track designation and is currently being evaluated in two clinical trials: a potentially registration-enabling Phase 2/3 trial of darovasertib and crizotinib combination in first-line HLA-A2(-) MUM (NCT05987332) and a Phase 2 trial (NCT03947385). Additionally, darovasertib as neoadjuvant monotherapy is currently being evaluated in a Phase 2 trial in primary uveal melanoma (NCT05907954). IDEAYA is also finalizing a clinical trial protocol and is targeting to initiate a potential Phase 3 registration-enabling study for neoadjuvant uveal melanoma patients in the first half of 2025.

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 progress of the clinical development of the darovasertib and crizotinib combination in first-line HLA-A2 (-) MUM trial, (ii) the potential clinical efficacy, safety and therapeutic benefit of the darovasertib/crizotinib combination (iii) the registrational trial enrollment schedule of darovasertib/crizotinib combination in MUM (iv) the US FDA Fast Track designation and potential accelerated approval of the darovasertib/crizotinib combination in MUM; (v) the unmet need of patients with HLA-A2(-)MUM; (vi) the development progress of Phase 2 trials of darovasertib as neoadjuvant monotherapy in primary uveal melanoma; (vii) the timing of initiating a potential Phase 3 registration enabling study for neoadjuvant uveal melanoma patients in the first half of 2025. 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.

Investor and Media Contact
IDEAYA Biosciences
Andres Ruiz Briseno
SVP, Head of Finance and Investor Relations
investor@ideayabio.com

SOURCE IDEAYA Biosciences, Inc.

---

https://media.ideayabio.com/2024-12-17-IDEAYA-Announces-IDMC-Recommendation-of-Move-Forward-Dose-in-Part-2a-of-Registration-Enabling-Trial-of-Darovasertib-and-Crizotinib-Combination-in-1L-HLA-A2-Negative-Metastatic-Uveal-Melanoma