IDEAYA Biosciences Announces Development Candidate Nomination of a Werner Helicase Inhibitor in Collaboration with GSK and Investor R&D Day

- Selected a Werner Helicase Inhibitor Development Candidate in collaboration with GSK
- Observed monotherapy complete responses preclinically in multiple *in vivo* xenograft MSI-High models and pharmacological sensitivity in therapy-refractory CRC organoid models
- Earned $3 million milestone from GSK in connection with IND-enabling studies with potential for up to an additional $17 million aggregate milestones through early Phase 1
- Targeting an IND in 2024 to enable first-in-human clinical evaluation of Werner Helicase Inhibitor Development Candidate for patients having tumors with MSI-High
- Subject to IND submission and clearance, GSK will lead clinical development and the global research and development costs will be shared between GSK (80%) and IDEAYA (20%)
- IDEAYA will be eligible to receive additional development milestones of up to $465.0 million and commercial milestones of up to $475.0 million and 50% of U.S. net profits
- IDEAYA is hosting an Investor R&D Day in Q4 2023, with participation of GSK

SOUTH SAN FRANCISCO, Calif., Oct. 9, 2023 /PRNewswire/ -- IDEAYA Biosciences, Inc. (Nasdaq:IDYA), a precision medicine oncology company committed to the discovery and development of targeted therapeutics, announces selection of a Werner Helicase Inhibitor Development Candidate (DC) and Investor R&D Day.

The Werner Helicase Inhibitor DC is a potent, selective, small molecule inhibitor of the helicase domain of Werner protein. IDEAYA is collaborating with GSK on IND-enabling studies to support the clinical evaluation of the Werner Helicase Inhibitor DC for patients having tumors characterized by high microsatellite instability (MSI-High). There is high prevalence of MSI-High across multiple solid tumor indications, including endometrial, colorectal, and gastric cancers (approximately 31%, 20%, and 19%, respectively), among others.

"Our Werner Helicase Inhibitor DC has demonstrated robust *in vivo* efficacy in multiple MSI-High cancer models. We are excited to advance the Werner Helicase Inhibitor DC into IND-enabling studies to support potential clinical evaluation in MSI-High solid tumors with monotherapy and potentially also with combination therapies," said Benjamin Schwartz, Ph.D., Vice President, Head of Oncology Synthetic Lethality Research Unit at GSK.

"Werner Helicase is one of the most well-validated synthetic lethality targets in the cancer genome. Werner protein is required for the survival of cancer cells with microsatellite instability. Inhibition of the helicase domain of Werner protein results in catastrophic double-strand DNA fragmentation in these MSI-High tumors, with exquisite selectivity relative to microsatellite stable (MSS) normal cells," said Michael White, Senior Vice President and Chief Scientific Officer of IDEAYA Biosciences.

"IDEAYA was one of the first groups to publish on the Werner Helicase and MSI-High synthetic lethal interaction. Werner Helicase was one of the earliest drug discovery programs we launched since the founding of IDEAYA, and it is extremely exciting to achieve the development candidate nomination milestone for this program with GSK, which represents our fifth potential first-in-class program," said Yujiro S. Hata, CEO at IDEAYA Biosciences.

IDEAYA and GSK are targeting an Investigational New Drug (IND) submission to the U.S. Food and Drug Administration (FDA) in 2024 for the Werner Helicase Inhibitor DC, subject to satisfactory completion of ongoing preclinical and IND-enabling studies, to enable first-in-human study initiation.

IDEAYA and GSK are collaborating on the ongoing IND-enabling studies and GSK will lead clinical development for the Werner Helicase program. GSK is responsible for 80% of global research and development costs and

IDEAYA is responsible for 20% of such costs. GSK holds a global, exclusive license to develop and commercialize the Werner Helicase Inhibitor DC. IDEAYA earned a $3 million milestone from GSK in connection with IND-enabling studies and has the potential to earn up to an additional $17 million aggregate milestone payments through early Phase 1. IDEAYA will also be eligible to receive additional future aggregate total development milestones of up to $465.0 million. Upon commercialization, IDEAYA will be eligible to receive up to $475.0 million of commercial milestones, 50% of U.S. net profits and tiered royalties on global non-U.S. net sales of the Werner Helicase Inhibitor DC – ranging from high single-digit to sub-teen double-digit percentages, subject to certain customary reductions.

IDEAYA plans to host an Investor R&D Day in the fourth quarter of 2023, with participation of GSK. The company will provide an outline of agenda topics and participating key opinion leaders for the Investor R&D Day in advance of the event.

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.

Forward-Looking Statements
This press release contains forward-looking statements, including, but not limited to, statements related to (i) the potential receipt and amount of development and commercial milestones, (ii) the timing of submission of an IND for the Werner Helicase Inhibitor DC, (iii) the timing and content of an Investor R&D Day, (iv) the prevalence of tumors with MSI-High, and (v) the potential combination strategy for the Werner Helicase Inhibitor DC. 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.

Investor and Media Contact
IDEAYA Biosciences
Andres Ruiz Briseno
Senior Vice President, Head of Finance and Investor Relations
investor@ideayabio.com

SOURCE IDEAYA Biosciences, Inc.

---

https://media.ideayabio.com/2023-10-09-IDEAYA-Biosciences-Announces-Development-Candidate-Nomination-of-a-Werner-Helicase-Inhibitor-in-Collaboration-with-GSK-and-Investor-R-D-Day