IDEAYA Biosciences Announces IND-Clearance for Werner Helicase Development Candidate IDE275 (GSK959) for a Phase 1 Study in MSI-High Solid Tumors

- IDE275 (GSK959) development is progressing into First-in-Human Phase 1 clinical trial(s) for the treatment of MSI-High solid tumors, representing IDEAYA's 5th potential first-in-class clinical program
- MSI-High prevalence in endometrial, colorectal, and gastric cancers is ~31%, 20%, and 19%, respectively, highlighting the market potential of IDE275 (GSK959)
- IDEAYA to receive a $7 million payment for IND acceptance, and potential future aggregate milestones of up to $950 million. IDEAYA has a 50/50 US Profit Share and an 80/20 (GSK/IDEAYA) global research and development cost share

SOUTH SAN FRANCISCO, Calif., Oct. 28, 2024 /PRNewswire/ -- IDEAYA Biosciences, Inc. (Nasdaq:IDYA), a precision medicine oncology company committed to the discovery and development of targeted therapeutics, announced the clearance of an investigational new drug (IND) application with the U.S. Food and Drug Administration (FDA) for the initiation of a Phase 1 clinical trial to evaluate IDE275 (GSK959), a potential first-in-class and best-in-class Werner Helicase (WRN) inhibitor. IDE275 (GSK959) has demonstrated robust and selective synthetic lethality preclinically in the high microsatellite instability (MSI-High) biomarker setting, and the Phase 1 clinical trial will enroll patients having tumors characterized by MSI-High.

"IDE275 represents IDEAYA's fifth potential first-in-class clinical program in our precision medicine oncology pipeline and has a potentially differentiated best-in-class profile that we are targeting to present at a future medical conference with GSK. The robust preclinical efficacy observed by IDE275 selectively in the MSH-High biomarker setting, including monotherapy regressions, provides a double-digit % prevalence target patient population across several major solid tumor types, including endometrial, colorectal and gastric cancer," added Yujiro S. Hata, President and Chief Executive Officer, IDEAYA Biosciences.

IDE275 (GSK959) is a potential first-in-class small molecule inhibitor of Werner Helicase that was discovered by IDEAYA in collaboration with GSK. In preclinical studies, IDE275 has demonstrated robust and selective synthetic lethality in the MSI-High biomarker setting, including single-agent tumor regressions *in-vivo* in MSI-High CDX and PDX models derived from colorectal, endometrial and gastric cancers. Initiation of the Phase 1 trial for IDE275 is projected in the fourth quarter of 2024. GSK is the sponsor of the IND application and plans to develop IDE275 (GSK959) as both a monotherapy agent and in combination with a PD-1 inhibitor in a Phase 1 clinical trial for patients having MSI-High tumors. The percent prevalence of MSI-High in solid tumors, including endometrial, colorectal, and gastric cancers, has been reported at approximately 31%, 20%, and 19%, respectively (JCO Precision Oncology, September 2017).

GSK is responsible for 80% of global research and development costs for IDE275 (GSK959) and IDEAYA is responsible for 20% of such costs. IDEAYA is eligible to receive a $7 million milestone payment upon acceptance of the IND by the U.S. Food and Drug Administration (FDA), and a potential additional $10 million milestone payment upon initiation of Phase 1 clinical dose expansion. IDEAYA may potentially also receive up to $465 million in further later-stage development and regulatory milestones. Upon potential commercialization, IDEAYA will be eligible to receive up to $475 million of commercial milestones 50% of U.S. net profits and tiered royalties on global non-U.S. net sales of IDE275 (GSK959) – ranging from high single-digit to sub-teen double-digit percentages, subject to certain customary reductions.

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 research and drug discovery capabilities to synthetic lethality – which represents an emerging class of precision medicine targets. IDEAYA's updated corporate presentation is available on its website, at its Investor Relations page: https://ir.ideayabio.com/.

Forward-Looking Statements

This press release contains forward-looking statements, including, but not limited to, statements related to (i) expectations regarding the clinical activity profile and potential advantages of IDEAYA's clinical programs, (ii) the initiation of a Phase 1 clinical trial to evaluate IDE275 (GSK959) and (iii) the receipt of development and regulatory milestones . Such forward-looking statements involve substantial risks and uncertainties that could cause IDEAYA's preclinical and clinical development programs, future results, performance or achievements to differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, the uncertainties inherent in the drug development process, including IDEAYA's programs' early stage of development, the process of designing and conducting preclinical and clinical trials, the regulatory approval processes, the timing of regulatory filings, the challenges associated with manufacturing drug products, IDEAYA's ability to successfully establish, protect and defend its intellectual property, and other matters that could affect the sufficiency of existing cash to fund operations. 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 Annual Report on Form 10-K dated February 20, 2024 and any current and periodic reports filed with the U.S. Securities and Exchange Commission.

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