IDEAYA Announces Achievement of First Milestone in Ongoing Collaboration with GSK for Potential First-in-Class Pol Theta Helicase Inhibitor Development Candidate

- Preclinical development milestone achieved in connection with ongoing IND-enabling studies to support evaluation of Pol Theta Helicase Inhibitor DC as combo with niraparib
- Potential to realize preclinical and clinical milestones up to $20 million total for preclinical to early Phase 1 clinical, including up to $10 million aggregate through IND effectiveness
- Targeting first-in-human clinical evaluation of Pol Theta Helicase Inhibitor DC in combination with niraparib in H1 2023 for patients having tumors with HRD

SOUTH SAN FRANCISCO, Calif. , Aug. 29, 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 it has achieved a preclinical development milestone in connection with ongoing IND-enabling studies for its Pol Theta Helicase Development Candidate (DC).

"We are excited to advance our Pol Theta Helicase Inhibitor DC toward the clinic. The achievement of this preclinical milestone supplements our balance sheet and reflects the continued progress IDEAYA and GSK are making to enable first-in-human studies with this development candidate in the first half of next year," said Michael White, Senior Vice President and Chief Scientific Officer of IDEAYA Biosciences.

The Pol Theta Helicase Inhibitor DC is a potential first-in-class small molecule inhibitor of the helicase domain of DNA Polymerase Theta. IDEAYA is collaborating with GSK on IND-enabling studies to support the evaluation of the Pol Theta Helicase DC in combination with niraparib, GSK's PARP inhibitor, for patients harboring tumors with BRCA or other homologous recombination (HR) mutations or homologous recombination deficiency (HRD).

IDEAYA and GSK are targeting an IND submission for the Pol Theta Helicase DC, subject to satisfactory completion of ongoing IND-enabling studies, to enable first-in-human studies in the first half of 2023.

GSK will lead clinical development for the Pol Theta program pursuant to its global, exclusive license to develop and commercialize the Pol Theta Helicase Inhibitor DC. GSK is responsible for all research and development costs for the program. IDEAYA is eligible to receive total development and regulatory milestones of up to $485 million aggregate, inclusive of preclinical and clinical milestones of up to $20 million aggregate for advancing the Pol Theta Helicase DC through early Phase 1 clinical.

Upon potential commercialization, IDEAYA will be eligible to receive up to $475 million of commercial milestones and tiered royalties on global net sales by GSK, its affiliates and their sublicensees ranging from high single digit to sub-teen double digit percentages, subject to certain customary reductions.

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 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 IND submission and first-in-human clinical evaluation of Pol Theta Helicase DC combination with niraparib and (ii) the potential achievement of and/or receipt of future GSK milestone payments. 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, the effects on IDEAYA's business of the worldwide COVID-19 pandemic, the ongoing military conflict between Russia and Ukraine, 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 recent Quarterly Report on Form 10-Q filed on August 15, 2022 and any current and periodic reports filed with the U.S. Securities and Exchange Commission.

SOURCE IDEAYA Biosciences, Inc.

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https://media.ideayabio.com/2022-08-29-IDEAYA-Announces-Achievement-of-First-Milestone-in-Ongoing-Collaboration-with-GSK-for-Potential-First-in-Class-Pol-Theta-Helicase-Inhibitor-Development-Candidate