IDEAYA Announces First Reported Case of Uveal Melanoma Patient Spared Enucleation in Phase 1 Neoadjuvant IST with Darovasertib Monotherapy

- Eye preservation reported for the first UM patient treated with darovasertib monotherapy under the amended IST protocol enabling neoadjuvant treatment up to 6 months
- Patient experience shared in an exclusive news report by medical reporterGabriella Rogers of Television 9 News Channel station in Sydney, Australia on June 21, 2023
- Multiple additional UM patients enrolled in enucleation cohort of Phase 1 IST inAustralia, led by clinical investigator Professor Anthony Joshua
- Clinical sites being activated globally for IDEAYA-sponsored Phase 2 study evaluating darovasertib monotherapy as neoadjuvant and adjuvant therapy in UM

SOUTH SAN FRANCISCO, Calif., June 22, 2023 /PRNewswire/ -- IDEAYA Biosciences, Inc. (Nasdaq:IDYA), a precision medicine oncology company committed to the discovery and development of targeted therapeutics, announced a first reported case of a uveal melanoma (UM) patient who was treated with single agent darovasertib as neoadjuvant therapy and was spared enucleation in an Investigator Sponsored Trial (IST).

"We are very excited to explore the potential of darovasertib as neoadjuvant and adjuvant therapy for patients with ocular melanoma. This case suggests that treatment with darovasertib as monotherapy can preserve the eye and may have vision-sparing utility as well as quality of life benefits," said Professor Anthony Joshua, MBBS, PhD, FRACP, Head Department of Medical Oncology, Kinghorn Cancer Centre, St. Vincent's Hospital in Sydney, a principal investigator in the IST. The IST, captioned as "Neoadjuvant / Adjuvant trial of Darovasertib in Ocular Melanoma" (NADOM), also includes participating sites of Alfred Health and the Royal Victorian Eye and Ear Hospital in Melbourne.

"Avoiding enucleations with darovasertib is a very promising development in the field of ocular oncology. We are looking forward to further research and trials using this approach," said Dr. William Glasson, MBBS, FRANZCO, Terrace Eye Center, Brisbane, Australia, who was the treating ophthalmologist for the first reported case of spared enucleation on darovasertib monotherapy.

In the reported case, the UM patient observed a 24% reduction in tumor size following four months of neoadjuvant treatment with darovasertib as monotherapy. The reduction in tumor size enabled plaque brachytherapy as a primary interventional treatment rather than originally planned enucleation. This UM patient shared his experience in an exclusive interview and report by medical reporter Gabriella Rogers of Television 9 News Channel station inSydney Australia on June 21, 2023. See link: https://www.9news.com.au/national/eye-cancer-melanoma-drug-trial-darovasertib-st-vincents-hospital/da15cb33-47fc-4ce8-b1ef-247e1327c6a3.

The eye preservation was observed in the first UM patient treated under the amended protocol of the NADOM study. Pursuant to the protocol, uveal melanoma patients who would otherwise undergo enucleation are instead treated with single agent darovasertib as neoadjuvant treatment for up to six months or maximum benefit – reflecting an increase in potential treatment duration versus the initial approach of one month neoadjuvant therapy. Multiple additional UM patients are also enrolled in the

Phase 1 NADOM study under the amended protocol.

IDEAYA is initiating clinical sites to support a company-sponsored Phase 2 clinical trial, designated as IDE196-009 (NCT05907954), to evaluate darovasertib as monotherapy in (neo)adjuvant uveal melanoma with potential near-term clinical endpoints such as organ preservation (avoiding enucleation) for large ocular tumors and reduction in radiation dose and/or vision preservation for small or medium ocular tumors. The Phase 2 clinical trial plans to enroll patients in U.S., Europe and Australia.

IDEAYA previously reported preliminary clinical activity observed in primary uveal melanoma, including tumor shrinkage in 9 of 9 patients following therapy with darovasertib as monotherapy or in combination with crizotinib, and an initial reported patient who was spared an enucleation following neoadjuvant treatment with the combination under a compassionate use protocol.

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 and an estimated prevalence of ~100,000 patients aggregate in the U.S. and Europe. UM has no approved systemic neoadjuvant or adjuvant therapies. 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). The FDA has designated darovasertib as an Orphan Drug in Uveal Melanoma, including primary and metastatic disease under 21 C.F.R Part 316. IDEAYA owns or controls all commercial rights in darovasertib in UM, subject to certain economic obligations pursuant to its exclusive, worldwide license 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 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 therapeutic benefits of darovasertib and (ii) the enrollment of study subjects in certain geographies. 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.

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https://media.ideayabio.com/2023-06-22-IDEAYA-Announces-First-Reported-Case-of-Uveal-Melanoma-Patient-Spared-Enucleation-in-Phase-1-Neoadjuvant-IST-with-Darovasertib-Monotherapy