IDEAYA Announces First-Patient-In for Phase I Clinical Trial to Evaluate Darovasertib Monotherapy in (Neo)Adjuvant Uveal Melanoma

- Investigator Sponsored Trial sites in Australia include St. Vincent's Hospital, Sydney, Alfred Health, Melbourne, and the Royal Victorian Eye and Ear Hospital, Melbourne

- Preliminary signals of clinical activity observed in the primary uvea, including tumor shrinkage following neoadjuvant darovasertib monotherapy treatment

- (Neo)adjuvant UM represents an unmet medical need and potential clinical expansion opportunity with annual incidence of approximately 8,700 patients in the US and EU

- Clinical proof-of-concept data for use in (neo)adjuvant UM setting will be presented with the interim darovasertib Phase 2 clinical data update in MUM in September 2022

SOUTH SAN FRANCISCO, Calif., Sept. 6, 2022 /PRNewswire/ -- IDEAYA Biosciences, Inc. (Nasdaq: IDYA), a synthetic lethality focused precision medicine oncology company committed to the discovery and development of targeted therapeutics, announced that it has initiated an Investigator Sponsored Trial, or IST, in coordination with St. Vincent's Hospital, Sydney, to evaluate darovasertib as monotherapy in neo-adjuvant and adjuvant settings in primary, non-metastatic uveal melanoma (UM) patients.

The study, captioned as "Neoadjuvant / Adjuvant trial of Darovasertib in Ocular Melanoma" (NADOM), is being led by principal investigator Professor Anthony Joshua, MBBS, PhD, FRACP, Head Department of Medical Oncology, Kinghorn Cancer Centre, St. Vincent's Hospital in Sydney with participating sites of Alfred Health and the Royal Victorian Eye and Ear Hospital in Melbourne. Pursuant to the protocol, the NADOM study will evaluate darovasertib as monotherapy in eligible adult patients having ocular melanoma to determine the feasibility and tolerability of (neo)adjuvant treatment.

"We are excited to be leading this ground-breaking clinical study treating patients with darovasertib in the neo-adjuvant and adjuvant settings. The concept for this study originated from anecdotal observations in a MUM patient treated with darovasertib who also had an intact primary lesion in the eye, where a reduction in the eye lesion was observed at an initial scan with improvement in visual symptoms," said Professor Anthony Joshua, MBBS, PhD, FRACP, Head Department of Medical Oncology, Kinghorn Cancer Centre, St. Vincent's Hospital Sydney.

"We are observing an early signal of clinical activity in the first patient enrolled in the NADOM study," said Professor Mark Shackleton MBBS, PhD, FRACP, Director of Oncology at Alfred Health and Professor of Oncology, Monash University. "Our coordinated patient care with eye specialists at the Royal Victorian Eye and Ear Hospital on this trial has enabled a potential paradigm-shifting approach to reduce the size of ocular tumors prior to primary treatment, which we hope will lead to better outcomes for patients," continued Professor Shackleton.

"There are currently limited treatment options for patients with uveal melanoma in the pre-metastatic setting. We are pleased to be collaborating with St. Vincent's Hospital in Sydney and with Alfred Health and Royal Victorian Eye and Ear Hospital in Melbourne to explore the potential for darovasertib monotherapy to be impactful for patients with primary uveal melanoma," said Dr. Matthew Maurer, M.D., Vice President, Head of Clinical Oncology and Medical Affairs, IDEAYA Biosciences.

Uveal melanoma is a rare, lethal form of melanoma that arises from melanocytes of the iris, the ciliary body, or

most commonly the choroid, with an annual potential incidence of approximately 8,700 patients aggregate in US and Europe. Current approaches for treatment of primary UM includes radiotherapy (plaque brachytherapy or stereotactic radiosurgery) and, for larger tumors, enucleation of the eye, with consequential patient impact including reduced vision, decreased depth perception, diminished social functioning and unsatisfactory cosmesis.

Darovasertib (IDE196) is a potent, selective small molecule inhibitor of protein kinase C (PKC). Mutations in GNAQ or GNA11 (GNAQ/11) have been identified in approximately 90% of patients with metastatic UM. These mutations are associated with activation of signaling pathways, including oncogenic RAS/RAF/MEK/ERK via Protein Kinase C (PKC) activation, driving tumor progression. In April 2022, the FDA designated darovasertib as an Orphan Drug in Uveal Melanoma.

In addition to supporting the NADOM study with St. Vincent's Hospital Sydney, IDEAYA is also evaluating the synthetic lethal combination of darovasertib and crizotinib, a small molecule cMET inhibitor, in metastatic uveal melanoma (MUM) in an ongoing Phase 2 clinical trial pursuant to a clinical trial collaboration and drug supply agreement with Pfizer.

IDEAYA is targeting interim Phase 2 clinical results for darovasertib and crizotinib synthetic lethal combination in first-line and any-line MUM patients in September 2022, including clinical efficacy in MUM (e.g., confirmed overall response rate by RECIST, median progression-free survival, median duration of response) and an adverse event summary. The company will also present data supporting clinical proof of concept for potential use of darovasertib in primary (neo)adjuvant UM.

About IDEAYA Biosciences
IDEAYA is a synthetic lethality focused 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 of darovasertib as a treatment for (neo)adjuvant uveal melanoma and (ii) the timing and content of an additional clinical data update for darovasertib, including the darovasertib and crizotinib combination and the use of darovasertib in primary (neo)adjuvant 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, the effects on IDEAYA's business of the worldwide COVID-19 pandemic, the ongoing military conflict between Russia and Ukraine, 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 recent Quarterly Report on Form 10-Q filed on August 15, 2022 and any current and periodic reports filed with the U.S. Securities and Exchange Commission.

SOURCE IDEAYA Biosciences, Inc.

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