IDEAYA Announces IND Clearance by U.S. FDA enabling Phase 1 Initiation for First-in-Class PARG Development Candidate IDE161

- Targeting to initiate dosing of Phase 1 clinical trial in Q1 2023 to evaluate IDE161 in patients having tumors with HRD, including BRCA1/2-mutant breast and ovarian cancer

- Starting dose of IDE161 in the Phase 1 dose escalation is one-half of the projected human efficacious dose, based on preclinical studies

- IDE161 monotherapy clinical focus includes ER+ / Her2- breast cancer with HRD, representing approximately 10% to 14% of breast cancer

- IDE161 preclinical profile and clinical development plans to be highlighted by IDEAYA at J.P. Morgan Healthcare Conference on Tuesday, January 10th, 2023, at 4:30 pm PT

SOUTH SAN FRANCISCO, Calif., Jan. 9, 2023 /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 completed its safety review of the Investigational New Drug (IND) application and concluded that IDEAYA's proposed clinical study may proceed to evaluate IDE161 in solid tumors.

"We are pleased to be able to clinically evaluate IDE161 as a potential first-in-class treatment for patients having tumors with homologous recombination deficiencies, such as breast and ovarian cancer patients with BRCA1 or BRCA2 mutations. IDE161 has an attractive preclinical profile, including single-agent tumor regressions in HRD models refractory to PARP inhibitors. Preclinical toxicology data supports a Phase 1 starting dose that is one-half of the estimated human efficacious dose, which we believe may enable a therapeutic dose in earlier cohorts of the dose escalation," said Dr. Darrin M. Beaupre, M.D., Ph.D., Senior Vice President and Chief Medical Officer, IDEAYA Biosciences.

"IDE161 represents our third potential first-in-class clinical stage precision medicine oncology program and provides further validation of our industry leading Synthetic Lethality platform. We look forward to evaluating IDE161's monotherapy activity in the HRD and BRCA1/2 biomarker settings in multiple solid tumors, with a strategic focus in breast cancer," said Yujiro S. Hata, President and Chief Executive Officer, IDEAYA Biosciences.

IDE161 is a potent, selective, small-molecule inhibitor of PARG, a novel and differentiated target in the same clinically validated pathway as poly (ADP-ribose) polymerase (PARP). IDEAYA plans to initiate dosing in a Phase 1 clinical trial in Q1 2023 to evaluate the safety, tolerability, pharmacokinetic and pharmacodynamic properties and preliminary efficacy of IDE161 as monotherapy in patients having tumors with homologous recombination deficiency (HRD), such as BRCA1/2-mutant breast and ovarian cancer patients.

A key clinical focus will include breast cancer patients having tumors with HRD which are estrogen receptor

positive (ER+) and human epidermal growth factor receptor 2 negative (Her2-). This patient population represents approximately 10% to 14% of breast cancer patients: ER+ / Her2− subtype occurs in ~68% of breast cancer patients, based on analysis of SEER (Surveillance, Epidemiology and End Results) database and ~14% to ~20% of ER+ / Her2− breast cancer patients may be HRD, based on analyses of Pan-Cancer Analysis of Whole Genomes (PCAWG) data.

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

Additional information on IDE161, including its preclinical profile and clinical development opportunities, will be highlighted in a company presentation at the 41st Annual J.P. Morgan Healthcare Conference on Tuesday, January 10th, 2023, at 4:30 pm PT / 7:30 pm ET. An updated corporate presentation is available on IDEAYA's website at https://ir.ideayabio.com.

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) timing for the initiation of the Phase 1 clinical trial to evaluate IDE161, (ii) the biomarker settings to be evaluated in the IDE161 Phase 1 clinical trial, (iii) the potential enablement of a therapeutic dose in earlier cohorts of the dose escalation, and (iv) participation in and/or presentation at and content to be presented at certain investor relations events. 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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