IDEAYA Biosciences Announces US FDA IND-Clearance for IDE849, a Potential First-in-Class DLL3 TOP1 ADC, for a Phase 1 Study in Solid Tumors

- Targeting to evaluate IDE849 (SHR-4849) in SCLC, NETs, and other DLL3-upregulated solid tumors, and in combination with IDE161/PARG to potentially enhance durability
- Targeting to present clinical data of over 40 SCLC patients, including the dose escalation and expansion, from partner Hengrui at medical conference in Q3 2025

SOUTH SAN FRANCISCO, Calif., May 6, 2025 /PRNewswire/ -- IDEAYA Biosciences, Inc. (NASDAQ: IDYA), a precision medicine oncology company committed to the discovery and development of targeted therapeutics, announced the clearance of an investigational new drug (IND) application with the U.S. Food and Drug Administration (FDA) for the initiation of a Phase 1 clinical trial to evaluate IDE849 (SHR-4849), a potential first-in-class delta-like ligand 3 (DLL3)-targeting Topo-I-payload antibody drug conjugate (ADC) program, in solid tumors.

"We are excited to advance IDE849, a potential first-in-class DLL3 TOP1 ADC, into a Phase 1 study in the U.S. DLL3 is upregulated in multiple solid tumor types, including small cell lung cancer (SCLC), neuroendocrine tumors (NETs), non-small cell lung cancer (NSCLC), melanoma, among other solid tumors, highlighting the potential to have a pipeline in a single asset. We look forward to the IDE849 clinical data update in SCLC at a medical conference in Q3 2025, including at multiple expansion doses," said Yujiro S. Hata, President and Chief Executive Officer, IDEAYA Biosciences.

"IDE849 is a potential first-in-class DLL3 TOP1 ADC, a target antigen that has demonstrated preliminary monotherapy clinical validation in SCLC. In addition, IDE849 aligns with our strategy to develop rational combination therapies, particularly with our potential first-in-class Phase 1 PARG inhibitor IDE161, where we have generated preclinical combination data with TOP1-based ADCs that demonstrates combination synergy and enhanced durability," said Dr. Darrin M. Beaupre, M.D., Ph.D., Chief Medical Officer, IDEAYA Biosciences.

IDE849 is in an ongoing multi-site open label Phase 1 clinical trial for advanced solid tumors (NCT06443489) by Jiangsu Hengrui Pharmaceuticals Co., Ltd. (Hengrui Pharma, SHA: 600276). In this ongoing Phase 1 study, IDE849 has reached therapeutic dose levels where multiple partial responses have been observed as of the data cut-off date of December 10, 2024. As of the data cut-off date, treatment related adverse events (TRAEs) were predominantly Grade 1 or 2, and the Phase 1 dose escalation is ongoing with no reported drug-related discontinuations, and the maximum tolerated dose has not yet been reached. The most common TRAEs observed were white blood cell count decreased, anemia, neutrophil count decreased, platelet count decreased, and nausea. Hengrui Pharma is targeting to present clinical efficacy and safety data on IDE849 in over 40 SCLC patients from a multi-site open label Phase 1 trial, including from the dose escalation phase and at multiple expansion doses, at a medical conference in Q3 2025.

In addition, IDEAYA is targeting to present preclinical combination mechanism and synergy efficacy data of IDE161/PARG with TOP1-payload based ADCs at a medical conference in the third quarter of 2025. We believe this potential first-in-class combination has the potential to enhance durability of IDEAYA's TOP1-payload based ADC pipeline, including IDE849 and IDE034 (B7H3/PTK7 Bispecific TOP1 ADC).

DLL3 has been reported to be upregulated in multiple solid tumor types, including in SCLC, NETs, NSCLC, melanoma, among others. DLL3 has limited extracellular expression in normal tissues, making it a promising potential therapeutic target in these solid tumors, for which there remains significant unmet medical need.

IDEAYA is targeting to evaluate IDE849 clinically in a multi-site global clinical trial as a monotherapy agent in

SCLC, NETs and multiple DLL3 upregulated solid tumor types, and to evaluate IDE849 in a clinical combination with IDEAYA's potential first-in-class Phase 1 PARG inhibitor, IDE161, in the second half of 2025.

Based on the U.S. FDA guidance, IDEAYA will begin the Phase 1 study in the U.S. at a IDE849 starting dose that is equivalent to one of the expansion doses being evaluated in the ongoing Phase 1 study (NCT06443489) by partner Hengrui Pharma, where multiple confirmed partial responses have been observed by RECIST 1.1.

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, including combination therapies; (ii) the timing and content of clinical trial updates and data readouts, including efficacy and safety data; (iii) the timing of and potential of clinical trials to evaluate IDE849 in SCLC, NETs, and other DLL3-upregulated solid tumors, and in combination with IDE161/PARG to potentially enhance durability. 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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