IDEAYA Biosciences Announces First-Patient-In for Phase 1 Clinical Trial Evaluating IDE397 and Trodelvy® Combination in MTAP-Deletion Bladder Cancer

- First-Patient-In (FPI) for Phase 1 combination treatment with IDE397, IDEAYA's MAT2A inhibitor, and Trodelvy®, Gilead's Trop-2 directed antibody-drug conjugate (ADC)
- The global Phase 1 clinical trial will evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics and efficacy of IDE397 in combination with Trodelvy
- MTAP-deletion is found in approximately 26% of patients with bladder cancer

SOUTH SAN FRANCISCO, Calif., June 25, 2024 /PRNewswire/ -- IDEAYA Biosciences, Inc. (Nasdaq:IDYA), a precision medicine oncology company committed to the discovery and development of targeted therapeutics, today announced that it has dosed its first patient in the IDEAYA-sponsored Phase 1 trial evaluating the combination of IDE397, IDEAYA's investigational MAT2A inhibitor, and Trodelvy® (sacituzumab govitecan-hziy), Gilead's Trop-2 directed ADC, in patients with MTAP-deletion bladder cancer.

"We are pleased to have dosed our first patient with MTAP-deletion bladder cancer in this Phase 1 trial evaluating combination treatment with IDE397 and Trodelvy. The MAT2A-Trop2 ADC combination targets two distinct, yet complementary nodes in patients with MTAP-deleted urothelial cancer and has first-in-class potential to improve clinical outcomes for bladder cancer patients with poor prognosis associated with MTAP-deletion," commented Dr. Darrin M. Beaupre, M.D., Ph.D., Chief Medical Officer, IDEAYA Biosciences.

The IDE397 and Trodelvy combination Phase 1 trial is included as an arm of an ongoing IDEAYA-sponsored clinical trial (NCT04794699), which includes a Phase 2 expansion arm of IDE397 monotherapy in MTAP-deletion solid tumors. The global Phase 1 clinical trial will evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics and efficacy of IDE397 in combination with Trodelvy. IDE397 is a potent and selective small molecule inhibitor targeting methionine adenosyltransferase 2 alpha (MAT2A) in patients having solid tumors with methylthioadenosine phosphorylase (MTAP) deletion.

Gilead's Trodelvy is currently approved in nearly 50 countries for 2L metastatic triple-negative breast cancer and in more than 30 countries for pre-treated HR+/HER2- metastatic breast cancer (mBC). In the U.S., Trodelvy has an accelerated approval for the treatment of patients with locally advanced or metastatic urothelial cancer (mUC) who have previously received a platinum-containing chemotherapy and anti-PD-(L)1 therapy.

Pursuant to the clinical study collaboration and supply agreement, IDEAYA and Gilead retain the commercial rights to its 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.

There is separately an Amgen-sponsored Phase 1/2 trial of IDE397 and AMG 193 combination in MTAP-Deletion NSCLC (NCT05975073) for which the companies intend to develop a joint publication strategy in 2024. The Company is targeting a clinical data update for the IDE397 Phase 2 monotherapy expansion dose in MTAP-deletion bladder and lung cancer in over ~15 evaluable patients in the second half of 2024. The Company is also advancing multiple preclinical stage MTAP-deletion programs to enable wholly-owned combinations with IDE397, including a program targeting a Development Candidate nomination in the second half of 2024.

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.

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 timing and content of clinical program updates and (ii) the timing for the development of a joint Amgen/IDEAYA publication strategy. 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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