

IDE849 (SHR-4849) DLL3 TOP1 ADC Updated Phase 1 Results at ESMO 2026 Demonstrates Promising Anti-Tumor Activity and Preliminary Overall Survival Results in Relapsed Small Cell Lung Cancer and Neuroendocrine Carcinomas

- 17.4-month median OS in 2L SCLC (n=51) and 14.7-month median OS in 2L + ≥3L SCLC (n=101)
- 72.5% (37/51) ORR and 60.8% (31/51) cORR in 2L SCLC with 6.9-month median PFS; 68.3% (69/101) ORR and 54.5% (55/101) cORR in 2L + ≥3L SCLC with 6.8-month median PFS
- 76.9% (20/26) ORR and 65.4% (17/26) cORR in SCLC patients with brain metastases
- Efficacy observed in NECs, with 52.6% (10/19) ORR, 36.8% (7/19) cORR, 7.0-month median PFS and an 82.4% nine-month OS rate
- Grade ≥3 TRAE of 33.3% at the 2.4 mg/kg expansion dose. 2.5% treatment-related discontinuation rate and 0.8% Grade ≥3 ILD rate observed across the study (n=122)
- In IDEAYA's separate IDE849 global clinical study at the 2.4 mg/kg and 3.5 mg/kg expansion doses a Grade ≥3 TRAE rate of 5% (1/20) and 22.2% (4/18) have been observed, respectively
- Following successful Type C meetings with the U.S. FDA, IDEAYA is targeting to initiate two Phase 3 registrational trials with IDE849 in ES-SCLC and NEC. Evaluation of a potential 1L ES-SCLC Phase 3 study design is ongoing with continued data generation from several clinical combinations

SOUTH SAN FRANCISCO, Calif., Oct. 23, 2026 /[PRNewswire](#)/ -- IDEAYA Biosciences, Inc. (Nasdaq: IDYA) today announced updated clinical results that show promising anti-tumor activity and preliminary overall survival results for IDE849 (SHR-4849), its investigational antibody-drug conjugate (ADC) directed against delta-like ligand 3 (DLL3) and carrying a topoisomerase I (TOP1) inhibitor payload. IDEAYA's partner, Jiangsu Hengrui Pharmaceuticals Co., Ltd. (Hengrui), is presenting the results from its Phase 1 study in China in relapsed small cell lung cancer (SCLC) and other neuroendocrine carcinomas (NECs) at the European Society for Medical Oncology (ESMO) Congress 2026.

The update builds on the initial findings Hengrui presented at the World Conference on Lung Cancer (WCLC) in 2025, adding longer follow-up, a larger patient population and the first OS results from the study. The findings show substantial anti-tumor activity together with more mature PFS results and encouraging preliminary overall survival, including median overall survival (OS) of 17.4 months in the second-line SCLC setting.

"We are highly encouraged by the first-reported preliminary median overall survival and 9-month landmark OS results observed for IDE849 monotherapy in both relapsed SCLC and NEC, respectively. We look forward to advancing IDE849 globally with our partner Hengrui, as we target to advance registrational studies in the high unmet medical need indications of SCLC and NEC. IDEAYA also looks forward to providing the first efficacy and safety update from our global clinical study of IDE849 monotherapy, including in the post-Imdelltra SCLC and relapsed NEC settings," said Yujiro S. Hata, Chief Executive Officer and Chairman, IDEAYA Biosciences, Inc.

Key data highlights from the ESMO 2026 presentation

At the August 21, 2026 data cutoff, 122 patients had enrolled, including 103 with SCLC and 19 with other NECs at IDE849 doses ≥1.8 mg/kg IV dosed once every 3-weeks (Q3W). Median follow-up was 12.1 months (interquartile range: 8.2–16.0 months). Among patients with SCLC, 78.6% (81/103) had received prior immunotherapy, 49.5% (51/103) had one prior line of therapy (2L), and 50.5% (52/103) were heavily pre-treated having received two or more prior lines (≥3L) of treatment.

Efficacy in previously treated SCLC

Overall response rate (ORR) and confirmed overall response rate (cORR) results for SCLC patients receiving IDE849 at doses ≥ 1.8 mg/kg IV Q3W are summarized below.

	All-Lines	2L	3L	Brain Metastases
ORR	68.3% (69/101)	72.5% (37/51)	61.8% (21/34)	76.9% (20/26)
cORR	54.5% (55/101)	60.8% (31/51)	50.0% (17/34)	65.4% (17/26)

ORR includes confirmed and unconfirmed responses. Response rates in the brain metastases subgroup represent overall tumor response; the poster does not report an intracranial response rate. In IDEAYA's separate ongoing global clinical study, intracranial tumor shrinkage has been observed in the SCLC setting.

