IDEAYA Expands Clinical Trial Collaboration and Supply Agreements with Pfizer to Support Registrational Trial Evaluating Darovasertib and Crizotinib Combination in First-Line Metastatic Uveal Melanoma

- Amended clinical trial collaboration and supply agreements with Pfizer to support evaluation of IDEAYA's planned Phase 2/3 registrational clinical trial to evaluate Daro + Crizo in 1L MUM
- Initiating Phase 2/3 registrational trial in Q2 2023 for darovasertib and crizotinib combination in First-Line HLA-A2 negative MUM, with median PFS as primary endpoint for potential AA

SOUTH SAN FRANCISCO, Calif., May 16, 2023 /PRNewswire/ -- IDEAYA Biosciences, Inc. (NASDAQ: IDYA), a precision medicine oncology company committed to the discovery and development of targeted therapeutics, announced that it has amended its clinical trial collaboration and supply agreements with Pfizer Inc. (NYSE: PFE) to support evaluation of darovasertib and crizotinib combination therapy in the company's planned Phase 2/3 registrational clinical trial in MUM and to continue support of the company's ongoing Phase 2 clinical trial in MUM.

"We are grateful to have Pfizer's continued support – including their clinical expertise as a collaboration partner and with respect to drug supply, as we target initiation of our Phase 2/3 registrational trial in Q2 2023 for the darovasertib and crizotinib combination in first-line HLA-A2 negative MUM, with PFS as primary endpoint for potential accelerated approval. The efficacy we observed in our Phase 2 clinical trial for first-line metastatic uveal melanoma patients suggests compelling clinical efficacy and a potential paradigm shift for treating MUM patients," said Dr. Darrin Beaupre, M.D., Ph.D., Chief Medical Officer, IDEAYA Biosciences.

IDEAYA is currently evaluating the combination of darovasertib, an investigational PKC inhibitor, and crizotinib, an investigational cMET inhibitor, in patients with metastatic uveal melanoma (MUM) in an ongoing Phase 2 clinical trial, pursuant to a clinical trial collaboration and supply agreement with Pfizer (Pfizer Agreement). IDEAYA reported updated clinical data from the ongoing Phase 2 expansion cohort which demonstrated robust clinical efficacy in first-line and any-line MUM patients with a manageable safety profile.

IDEAYA plans to initiate a potential registration-enabling Phase 2/3 clinical trial in the second quarter of 2023 to evaluate the darovasertib and crizotinib combination in first-line MUM patients under a second clinical trial collaboration and supply agreement with Pfizer (Second Pfizer Agreement). The protocol for the registrational trial includes an integrated Phase 2/3 open-label study-in-study design in first-line MUM patients with an HLA-A*02:01 (HLA-A2) negative serotype. The clinical trial design includes a Phase 2 portion (~n=200) with progression free survival (PFS) as a primary endpoint for potential accelerated approval (AA). Patients enrolled in Phase 2 will continue on treatment within the same clinical trial and will be considered together with additional enrolled patients (n=~120) to evaluate OS in support of a potential Phase 3 confirmational approval.

IDEAYA and Pfizer amended the Second Pfizer Agreement relating to the supply of crizotinib in support of IDEAYA's planned potential registration-enabling Phase 2/3 clinical trial. Pursuant to the as-amended Second

Pfizer Agreement, Pfizer will provide IDEAYA with a first defined quantity of crizotinib at no cost to the Company, as well as an additional second defined quantity of crizotinib at a lump-sum cost to IDEAYA. The Company anticipates that the supply of crizotinib under the Second Pfizer Agreement, as amended, will be sufficient to support the planned Phase 2 and Phase 3 portions of the Phase 2/3 registrational clinical trial.

Separately, IDEAYA and Pfizer also amended the Pfizer Agreement relating to the supply of crizotinib in support of IDEAYA's ongoing Phase 2 clinical trial evaluating darovasertib in combination with crizotinib in MUM patients. Pursuant to this amendment, Pfizer will continue to provide IDEAYA with an additional defined quantity of crizotinib at no cost to the Company.

Under each of the Pfizer Agreement and the Second Pfizer Agreement, IDEAYA is the sponsor of the ongoing darovasertib and crizotinib Phase 2 clinical trial and the planned Phase 2/3 registrational trial, respectively. IDEAYA and Pfizer will jointly own clinical data from the combination studies and will also jointly own inventions, if any, relating to the combined use of darovasertib and crizotinib. IDEAYA and Pfizer have formed a joint development committee responsible for coordinating all regulatory and other activities under the agreement.

IDEAYA owns or controls all commercial rights in its darovasertib program, including in MUM and in primary UM, subject to certain economic obligations pursuant to its exclusive, worldwide license to darovasertib with Novartis.

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 early research and drug discovery capabilities to precision medicine targets, including 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) timing of initiation of the darovasertib and crizotinib Phase 2/3 registrational clinical trial and (ii) the sufficiency of the supply of crizotinib for the Phase 2/3 registrational clinical trial. 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 Quarterly Report on Form 10-Q filed on May 9, 2023 and any current and periodic reports filed with the U.S. Securities and Exchange Commission.

Investor and Media Contact

IDEAYA Biosciences
Paul Stone

Senior Vice President and Chief Financial Officer

investor@ideayabio.com

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