IDEAYA Biosciences Announces Successful US FDA Type C Meeting on Phase 2/3 Registrational Trial Designs to Support Potential Accelerated and Full Approval for IDE849, a Potential Best-in-Class DLL3 TOP1 ADC, in Neuroendocrine Carcinomas

- *Single-arm extension cohort of approximately 90 refractory GEP-NEC patients to support potential accelerated approval, with ORR by BICR as the primary endpoint*
- *Randomized Phase 3 trial in multiple refractory NEC subtypes, including GEP-NEC and LC-NEC, is planned to support full approval, with OS as the primary endpoint*
- *IDE849 has demonstrated a 52.6% ORR (10/19), median PFS of 7.0 months, and an estimated 9-month OS rate of 82.4% in 2L+ NEC*
- *Global Phase 1/2 trial of IDE849 has shown a Grade ≥3 TRAE rate of 5% (1/20) and 22.2% (4/18) at the 2.4 mg/kg and 3.5 mg/kg expansion doses, respectively*
- *IDEAYA is targeting to initiate two randomized Phase 3 registrational trials in the refractory NEC and post-Imdelltra ES-SCLC settings, and a potential registration-enabling single-arm extension cohort in refractory GEP-NEC, by the end of 2026*

SOUTH SAN FRANCISCO, Calif., Nov. 16, 2026 /PRNewswire/ -- IDEAYA Biosciences, Inc. (Nasdaq: IDYA), a precision medicine oncology company committed to the discovery, development and commercialization of transformative therapies to address unmet medical needs in cancer, today announced its registrational strategy for IDE849, a potential best-in-class delta-like ligand 3 (DLL3)-targeting Topo-I-payload antibody drug conjugate (ADC), in previously treated (2L+) neuroendocrine carcinomas (NEC). IDEAYA is planning to initiate registrational trials in both previously treated NEC and extensive-stage small cell lung cancer (ES-SCLC) by the end of the year.

"NEC is an aggressive disease with limited treatment options after first-line platinum-based chemotherapy. Our recent IDE849 data presented at ESMO in refractory NEC provides strong support for the clinical benefit that a DLL3-targeted ADC may offer for patients with this devastating disease," said Yujiro S. Hata, President and Chief Executive Officer of IDEAYA Biosciences. "In light of the fast-evolving landscape of DLL3-targeting agents we have completed two Type C meetings with the U.S. FDA and leading clinical investigators globally to align on the study designs for our registrational trials in both refractory NEC and ES-SCLC, including for accelerated approval, to ensure IDE849 is well positioned to become a viable new potential treatment option for patients with these difficult to treat cancers."

Registrational Strategy for IDE849 in NEC

Following a successful Type C meeting with the U.S. Food and Drug Administration (FDA) IDEAYA plans to advance a registrational development program for IDE849 in neuroendocrine carcinoma (NEC) by the end of 2026. The company intends to initiate a single-arm extension cohort within its ongoing Phase 1/2 clinical trial, enrolling approximately 90 previously treated patients with gastroenteropancreatic NEC (GEP-NEC). The cohort is intended to support a potential accelerated approval application, with a primary endpoint of confirmed overall response rate (ORR) assessed by blinded independent central review (BICR), supported by duration of response. Based on data from their ongoing global Phase 1/2 dose escalation and expansion trial, IDEAYA intends to evaluate IDE849 at doses of 2.4 mg/kg and 3.5 mg/kg IV dosed once every three weeks (Q3W). If successful, this single-arm extension cohort could support an accelerated approval for IDE849 in GEP-NEC.

IDEAYA also plans to submit a protocol for a randomized, confirmatory Phase 3 trial of IDE849 in multiple NEC

subtypes, including GEP-NEC and large cell NEC (LC-NEC), to support trial initiation by the end of the year. The randomized Phase 3 trial is intended to verify clinical benefit and support conversion of the potential accelerated approval to full approval in GEP-NEC and to expand approval in additional NEC subtypes, including LC-NEC, with the primary endpoints of progression free survival (PFS) for accelerated approval and overall survival (OS) for full approval. IDEAYA expects this trial to be well underway to fully enrolled at the time of the anticipated topline results from the single-arm trial.

In ES-SCLC, IDEAYA is on track to initiate a randomized Phase 3 registrational trial of IDE849 monotherapy in the post-Imdelltra setting by the end of the year, while continuing to evaluate several potential first-line study designs based on rational combinations that could offer differentiated safety and efficacy compared to current treatment standards.

Clinical Data Supporting the NEC Registrational Strategy

In October 2026, IDEAYA's partner Hengrui presented updated Phase 1 results for IDE849 at doses ≥1.8 mg/kg IV Q3W at the European Society for Medical Oncology (ESMO) Congress. Among 19 patients with 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). The median PFS was 7.0-months and the nine-month OS rate was 82.4%, complementing the promising clinical efficacy also reported from refractory SCLC patients in the trial. Across a total of 122 patients in the trial, IDE849 continued to demonstrate a favorable safety profile, with Grade 1-2 interstitial lung disease (ILD) observed in 6.6% (n=8) of patients and Grade ≥3 ILD in 0.8% (n=1). IDEAYA is evaluating IDE849 in an ongoing Phase 1/2 global trial in both ES-SCLC and NEC, where a Grade ≥3 TRAE rate of 5% (1/20) at 2.4 mg/kg and 22.2% (4/18) at 3.5 mg/kg expansion doses has been observed.

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 ES-SCLC and other NECs. In December 2024, IDEAYA licensed the global development and commercialization rights to IDE849 outside of Greater China from Hengrui.

About NECs

High DLL3 expression has been reported across multiple solid tumor subtypes of NECs that remain areas of high unmet medical need with few treatment options, including 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 United States, EU5, and Japan, the annual incidence of metastatic GEP-NEC and LC-NEC is projected to be approximately 7,000 patients and 8,000 patients, respectively. Multiple other subtypes of NECs also have high DLL3 expression, including bladder and cervical, among others.

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, including statements regarding IDEAYA's registrational strategy for IDE849 in NEC and ES-SCLC, including the planned expansion of Arm 5 of the Phase 1 study, the planned randomized confirmatory Phase 3 trial, and trial design, endpoints, patient population, enrollment, comparator, timing and dose selection; the potential for accelerated and full approval; and the potential clinical profile of IDE849. Such statements are subject to risks and uncertainties, including that the FDA's feedback from regulatory meetings is preliminary and nonbinding, and the FDA may subsequently require modifications to the proposed trial designs, endpoints, patient population, statistical analysis plan or regulatory strategy, or require additional data or trials; the FDA may determine that a single-arm study or overall response rate does not support accelerated approval, may require that a confirmatory trial be underway prior to approval, or that the trial results do not verify clinical benefit or support full approval; IDEAYA may experience delays in selecting a recommended Phase 3 dose or in initiating, enrolling, conducting or completing clinical trials; early clinical results, including those from a Phase 1 trial conducted by Hengrui in China, may not be reproduced in later trials; and other risks described in IDEAYA's filings with the Securities and Exchange Commission. IDEAYA undertakes no obligation to update forward-looking statements except as required by law.

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https://media.ideayabio.com/2026-11-16-IDEAYA-Biosciences-Announces-Successful-US-FDA-Type-C-Meeting-on-Phase-2-3-Registrational-Trial-Designs-to-Support-Potential-Accelerated-and-Full-Approval-for-IDE849,-a-Potential-Best-in-Class-DLL3-TOP1-ADC,-in-Neuroendocrine-Carcinomas