IDEAYA Biosciences Announces Phase 1/2 Expansion for IDE397 and Trodelvy® Combination in MTAP-Deletion Urothelial Cancer

- Initiated Phase 1/2 study expansion for IDE397, IDEAYA's MAT2A inhibitor, in combination with Trodelvy®, Gilead's Trop-2 directed ADC, in MTAP-deletion urothelial cancer based on preliminary safety and clinical efficacy data
- MTAP-deletion prevalence in urothelial cancer is estimated to be approximately 26%

SOUTH SAN FRANCISCO, Calif., April 10, 2025 /PRNewswire/ -- IDEAYA Biosciences, Inc. (Nasdaq:IDYA), a precision medicine oncology company committed to the discovery and development of targeted therapeutics, announced the initiation of a Phase 1/2 expansion in the clinical trial evaluating IDE397, its investigational, potential first-in-class, small molecule methionine adenosyltransferase 2a (MAT2A) inhibitor, in combination with Gilead's Trodelvy® (sacituzumab govitecan-hziy), a Trop-2 directed antibody-drug conjugate (ADC), in methylthioadenosine phosphorylase (MTAP)-deletion urothelial cancer (UC) based on preliminary safety and clinical efficacy data.

IDE397 is a potent and selective small molecule inhibitor targeting (MAT2A), in patients having solid tumors with MTAP-deletion. The prevalence of MTAP-deletion is estimated to be approximately 26% in UC.

"We are pleased to advance the potential first-in-class clinical combination of IDE397 and Trodelvy into an initial Phase 1/2 expansion in MTAP-deletion UC based on preliminary safety and clinical efficacy observed. We are excited to continue to explore this novel combination given the high unmet medical need, as there are no approved therapies specifically for MTAP-deletion UC," said Darrin Beaupre, M.D., Ph.D., Chief Medical Officer, IDEAYA Biosciences.

Trodelvy is currently approved 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. The use of Trodelvy in MTAP-deletion UC is investigational, and the safety and efficacy of this use have not been established.

A clinical program update on the IDE397 and Trodelvy combination is planned in 2025. In addition to the clinical trial program evaluating IDE397 in combination with Trodelvy, IDEAYA is has a monotherapy expansion study in MTAP-deletion NSCLC and UC 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 18, 2025 and any current and periodic reports filed with the U.S. Securities and Exchange Commission.

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