IDEAYA Announces Further Gilead Sciences Clinical Study Collaboration Evaluating Combination of Trodelvy® and IDE397 in MTAP-Deletion NSCLC

- Entered into an additional clinical study collaboration and supply agreement with Gilead to evaluate IDE397, IDEAYA's
 MAT2A inhibitor, in combination with Trodelvy, Gilead's Trop-2 directed ADC, in MTAP-deletion NSCLC
- The potential first-in-class clinical combination of IDE397 and Trodelvy targets two mechanistically distinct and complementary nodes of MTAP-deletion in solid tumors
- MTAP-deletion prevalence in NSCLC is estimated to be approximately 15%

SOUTH SAN FRANCISCO, Calif., Feb. 13, 2025 / PRNewswire / -- IDEAYA Biosciences, Inc. (Nasdaq:IDYA), a precision medicine oncology company committed to the discovery and development of targeted therapeutics, announced it has entered into an additional clinical study collaboration and supply agreement with Gilead Sciences, Inc. (Gilead) to evaluate the efficacy and safety of IDE397, its investigational, potential first-in-class, small molecule MAT2A inhibitor, in combination with Gilead's Trodelvy® (sacituzumab govitecan-hziy), a Trop-2 directed antibody-drug conjugate (ADC), in methylthioadenosine phosphorylase (MTAP)-deletion non-small cell lung cancer (NSCLC).

"We are pleased to broaden the ongoing evaluation of the potential first-in-class clinical combination of IDE397 and Trodelvy to now include patients with MTAP-deletion NSCLC in our ongoing Phase 1 trial currently evaluating the combination in MTAP-deletion urothelial cancer. We are excited to continue to explore this potential first-in-class combination in MTAP-deletion solid tumors and look forward to providing clinical program updates in 2025," said Darrin Beaupre, M.D., Ph.D., Chief Medical Officer, IDEAYA Biosciences.

IDE397 is a potent and selective small molecule inhibitor targeting methionine adenosyltransferase 2a (MAT2A), in patients having solid tumors with MTAP-deletion. The prevalence of MTAP-deletion is estimated to be approximately 26% in urothelial cancer (UC) and approximately 15% in NSCLC, representing approximately 48,000 cases in the U.S. annually.

Trodelvy is currently approved in in more than 50 countries for second-line or later metastatic triple-negative breast cancer (TNBC) patients and in more than 40 countries for certain patients with pre-treated HR+/HER2- metastatic breast cancer.

In addition to the Phase 1/2 trial evaluating IDE397 in combination with Trodelvy in UC and NSCLC, IDEAYA is actively enrolling patients into a monotherapy expansion in MTAP-deletion NSCLC and urothelial cancer and is expecting to initiate a wholly-owned clinical combination trial of IDE397 and IDE892, IDEAYA's potential best-in-class, MTA-cooperative PRMT5 inhibitor in the second half of 2025.

Pursuant to the clinical study collaboration and supply agreement, IDEAYA and Gilead retain the commercial rights to their respective compounds, including with respect to use as a monotherapy or combination agent. IDEAYA is the study sponsor and Gilead will provide the supply of Trodelvy to IDEAYA.

IDE397 monotherapy or in combination with Trodelvy has not been approved by any regulatory agency and the efficacy and safety of this combination has not been established.

Trodelvy and Gilead are trademarks of Gilead Sciences, Inc., or its related companies.

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 (i) the prevalence of MTAP-deletion and (ii) the potential therapeutic benefits of the combination of IDE397 and Trodelvy. 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.

Investor and Media Contact

IDEAYA Biosciences
Andres Ruiz Briseno
SVP, Head of Finance and Investor Relations
investor@ideayabio.com

SOURCE IDEAYA Biosciences, Inc.

https://media.ideayabio.com/2025-02-13-IDEAYA-Announces-Further-Gilead-Sciences-Clinical-Study-Collaboration-Evaluating-Combination-of-Trodelvy-R-and-IDE397-in-MTAP-Deletion-NSCLC