IDEAYA Biosciences Announces Clinical Program Updates for IDE397 a Potential First-in-Class Phase 2 MAT2A Inhibitor Targeting MTAP-Deletion Solid Tumors

- Targeting IDE397 Phase 2 monotherapy expansion dose clinical data update in over ~15 evaluable MTAP lung and bladder cancer patients in H2 2024, including RECIST 1.1 clinical efficacy waterfall, swim-lane plot, ctDNA molecular response analysis, AE profile, PK and pharmacodynamics
- Initiating IDE397 Phase 2 monotherapy expansion in MTAP bladder cancer, in addition to the earlier reported Phase 2 expansion in MTAP squamous lung cancer
- Activated over 35 clinical trial sites globally across the U.S., Canada, Europe, and Asia Pacific to enable potential rapid enrollment for the IDE397 Phase 2 clinical program

SOUTH SAN FRANCISCO, Calif., June 24, 2024 /PRNewswire/ -- IDEAYA Biosciences, Inc. (Nasdaq:IDYA), a precision medicine oncology company committed to the discovery and development of targeted therapeutics, today announced clinical program updates for IDE397, a potential first-in-class Phase 2 MAT2A inhibitor targeting MTAP-deletion solid tumors.

"We are excited about activating over 35 clinical trial sites globally and the broad advancement of the IDE397 Phase 2 program, including multiple potential first-in-class clinical combinations and Phase 2 monotherapy expansion in priority MTAP-deletion solid tumor types of lung and bladder cancer. We are delighted to provide updated corporate guidance for the IDE397 clinical program, including a clinical date update for the IDE397 Phase 2 monotherapy expansion dose in the second half of 2024," said Yujiro S. Hata, Chief Executive Officer, IDEAYA Biosciences.

The Company is now targeting an IDE397 clinical data update for the IDE397 Phase 2 monotherapy expansion dose in MTAP-deletion bladder and lung cancer in over approximately 15 evaluable patients in the second half of 2024. The clinical data update is anticipated to include a clinical efficacy summary, including a RECIST 1.1 clinical efficacy waterfall, swim-lane plot, and ctDNA molecular response analysis. In addition, at this update the Company also anticipates providing an adverse event, pharmacokinetics and pharmacodynamics summary at the IDE397 Phase 2 monotherapy expansion dose. Next, the Company is initiating an IDE397 Phase 2 monotherapy expansion in MTAP-deletion bladder cancer, in addition to the earlier reported Phase 2 expansion in MTAP-deletion squamous lung cancer. The Company has activated over 35 clinical trial sites globally in the U.S., Canada, Europe, and Asia Pacific to enable potential rapid enrollment for the IDE397 Phase 2 monotherapy expansion in MTAP-deletion lung and bladder cancer, and for the IDEAYA sponsored clinical combination(s).

IDE397 is a potential first-in-class potent and selective small molecule inhibitor targeting methionine adenosyltransferase 2 alpha (MAT2A) in patients having solid tumors with methylthioadenosine phosphorylase (MTAP) deletion.

There is an ongoing Phase 2 expansion of IDE397 monotherapy in MTAP-deletion solid tumors (NCT04794699), and 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. Next, there is a Phase 1 clinical trial that will evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics and efficacy of IDE397 in combination with Trodelvy (NCT04794699). IDEAYA 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.

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 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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