IDEAYA and Pfizer Expand Clinical Trial Collaboration and Supply Agreements for Evaluation of Darovasertib and Crizotinib Combination in Metastatic Uveal Melanoma and Additional cMET-Driven Tumors

SOUTH SAN FRANCISCO, Calif., March 14, 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 entered into additional clinical trial collaboration and supply agreements with Pfizer Inc. (NYSE: PFE) to support further evaluation of darovasertib and crizotinib combination therapy in a Phase 2 potential registration-enabling clinical trial in patients with metastatic uveal melanoma (MUM) and in a Phase 1 clinical trial in patients with cMET-driven tumors, such as hepatocellular carcinoma (HCC) and/or non-small cell lung cancer (NSCLC).

IDEAYA is currently evaluating the 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 skin melanoma in an ongoing Phase 1/2 clinical trial, pursuant to a clinical trial collaboration and supply agreement with Pfizer.

"We are pleased to have Pfizer's support in connection with a potential registrational clinical trial as our clinical data on the darovasertib / crizotinib combination in MUM continues to mature. Our preliminary clinical data on the darovasertib and crizotinib combination in MUM, reported in December 2021, showed robust clinical activity with a manageable side effect profile. We have an opportunity to positively impact the treatment of patients in this high unmet medical need population," said Dr. Matthew Maurer, M.D., Vice President and Head of Clinical Oncology and Medical Affairs at IDEAYA Biosciences.

"The clinical efficacy of the combination therapy in MUM patients provides proof of concept for potential expansion opportunities in other cMET-driven tumors. We believe that the darovasertib and crizotinib combination therapy can potentially improve on current standard of care treatment paradigms, for example in HCC, where response rates are modest," added Michael White, Ph.D., Senior Vice President and Chief Scientific Officer at IDEAYA Biosciences.

IDEAYA is targeting a clinical data update for its Phase 1/2 clinical trial evaluating the darovasertib and crizotinib combination in MUM in mid-year 2022, including tolerability and clinical efficacy. IDEAYA is also planning to seek FDA regulatory guidance for potential registration-enabling trial design to evaluate darovasertib and crizotinib combination in MUM in mid-year 2022. The timing of the clinical data and FDA regulatory guidance may be influenced by data maturity, including for example, appropriate interim assessments of supportive median duration of response (DoR) and/or median progression free survival (mPFS).

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 potential impact of the darovasertib and crizotinib combination, (ii) the timing and content of a clinical data update for the darovasertib and crizotinib combination, and (iii) the timing of seeking 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 Quarterly Report on Form 10-Q filed on November 15, 2021, and any current and periodic reports filed with the U.S. Securities and Exchange Commission.

SOURCE IDEAYA Biosciences, Inc.

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