IDEAYA Biosciences Receives Orphan Drug Designation for Darovasertib, a PKC Inhibitor, for the Treatment of Uveal Melanoma

- Darovasertib designated as an Orphan Drug by the U.S. FDA, entitling IDEAYA to certain tax credits, exemption from user fees, and potential statutory marketing exclusivity

- Targeting a clinical data update for darovasertib and crizotinib combination and FDA regulatory guidance for a potential registration-enabling trial design in mid-2022

SOUTH SAN FRANCISCO, Calif., May 2, 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 the U.S. Food and Drug Administration (FDA) has granted orphan-drug designation to darovasertib, a potential first-in-class protein kinase C (PKC) inhibitor, for the treatment of uveal melanoma.

IDEAYA is currently evaluating the synthetic lethal combination of darovasertib, a PKC inhibitor, and crizotinib, a cMET inhibitor, in patients with metastatic uveal melanoma (MUM) and in patients with GNAQ or GNA11 mutant solid tumors, in an ongoing Phase 1/2 clinical trial (NCT03947385) pursuant to a clinical trial collaboration and supply agreement with Pfizer.

"We are excited to advance darovasertib towards a potential registration-enabling trial in metastatic uveal melanoma, and the orphan-drug designation is an important step towards our goal to bring this novel therapy to patients," said Matthew Maurer, M.D., Vice President, Head of Clinical Oncology and Medical Affairs, at IDEAYA Biosciences.

Orphan-drug designation (ODD) is granted by the FDA to a drug or biologic intended to treat a rare disease or condition, which generally includes a disease or condition that affects fewer than 200,000 individuals in the U.S. Under the ODD, IDEAYA may be entitled to certain tax credits, exemption from user fees, and seven years of statutory marketing exclusivity, subject to FDA approval of a marketing application for darovasertib as a designated orphan-drug product.

As of May 1, 2022, Darovasertib has been evaluated in over 200 patients, including 74 patients in combination with crizotinib. The company is targeting a clinical data update for darovasertib and crizotinib combination in mid-2022, including tolerability and clinical efficacy. IDEAYA is also planning to seek FDA regulatory guidance for a potential registration-enabling trial design to evaluate the darovasertib and crizotinib combination in MUM in mid-2022. IDEAYA is preclinically evaluating potential expansion opportunities for darovasertib in other oncology indications, including in additional cMET-driven tumors, such as hepatocellular carcinoma and non-small cell lung cancer, and in KRAS G12C non-small cell lung cancer.

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 early 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 and content of an additional clinical data update for the darovasertib and crizotinib combination and (ii)the timing of obtaining FDA guidance for potential registration-enabling trial design to evaluate the darovasertib and crizotinib combination. 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 filed on March 18, 2022, and any current and periodic reports filed with the U.S. Securities and Exchange Commission.

SOURCE IDEAYA Biosciences, Inc.

For further information: Investor and Media Contact: IDEAYA Biosciences, Paul Stone, Senior Vice President and Chief Financial Officer, investor@ideayabio.com

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