IDEAYA Biosciences Announces Selection of Move-Forward Phase 2 Expansion Dose for IDE397 Monotherapy in MTAP-Deletion Squamous Non-Small Cell Lung Cancer

- Selected a move-forward Phase 2 expansion dose for IDE397 monotherapy in MTAP-deletion squamous NSCLC, based on AE profile and preliminary clinical efficacy observed, including multiple partial responses by RECIST 1.1

- Evaluating over 40 MTAP PDX preclinical models, squamous NSCLC was identified as the most sensitive tumor type to IDE397 monotherapy where ~50% of the models observed tumor regressions at 30mg/kg QD

- Over 100,000 global annual incidence of MTAP-deletion squamous NSCLC

SOUTH SAN FRANCISCO, Calif., April 22, 2024 /PRNewswire/ -- IDEAYA Biosciences, Inc. (Nasdaq: IDYA), a precision medicine oncology company committed to the discovery and development of targeted therapeutics, announced selection of a move-forward Phase 2 expansion dose for IDE397 monotherapy in MTAP-deletion squamous non-small cell lung cancer (NSCLC), based on adverse event profile and preliminary clinical efficacy observed, including multiple partial responses by RECIST 1.1.

"We are excited to select a move-forward Phase 2 expansion dose for IDE397 monotherapy in MTAP-deletion squamous NSCLC, based on AE profile and multiple responses observed at this dose. We believe MTAP-deletion squamous NSCLC is an area of high unmet medical need, and we are excited to further evaluate clinically our potential first-in-class MAT2A inhibitor IDE397 in this tumor setting, while in parallel advancing multiple rational combinations with our pharma collaborators and internal wholly owned pipeline," said Darrin Beaupre, M.D., Ph.D., Chief Medical Officer, IDEAYA Biosciences.

"We believe IDE397 is well positioned as a potential first-in-class MAT2A inhibitor and encouraged to see preliminary translation of our preclinical activities to the clinic in the MTAP-deletion squamous NSCLC setting. Next, through this year we look forward to the potential to clinically validate several important preclinical hypotheses we have generated on several mechanistically high conviction rational combinations in the MTAP-deletion setting," said Michael White, Ph.D., Chief Scientific Officer, IDEAYA Biosciences.

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. The Company continues to focus on evaluating IDE397 in two trials, including as monotherapy and in multiple clinical combinations:

- IDE397-001 (NCT04794699) is a Phase 2 monotherapy expansion of IDE397 in MTAP-deletion solid tumors
- Phase 1/2 trial of IDE397 + AMG 193 in MTAP-Deletion NSCLC (Amgen-sponsored study, NCT05975073)
- Phase 1 trial of IDE397 + Trodelvy in MTAP-deletion bladder cancer (IDEAYA-sponsored, NCT04794699)

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 therapeutic benefits of IDEAYA therapeutics, (ii) the translation of preliminary clinical trial results into future clinical trial results, and (iii) the estimate of patient populations. 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, the effects on IDEAYA's business of the worldwide COVID-19 pandemic, the ongoing military conflict between Russia and Ukraine, banking sector volatility, 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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