IDEAYA Biosciences Receives Fast Track Designation for Darovasertib Combination Therapy with Crizotinib for the Treatment of Metastatic Uveal Melanoma

- Fast Track designation granted by U.S. FDA for evaluation of darovasertib in combination with crizotinib in adult patients being treated for metastatic uveal melanoma (MUM)
- Enables darovasertib / crizotinib development program to access expedited regulatory review processes, including potential eligibility for accelerated approval / priority review

SOUTH SAN FRANCISCO, Calif., Dec. 5, 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 Fast Track designation to IDEAYA's development program investigating darovasertib, a potential first-in-class protein kinase C (PKC) inhibitor, for use in combination with crizotinib, an investigational cMET inhibitor, for the treatment of adult patients with metastatic uveal melanoma.

"We are extremely pleased to receive the U.S. FDA Fast Track designation as we prepare to initiate a potential Phase 2/3 registrational trial to evaluate the darovasertib and crizotinib combination in patients with MUM. The Fast Track designation acknowledges MUM as a serious condition and the potential for the darovasertib / crizotinib combination to treat this unmet medical need," said Dr. Darrin Beaupre, Senior Vice President and Chief Medical Officer at IDEAYA Biosciences.

Fast Track is a U.S. FDA process designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need. Under the Fast Track designation, the darovasertib / crizotinib development program in MUM is eligible for various expedited regulatory review processes, including generally more frequent FDA interactions (e.g., meetings, written communications), potential eligibility for rolling review of a New Drug Application (NDA) and potential accelerated approval and priority review of an NDA.

Darovasertib was previously also designated as an Orphan Drug by the U.S. FDA in Uveal Melanoma (UM), including in MUM, entitling IDEAYA to certain potential tax credits, exemptions from user fees, and statutory marketing exclusivity.

IDEAYA is targeting initiation of a potential registration-enabling trial for the darovasertib and crizotinib combination in MUM in Q1 2023, subject to FDA feedback and guidance.

IDEAYA is also planning to initiate a company-sponsored Phase 1 clinical trial in Q4 2022 to evaluate darovasertib monotherapy in neoadjuvant UM patients. The preliminary development approach contemplates clinical endpoints such as organ preservation and/or vision preservation proximal to primary interventional treatments. Additional information on the company's plans to evaluate darovasertib, including scientific insights and clinical development opportunities in the neoadjuvant setting, will be highlighted in an Investor R&D Day webcast being hosted by IDEAYA on December 12, 2022, at 8:00 am - 9:30 am ET. Registration is available at https://ir.ideayabio.com/events or https://lifescievents.com/event/ideaya-rd-day/.

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 of initiating a potential registration-enabling trial for the darovasertib and crizotinib combination in MUM, (ii) the timing of initiating a company-sponsored Phase 1 clinical trial to evaluate darovasertib monotherapy in neoadjuvant UM patients, and (iii) the timing and content of IDEAYA's Investor R&D Day webcast. 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 8, 2022, 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

SOURCE IDEAYA Biosciences, Inc.

---

https://media.ideayabio.com/2022-12-05-IDEAYA-Biosciences-Receives-Fast-Track-Designation-for-Darovasertib-Combination-Therapy-with-Crizotinib-for-the-Treatment-of-Metastatic-Uveal-Melanoma?elqTrack=true&elqTrackId=7f289b631a9d4b1bb2a060f8388583b6