IDEAYA Receives Fast Track Designation for Potential First-in-Class PARG Inhibitor, IDE161, for Treatment of Pretreated, Platinum-Resistant Advanced or Metastatic Ovarian Cancer Patients having tumors with BRCA1/2 Mutations

- Fast Track designation granted by U.S. FDA for evaluation of IDE161 in adult patients with BRCA1/2 mutant advanced or metastatic ovarian cancer who are platinum resistant and have received prior antiangiogenic and PARP inhibitor therapies
- Enables IDE161 development program to access expedited regulatory review processes, including potential eligibility for accelerated approval / priority review
- Ongoing Phase 1 expansion, with focus in ER+, Her2(-), HRD+ breast cancer, HRD+ ovarian cancer and other HRD+ solid tumors, including endometrial and colon cancer

SOUTH SAN FRANCISCO, Calif., Sept. 26, 2023 /PRNewswire/ -- IDEAYA Biosciences, Inc. (NASDAQ: IDYA), a precision medicine oncology company committed to the discovery and development of targeted therapeutics, announces that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to IDEAYA's development program investigating IDE161, a potent and selective inhibitor of poly (ADP-ribose) glycohydrolase (PARG), for the treatment of adult patients having advanced or metastatic ovarian cancer with germline or somatic BRCA 1/2 mutations who are platinum resistant and have received prior antiangiogenic and poly (ADP-ribose) polymerase (PARP) inhibitor therapies.

"We are extremely pleased to receive the U.S. FDA Fast Track designation for IDE161 based on the FDA's review of preclinical and emerging clinical efficacy and tolerability data. We recently reported preliminary clinical proof-of-concept with expansion into priority HRD+ solid tumor indications in our Phase 1 clinical trial. The Fast Track designation has been provided for platinum-resistant BRCA1/2 mutant advanced or metastatic ovarian cancer, which represents a serious condition, and acknowledges the potential for IDE161 to treat this indication," said Dr. Darrin Beaupre, 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 IDE161 development program in BRCA1/2m ovarian cancer, as specified in the Fast Track designation, 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.

IDEAYA's Phase 1 first-in-human clinical trial is evaluating the safety, tolerability, pharmacokinetic and pharmacodynamic properties and preliminary efficacy of IDE161 in patients having solid tumors with homologous recombination deficiency (HRD). Early clinical data from the dose escalation cohorts showed preliminary tumor shrinkage in multiple patients having solid tumors with HRD, including a BRCA 1/2m endometrial cancer subject. These data supported expansion into priority tumor indications in parallel with continuing evaluation of the optimal move-forward dose for Phase 2 expansion.

The expansion portion of the Phase 1 trial will include patients having HRD+ associated breast cancer and ovarian cancer, as well as a basket of other selected solid tumors. The breast cancer focus is on estrogen receptor positive (ER+), human epidermal growth factor receptor 2 negative (Her2-) tumors with HRD, which represent approximately 10% to 14% of breast cancer patients. Ovarian cancer tumors with HRD represent approximately 50% of ovarian cancer patients.

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.

About IDEAYA Biosciences

IDEAYA is a 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 therapeutic benefit of IDE161 and (ii) the prevalence of tumors with HRD. 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 August 10, 2023, and any current and periodic reports filed with the U.S. Securities and Exchange Commission.

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