IDEAYA Announces Dosing of First Patient of MAT2A Inhibitor IDE397 in Phase 1 Clinical Trial Evaluating MTAP-Deletion Solid Tumors

- IDE397 demonstrates significant single-agent anti-tumor activity in a 40-plus MTAP-deletion PDX study, including tumor regressions, across major solid tumor types, such as NSCLC, gastric, esophageal, and bladder cancers (AACR 2021)
- Multiple clinical trial sites being activated across the U.S. to evaluate IDE397 clinically in patients having tumors with MTAP-deletion
- Next Generation Sequencing (NGS) platforms and a MTAP-IHC assay will be utilized to identify MTAP-deletion patients for enrollment
- IDE397 program update, including clinical development plan, will be presented during the inaugural IDEAYA Synthetic Lethality Investor Day on April 20, 2021

SOUTH SAN FRANCISCO, Calif., April 15, 2021 /PRNewswire/ -- IDEAYA Biosciences, Inc. (NASDAQ: IDYA), a synthetic lethality-focused precision medicine oncology company committed to the discovery and development of targeted therapeutics, announced First-Patient-In (FPI) in the Phase 1 clinical trial evaluating IDE397 (ClinicalTrials.gov Identifier: NCT04794699). IDE397 is a potential best-in-class methionine adenosyltransferase 2a (MAT2A) inhibitor being evaluated in cancer patients harboring methylthioadenosine phosphorylase (MTAP) deletion.

"We are excited to dose the first patient in the evaluation of IDE397 targeting MAT2A in MTAP deletion patients. IDE397 has the potential to be broadly impactful for cancer patients with MTAP deletion, which is prevalent in approximately 15% of solid tumors," said Anthony Tolcher, M.D., Director of Clinical Research, Founder and CEO at NEXT Oncology.

IDE397 is an internally discovered potential best-in-class MAT2A inhibitor that received IND-clearance from the U.S. FDA to initiate Phase 1 in Q1 2021. As reported at AACR 2021, IDE397 demonstrated significant single-agent anti-tumor activity in a 40-plus MTAP-deletion study, including tumor regressions, across major solid tumor types, such as NSCLC, gastric, esophageal, bladder, among others. In addition to IDE397 monotherapy, IDEAYA is evaluating multiple potential combinations preclinically, including in the PRMT pathway and with taxanes, among others. Multiple clinical trial sites are being activated across the U.S. to evaluate IDE397 clinically, and MTAP-deletion patients will be identified for study enrollment through commercially available Next Generation Sequencing (NGS) platforms and with an MTAP-IHC assay which IDEAYA has developed in collaboration with Ventana.

"We believe that IDE397 is a differentiated small molecule MAT2A inhibitor, with the potential for monotherapy clinical development in genetically defined MTAP deleted cancers," said Matthew Maurer, M.D., Vice President, Head of Clinical Oncology and Medical Affairs at IDEAYA Biosciences. "Dosing our first patient for IDE397 in our Phase 1 MTAP-deletion solid tumor trial is a substantial company milestone. IDEAYA is targeting to advance our next two Synthetic Lethality programs in PARG and Pol Theta to development candidate stage in 2021 and advancing our internal pipeline in the MTAP-deletion synthetic lethality space to complement our Phase 1 MAT2A inhibitor IDE397," said Yujiro S. Hata, President and Chief Executive Officer, IDEAYA Biosciences.

IDEAYA is a synthetic lethality-focused 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 early 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 activation of clinical trial sites, (ii) the utilization of NGS platforms and MTAP-IHC assay, (iii) the timing and content of IDE397 program update, (iv) the best-in class potential of IDE397, (v) the potential impact and single agent activity IDE397 and (vi) the timing for development candidate identification for PARG and Pol Theta programs. 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, 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 recent Annual Report on Form 10-K filed on March 23, 2021 and any current and periodic reports filed with the U.S. Securities and Exchange Commission.

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