Elpiscience Presents Phase I Data for First-in-Class ES014 (CD39/TGF-β Bispecific) in Oral Session at ESMO Asia

On December 5, 2025, Elpiscience, a clinical-stage biopharmaceutical company dedicated to developing innovative immunotherapies, presented phase I clinical trial results for its internally developed bispecific antibody, ES014, in an oral presentation at the ESMO Asia Congress.

ES014 is a first-in-class CD39/TGF-β bispecific antibody developed by Elpiscience, and the first molecule globally to enter the clinical stage that simultaneously targets the CD39-adenosine and TGF-β pathways—two critical immunosuppressive mechanisms in the tumor microenvironment. ES014 holds the potential for treating a variety of solid tumors. Preclinical studies have demonstrated a favorable safety profile and antitumor activity, indicating its potential both as a monotherapy and in combination with other agents such as chemotherapy and PD-1 checkpoint inhibitors.

Elpiscience announced that the first-in-human Phase I clinical results of ES014, the world's first-in-class CD39/TGF-β bispecific antibody developed in-house, will be presented as an oral presentation at the Proffered Paper Session during ESMO Asia 2025, scheduled to take place on December 5, 2025, in Singapore.

The presented data are based on an ongoing open-label, multi-center phase I clinical trial of ES014 in China (comprising the dose escalation part and the cohort expansion part), designed to evaluate the safety and efficacy of ES014 monotherapy in patients with advanced solid tumors. Patient enrollment was completed in June 2025. The dose escalation part included five dose levels (20 mg to 1400 mg, administered every two weeks). The cohort expansion part enrolled patients with various tumor types, including non-small cell lung cancer (NSCLC), gastrointestinal stromal tumors (GIST), and desmoid tumors (DT). The primary endpoints were safety and tolerability, and the secondary endpoints included pharmacokinetics, immunogenicity, and preliminary anti-tumor activity.

The study enrolled a total of 75 patients, including 43 patients with NSCLC (57.3%), 10 patients with GIST (13.3%), 5 patients with DT (6.7%), and 17 patients with other solid tumors. 45% of patients had received three or more prior lines of therapy. The median age was 64 years. 54 patients were male (72%) and 21 were female (28%).

ES014 demonstrated a favorable safety profile with no observed DLTs and most adverse events were mild.

Results showed that ES014 has a very favorable safety profile, with no dose-limiting toxicities (DLTs) observed. Most adverse events were mild (Grade 1 or 2). The most common treatment-related adverse events (TRAEs) included anaemia, rash, and pruritus, all of which are known to be associated with TGF-β inhibition. Grade 3 or higher TRAEs occurred in 16% of patients, and there were no treatment-emergent adverse events (TEAEs) leading to death.

ES014 demonstrated monotherapy efficacy across multiple solid tumors, achieving 40% ORR in Desmoid Tumors (DT).

ES014 exhibited significant monotherapy activity in patients with DT. Among the 5 DT patients treated with ES014, 2 achieved partial response (PR) and 3 achieved stable disease (SD), resulting in an objective response rate (ORR) of 40% and a disease control rate (DCR) of 100%. Both patients who achieved PR remain on treatment. As a rare tumor characterized by high local aggressiveness and recurrence rates, DT currently lacks effective and safe treatment options, representing a significant unmet clinical need. With its superior efficacy and safety profile, ES014 holds promise to bring new hope to DT patients.

In the NSCLC cohort, the study found a significant correlation between baseline CD39 combined positive score (CPS) and clinical benefit. Among the 21 response-evaluable NSCLC patients treated at the recommended doses who had high baseline CD39 expression baseline CD39 CPS ≥ 5), 1 achieved PR and 10 achieved SD, resulting in a DCR of 52.4%. By contrast, among the 8 response-evaluable NSCLC patients treated at the recommended doses who had low baseline CD39 expression (CD39 CPS < 5), only 1 achieved SD, resulting in a DCR of 12.5%. These results demonstrate a significant correlation between baseline CD39 expression levels and treatment response in the NSCLC cohort, supporting CD39 as a potential biomarker for selecting NSCLC patients for ES014 treatment.

ES014 also showed positive signals of clinical benefit in the gastrointestinal stromal tumor (GIST) patient population. Among 10 GIST patients treated with ES014, 1 achieved PR and 6 achieved SD, resulting in a DCR of 70%. Notably, in the subgroup of 4 wild-type GIST patients, tumor shrinkage was observed in 2 patients, with 1 achieving PR. These results suggest that ES014 has the potential to provide a new treatment option for GIST, particularly for patients with wild-type GIST.

Professor Shun Lu, Academic Leader of the Department of Oncology at Shanghai Chest Hospital and Director of the Shanghai Lung Tumor Clinical Medical Center

noted,"ES014 innovatively blocks two key immunosuppressive pathways, CD39 and TGF-β, providing a novel strategy for clinical oncology treatment. The results of this phase I study show that ES014 has a favorable safety profile and clear pharmacodynamic characteristics. Preliminary efficacy signals were observed in multiple tumor types, including non-small cell lung cancer, gastrointestinal stromal tumors, and desmoid tumors, which is very encouraging. This study fully demonstrates ES014's strong potential for treating various solid tumors and is expected to bring a novel and effective treatment option to these patients."

Dr. Xiaohui Ji, Co-founder and CEO of Elpiscience noted,"ES014 is a significant innovation resulting from Elpiscience's deep commitment to immunology. The clinical progress announced at ESMO Asia further validates the innovation of ES014 as a first-in-class asset and its clinical application potential in the field of solid tumors. We are delighted to see ES014 safely and effectively addressing unmet clinical needs for cancer patients, especially for diseases like desmoid tumors that lack standard treatments. In the future, Elpiscience will accelerate the subsequent development of ES014 to bring breakthrough treatment solutions to more cancer patients."

About Elpiscience

Elpiscience is a clinical-stage biopharmaceutical company dedicated to the development of innovative immunotherapies for oncology and autoimmune diseases. By advancing breakthrough biologics and leveraging global strategic partnerships, Elpiscience has built a differentiated pipeline to deliver transformative treatment solutions for patients worldwide.

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