- In second-line (2L) SCLC (n=51), median OS was 17.4 months (95% CI: 9.9–not reached), and median PFS was 6.9 months (95% CI: 5.5–8.3).
- Across previously treated (2L + ≥ 3 L) SCLC patients (n=101) receiving doses ≥ 1.8 mg/kg, median OS was 14.7 months (95% CI: 11.9–18.3), and median PFS was 6.8 months (95% CI: 5.5–8.1). The survival analyses included 55 OS events (53.9%) and 86 PFS events (84.3%).
- In patients with brain metastases, confirmed ORR was 65.4% (17/26; 95% CI: 44.3–82.8), with disease control observed in all 26 patients.

The longer follow-up provides a more mature assessment of progression free survival (PFS) and the first assessment of preliminary OS reported from the study. The WCLC 2025 analysis had a median follow-up of 3.5 months and reported median PFS of 6.7 months in previously treated SCLC, with median PFS not yet reached in the second-line setting. The ESMO update includes a larger population and patients treated at doses ≥ 1.8 mg/kg Q3W.

Efficacy in other neuroendocrine carcinomas

Among 19 patients with other NECs, ORR was 52.6% (10/19; 95% CI: 28.9–75.6), confirmed ORR was 36.8% (7/19; 95% CI: 16.3–61.6), and disease control rate was 84.2% (16/19). Median PFS was 7.0 months and the nine-month OS rate was 82.4%, supporting further evaluation beyond SCLC.

High DLL3 expression (*reference: Front. Endocrinol.*, 11 August 2026) has been reported across multiple solid tumor subtypes of NECs that remain areas of high unmet medical need with few treatment options, including gastroenteropancreatic neuroendocrine carcinoma (GEP-NEC) and large cell neuroendocrine carcinoma (LC-NEC). The projected annual incidence of GEP-NEC and LC-NEC globally (excluding China) in the metastatic setting, is projected to be approximately 40,000 patients and 30,000 patients, respectively. In the major market countries of the US, EU5, and Japan, the GEP-NEC and LC-NEC metastatic annual incidence is projected to be approximately, 7,000 patients and 8,000 patients, respectively. There are multiple additional subtypes of NECs that have high DLL3 expression, including bladder and cervical, among others.

Safety in SCLC and other neuroendocrine carcinomas

At the expansion dose of 2.4 mg/kg, the most common treatment-related adverse events were neutrophil count decrease, white blood cell count decrease, and anemia. At the 2.4 mg/kg expansion dose, the Grade 3 or higher treatment-related adverse events (TRAEs) occurred in 33.3% of patients and the serious TRAEs occurred in 15.2% of patients.

The investigators reported a safety profile comparable to that observed previously and reported at the WCLC in 2025. Across all 122 patients and all dose levels, the most common Grade 3 or higher TRAEs were hematologic.

- Across the dose escalation, Grade 3 or higher TRAEs occurred in 59.8% (73/122) of patients, and serious TRAEs occurred in 21.3% (26/122).
- TRAEs led to dose reductions in 18.9% (23/122) and treatment discontinuation in 2.5% (3/122) of patients. One treatment-related death due to pneumonia was reported (0.8%), which is the same patient that was reported at WCLC 2025.
- Across the study (n=122), Grade 1 to 2 interstitial lung disease (ILD) was observed in 6.6% (n=8) of patients and Grade ≥ 3 ILD in 0.8% (n=1).

IDEAYA's separate ongoing Phase 1/2 global study of IDE849 in extensive-stage SCLC (ES-SCLC) and NEC is enrolling patients in the Americas, Europe, and Asia. The company is evaluating several expansion doses to determine the recommended Phase 3 dose (RP3D), including 2.4 mg/kg and 3.5 mg/kg IV Q3W. As of an October 1, 2026 data cut-off, a Grade ≥ 3 TRAE rate of 5% (1/20) at 2.4 mg/kg and 22.2% (4/18) at 3.5 mg/kg have been observed. The most common adverse events were hematologic, including neutropenia, white blood cell count decrease, and anemia, and the maximum tolerated dose (MTD) was determined to be 4.2 mg/kg.

