IDEAYA Biosciences and Hengrui Pharma Present Positive Phase 1 Data for IDE849 (SHR-4849), a Potential First-in-Class DLL3 TOP1 ADC, in Small Cell Lung Cancer at the IASLC 2025 World Conference on Lung Cancer

- 80.0% (8/10) ORR and 70.0% (7/10) confirmed ORR in 2L SCLC; a 73.7% (14/19) ORR and 57.9% (11/19) confirmed ORR (1 pending confirmation) were observed across all lines of SCLC at the 2.4 mg/kg expansion dose of IDE849

- 77.1% (27/35) ORR and 60.0% (21/35) confirmed ORR (4 pending confirmation) in 2L SCLC; a 73.2% (52/71) ORR and 47.9% (34/71) confirmed ORR (10 pending confirmation) were observed across all lines of SCLC at all expansion doses of IDE849

- In patients with baseline brain metastases, a 83.3% (5/6) confirmed ORR at the 2.4 mg/kg dose was observed; across all doses ≥2.4 mg/kg (n=18), a 66.7% (12/18) confirmed ORR (1 pending confirmation) was observed

- 14.1% (10/71) of patients across all doses ≥2.4 mg/kg are still pending confirmation, as well as multiple patients that have had limited follow-up (e.g. one post-baseline scan) highlighting the study has not yet achieved a fully mature confirmed ORR%

- 6.7 month median progression free survival (PFS) across all lines of SCLC across all dose levels (≥2.4 mg/kg); mPFS not reached in 2L SCLC patients

- Manageable safety profile observed across multiple expansion cohorts, including the 2.4 mg/kg, 3.0 mg/kg, and 3.5 mg/kg dose levels with a once every 3-week dosing interval

SHANGHAI and SOUTH SAN FRANCISCO, Calif., Sept. 7, 2025 /PRNewswire/ -- IDEAYA Biosciences, Inc. (Nasdaq: IDYA), a leading precision medicine oncology company, and Hengrui Pharma, a global pharmaceutical company focused on scientific and technological innovation, presented initial data from Hengrui's Phase 1 clinical trial of IDE849 (SHR-4849), a potential first-in-class delta-like ligand 3 (DLL3)-targeting Topoisomerase-1 (TOP1) antibody drug conjugate (ADC), in an oral presentation today at the IASLC 2025 World Conference on Lung Cancer (WCLC) in Barcelona, Spain. The presentation included data from a total of 100 patients who received IDE849 at doses between 0.8 mg/kg to 4.2 mg/kg with a once every 3-week dosing interval.

"We believe the ORR, median PFS, and overall safety data presented at WCLC 2025 in over 70 efficacy evaluable SCLC patients provides a potential best-in-class DLL3 TOP1 ADC profile," said Yujiro S. Hata, President and Chief Executive Officer, IDEAYA Biosciences. "We look forward to advancing the global clinical development of IDE849 in SCLC, NETs, and additional DLL3 upregulated solid tumors, as both a potential first-in-class and best-in-class DLL3 TOP1 ADC to address areas of high unmet medical need in cancer."

Data in the presentation were as of a cut-off date of June 20, 2025, and included 87 patients with small-cell lung cancer (SCLC) and 13 patients with other neuroendocrine carcinomas (NEC). All patients had progressed after front-line therapy, with 33%

having progressed after two prior lines and 15% after three or more prior lines of therapy. Of the 87 SCLC patients enrolled, 72.4% (63/87) had received prior immunotherapy. A total of 71 patients with refractory SCLC (2L+) were evaluated for initial efficacy at doses of 2.4 mg/kg (n=19), 3.0 mg/kg (n=18) and 3.5 mg/kg (n=31) in the expansion phase of the trial. Patients in the 4.2 mg/kg cohort (n=3) of the dose escalation phase were also included in the analysis. All efficacy-evaluable patients had received at least one post-baseline tumor assessment per RECIST v1.1.

Key data highlights from the presentation

Efficacy (n=71 evaluable SCLC patients treated with IDE849)

	IDE849 Dose Level			
	2.4 mg/kg		**Total (≥2.4 mg/kg)**	
Treatment setting *(# patients)*	2L *(n=10)*	All-lines *(n=19)*	2L *(n=35)*	All-lines *(n=71)*
ORR (%, n)	80.0% (8/10)	73.7% (14/19)	77.1% (27/35)	73.2% (52/71)
Confirmed ORR (%, n)	70.0% (7/10)	57.9% (11/19)	60.0% (21/35)	47.9% (34/71)
Pending confirmation	--	5.3% (1/19)	11.4% (4/35)	14.1% (10/71)
DCR	100% (10/10)	94.7% (18/19)	97.1% (34/35)	93.0% (66/71)

- Robust overall response rate (ORR) and disease control rate (DCR) were consistently observed across all expansion doses evaluated and in patients across all lines of therapy, with a modest reduction in ORR/DCR observed in later-line patients, consistent with their more advanced stage of disease.

- 14.1% (10/71) of patients across all doses ≥2.4 mg/kg are still pending confirmation, as well as multiple patients who have had limited follow-up (e.g. one post-baseline scan) highlighting the study has not yet achieved a fully mature confirmed ORR%.

- In patients with baseline brain metastasis, a confirmed ORR of 83.3% (5/6) and a DCR of 100% (6/6) was observed at the 2.4 mg/kg dose. Across all doses ≥2.4 mg/kg (n=18) with baseline brain metastasis, the confirmed ORR was 66.7% (12/18) with a DCR of 100% (18/18). A confirmation scan for one unconfirmed partial response is pending, which if confirmed, would increase the confirmed ORR to 72.2% (13/18).

- Median PFS was 6.7 months across all lines of treatment at doses of IDE849 ≥2.4 mg/kg (n=86); median PFS was not yet reached (NR) in 2L patients (n=42).

- As of the cut-off date of June 20, 2025 the median length of follow-up was 3.5 months.

Safety (n=100 SCLC and NEC patients treated with IDE849)

- Across all patients and all dose levels (n=100), Grade 3 or higher (Gr≥3) treatment-related adverse events (TRAEs) occurred in 48% (48/100) and serious TRAEs in 16% (16/100) of patients. The most common TRAEs were white blood cell reduction (27% Gr≥3), neutropenia (33% Gr≥3), anemia (6% Gr≥3) and nausea (0% Gr≥3).

- TRAEs leading to dose reduction in 15% (15/100) of patients; treatment-related discontinuation rate of 2% (2/100) with no treatment-related deaths reported.

IDEAYA will review the data that was presented by Hengrui at their 10-Year Anniversary R&D Day on September 8th in New York. A link to the oral presentation from WCLC will be available on the Investor Relations page of the IDEAYA corporate website: https://ir.ideayabio.com/.

In December 2024, Hengrui Pharma granted IDEAYA an exclusive worldwide license to develop and commercialize SHR-4849 (IDE849) outside of Greater China. The partners will collaborate to accelerate global development of this innovative therapy for patients worldwide.

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 potential therapeutic benefits of IDE849, including combination therapies; and (ii) the timing of and potential of clinical trials to evaluate TOP1-payload based ADCs in SCLC, NETs, and other DLL3-upregulated solid tumors. 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.

Investor and Media Contact

IDEAYA Biosciences

Joshua Bleharski, Ph.D.

Chief Financial Officer

investor@ideayabio.com

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