IDEAYA Biosciences Announces Submission of IND Application to the U.S. FDA for PARG Development Candidate IDE161

- IDE161 is being developed as a potential first-in-class PARG inhibitor for patients having tumors with HRD, with an initial focus in BRCA1/2-mutant Breast and Ovarian Cancer

- Proposed clinical development plan for IDE161 to be highlighted in Investor R&D Day webcast being hosted by IDEAYA today, December 12, 2022, at 8:00 am ET

SOUTH SAN FRANCISCO, Calif., Dec. 12, 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 it has submitted an Investigational New Drug (IND) application with the U.S. Food and Drug Administration (FDA) for initiation of a Phase 1/2 clinical trial to evaluate IDE161, a small molecule inhibitor of poly (ADP-ribose) glycohydrolase (PARG), for the treatment of patients having solid tumors with homologous recombination deficiency (HRD).

"IDE161 has an attractive preclinical profile, including single-agent tumor regressions in PARP inhibitor-resistant BRCA1/2 xenograft models, and a favorable preliminary preclinical myelosuppression safety profile relative to certain approved PARP inhibitors. The IND submission for IDE161 is a significant milestone for IDEAYA and reflects our unique platform capabilities in synthetic lethality for target and biomarker identification, and drug discovery," said Michael White, Ph.D., Senior Vice President and Chief Scientific Officer, IDEAYA Biosciences.

"There remains a significant unmet medical need for patients having tumors with homologous recombination deficiencies, such as BRCA1/2, and IDE161 has a potential opportunity for clinical differentiation in patients who are non-responsive to PARP inhibitors or to platinum-based treatments," said Dr. Darrin M. Beaupre, M.D., Ph.D., Senior Vice President and Chief Medical Officer, IDEAYA Biosciences.

IDE161 is a potent, selective, potential first-in-class small-molecule inhibitor of PARG, a novel and differentiated target in the same clinically validated pathway as poly (ADP-ribose) polymerase (PARP). Subject to effectiveness of the IND following FDA review, IDEAYA plans to evaluate the safety, tolerability, pharmacokinetic and pharmacodynamic properties and preliminary efficacy of IDE161 as monotherapy in BRCA1/2-mutant breast and ovarian cancer patients.

IDEAYA owns or controls all commercial rights in IDE161, subject to certain economic obligations pursuant to its exclusive, worldwide license with Cancer Research UK and University of Manchester.

Additional information on IDE161, including scientific insights and clinical development opportunities, will be highlighted in an Investor R&D Day webcast being hosted by IDEAYA this morning, 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 and content of the Investor R&D Day webcast, (ii) potential clinical differentiation of IDE161, and (iii) the clinical development plan for IDE161. 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.

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