IDEAYA is targeting to provide a clinical efficacy and safety update from the global Phase 1/2 trial of IDE849 monotherapy by the end of 2026 or early in 2027, with a focus on post-Imdelltra ES-SCLC and relapsed NEC. Based on successful Type C meetings with the U.S. Food and Drug Administration (FDA), IDEAYA is targeting to initiate two randomized global Phase 3 registrational trials with IDE849 in ES-SCLC (post-Imdelltra) and NEC. The company is also evaluating a potential trial design for a Phase 3 registrational trial in 1L SCLC, pending data from its Phase 1 combination cohorts with IDE161 (PARG inhibitor) and Astra Zeneca's PD-L1 antibody, durvalumab.

ESMO 2026 presentation details

Poster number: 3815P

Title: SHR-4849 (IDE849), an ADC targeting delta-like ligand 3 (DLL3), in relapsed small cell lung carcinoma (SCLC) and other neuroendocrine carcinomas (NECs): long-term results from the phase 1 study

Lead author: Haifeng Liu, Clinical Research Ward, Jilin Cancer Hospital, Changchun, China

Presentation date and time: Monday, October 26, 12:00-12:45pm CET

About IDE849

IDE849 (SHR-4849) is an investigational ADC that combines a humanized anti-DLL3 IgG1 antibody with a TOP1 inhibitor payload through a cleavable linker. The program is designed to target DLL3-expressing cancers, including SCLC and other NECs. In December 2024, IDEAYA licensed the global development and commercialization rights to IDE849 outside of Greater China from Hengrui.

About IDEAYA Biosciences

IDEAYA is a precision medicine oncology company committed to the discovery, development, and commercialization of transformative therapies to address unmet medical needs in cancer. The company integrates small-molecule drug discovery, structural biology and bioinformatics with extensive capabilities in identifying and validating translational biomarkers to develop potentially first-in-class targeted therapies for selected patient populations. IDEAYA has built a robust pipeline of targeted therapies focused on synthetic lethality and antibody-drug conjugates, or ADCs, including bispecifics, with the goal of improving clinical outcomes for patients with cancer.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and other applicable securities laws. Statements other than statements of historical fact are forward-looking statements, including, without limitation, statements regarding the implications of the Phase 1 IDE849 data presented at ESMO 2026 for future clinical development and outcomes; the potential significance of the observed response, progression-free survival, overall survival and safety results in relapsed SCLC and other NECs; the potential therapeutic benefit, clinical activity, safety and tolerability of IDE849 as monotherapy and in combination with other therapies; the selection of a recommended Phase 3 dose; the timing, availability and content of an efficacy and safety update from IDEAYA's global clinical study, including the planned update by the end of 2026 or early 2027 in post-Imdelltra ES-SCLC and relapsed NEC; IDEAYA's plans to initiate two randomized global Phase 3 registrational trials of IDE849 in post-Imdelltra ES-SCLC and NEC, including their timing and design; the evaluation of a potential Phase 3 registrational trial in first-line SCLC and the potential for data from Phase 1 combination cohorts with IDE161 and durvalumab to support such a trial; the projected incidence of metastatic NEC subtypes and the associated potential market opportunity; and the anticipated benefits of IDEAYA's collaboration with Hengrui.

These statements reflect IDEAYA's current expectations and assumptions and are subject to risks and uncertainties that could cause actual results to differ materially. The data reported from Hengrui's Phase 1 study and IDEAYA's ongoing global Phase 1 study may change with additional follow-up and may not be reproduced in subsequent trials. Results across studies, dose levels, patient populations and treatment settings may differ. Early clinical results from small patient populations may not predict results in larger or later-stage trials, and single-arm studies do not establish comparative efficacy or safety. IDE849 may not demonstrate the anticipated efficacy, survival benefit, safety or tolerability, and adverse events may emerge with further treatment and follow-up. IDEAYA may experience delays in dose selection, clinical data updates, trial initiation or enrollment. Regulatory authorities may require changes to proposed trial designs or additional data, and clinical results may not support further development or regulatory approval. FDA feedback from Type C meetings does not guarantee acceptance of final trial designs or regulatory approval. Estimates of disease incidence and potential market opportunity are subject to uncertainty and may differ from actual patient populations or commercial opportunities. IDEAYA also depends on Hengrui and other third parties for aspects of the IDE849 program.

Additional risks and uncertainties are described in IDEAYA's filings with the Securities and Exchange Commission, including its Annual Report on Form 10-K filed February 17, 2026, subsequent Quarterly Reports on Form 10-Q and Current Reports on Form 8-K. These forward-looking statements speak only as of the date of this press release. IDEAYA undertakes no obligation to update or revise them, except as required by law.

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