IDEAYA Biosciences Announces IND Clearance for IDE034, a Potential First-in-Class Bispecific B7H3/PTK7 TOP1 ADC Targeting Multiple Solid Tumor Types

- B7H3 and PTK7 is co-expressed in multiple solid tumor types, including lung, colorectal, and head and neck cancers, at approximately 30%, 46%, and 27%, respectively
- Deep and durable regressions observed with IDE034 monotherapy in multiple preclinical in-vivo models with B7H3 and PTK7 co-expression
- Enhanced durability with IDE034 and IDE161 PARG inhibitor combination in preclinical *in vivo* models; targeting to share additional preclinical data supporting mechanistic rationale at a medical conference in H1 2026

SOUTH SAN FRANCISCO, Calif. and SHANGHAI, Dec. 1, 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 IDE034, a potential first-in-class bispecific B7H3/PTK7 TOP1 antibody-drug conjugate (ADC). IDEAYA expects to begin enrolling the study in Q1 2026, initially evaluating patients with solid tumors known to express B7H3 and PTK7, including lung, colorectal, head and neck and ovarian/gynecological cancers. Based on the Human Protein Atlas database, B7H3/PTK7 has been reported to be co-expressed in lung, colorectal, and head and neck cancers at approximately 30%, 46% and 27%, respectively.

"IND clearance for IDE034 is an important step in expanding our potential first-in-class TOP1 ADC clinical pipeline into bispecific, precision-guided approaches," said Darrin M. Beaupre, M.D., Ph.D., Chief Medical Officer of IDEAYA Biosciences. "IDE034 has demonstrated robust antitumor activity and selective targeting of B7H3- and PTK7-expressing solid tumor models. The high prevalence of B7H3/PTK7 co-expression in solid tumors such as lung, colorectal, and head and neck cancers underscores its broad indication potential."

"We are excited to advance our differentiated clinical strategy with now three potentially first-in-class clinical-stage programs focused on enhancing the efficacy of TOP1 ADCs through the PARG DDR combination mechanism. We believe this approach addresses a key unmet need by improving the durability of response to TOP1 payload-based ADC therapies. We are targeting to share additional preclinical data to support the PARG and TOP1 ADC combination rationale at a major medical conference in H1 2026," said Yujiro S. Hata, President and Chief Executive Officer of IDEAYA Biosciences.

Preclinical studies have demonstrated strong anti-tumor activity in B7H3/PTK7-positive tumor models, including deep and durable tumor regressions with IDE034 monotherapy, supporting advancement into clinical development. This co-expression pattern supports the potential for broad monotherapy activity, while the TOP1 payload provides a strong mechanistic rationale for combining IDE034 with IDEAYA's PARG inhibitor, IDE161. TOP1 inhibition induces replication stress and DNA damage, which can increase reliance on the PARG pathway; therefore, a IDE034 and IDE161 combination approach may enhance anti-tumor activity in patients with solid tumors that co-express B7H3 and PTK7, consistent with the results that were observed preclinically with this combination.

About IDEAYA Biosciences

IDEAYA is a precision medicine oncology company committed to the discovery, development, and commercialization of transformative therapies for cancer. Our approach integrates expertise in small-molecule drug discovery, structural biology and bioinformatics with robust internal capabilities in identifying and validating translational biomarkers to develop tailored, potentially first-in-class targeted therapies aligned to the genetic

drivers of disease. We have built a deep pipeline of product candidates focused on synthetic lethality and antibody-drug conjugates, or ADCs, for molecularly defined solid tumor indications. Our mission is to bring forth the next wave of precision oncology therapies that are more selective, more effective, and deeply personalized with the goal of altering the course of disease and improving clinical outcomes for patients with cancer.

Forward-Looking Statements

This press release contains forward-looking statements, including, but not limited to, statements related to: (i) the timing of the initiation of and enrollment of subjects for the Phase 1 clinical trial to evaluate IDE034; (ii) the potential frequency of B7H3/PTK7 co-expressed in solid tumors types, including lung, colorectal, and head and neck cancers; (iii) the potential therapeutic benefit of IDE034 as monotherapy and in combination with IDE161, a PARG inhibitor; and (iv) the timing of a data presentation related to the IDE034 and IDE161, PARG inhibitor, combination at a medical conference. Preclinical study results are not necessarily predictive of future clinical trial results and/or approval. 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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