New Antibody-Drug Conjugate Shows Clinical Benefit for Advanced Ovarian Cancer

The investigational drug led to objective response and disease control in patients with late-stage disease.

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San Diego – Patients with advanced platinum-resistant ovarian cancer whose disease had progressed on standard therapy experienced clinical benefit when treated with the investigational antibody-drug conjugate (ADC) QLS5132, according to results from a Phase I clinical trial presented at the American Association for Cancer Research (AACR) Annual Meeting 2026, held April 17-22.

Patients diagnosed with platinum-resistant ovarian cancer face both a poor prognosis and limited treatment options, explained Tao Zhu, MD, chief physician and vice president of Zhejiang Cancer Hospital in China, who presented the study.

Zhu and collaborators tested an investigational ADC, QLS5132, which targets the protein CLDN6. QLS5132 combines a CLDN6-targeting monoclonal antibody with a cytotoxic payload, topoisomerase-1 inhibitor, at a drug-to-antibody ratio of 8:1. CLDN6, Zhu said, makes an ideal target as a protein with very high expression on the surface of ovarian cancer cells and minimal cell-surface expression in healthy tissues.

“The primary purpose of this first-in-human study was to evaluate the safety, tolerability, and pharmacokinetic profile of QLS5132 in patients with platinum-resistant ovarian cancer and determine the recommended phase II dose for future clinical development,” Zhu said. “Additionally, we aimed to assess preliminary antitumor activity to establish an early signal of clinical benefit in this heavily pretreated population with limited options.”

The Phase I, single-arm, dose-escalation trial enrolled 28 patients with a median age of 57.5 who had been diagnosed with advanced platinum-resistant ovarian cancer and who had experienced progression while on standard therapy. The research team administered QLS5132 as an intravenous infusion every three weeks at dose levels of 1.6 mg/kg, 3.2 mg/kg, 4.8 mg/kg, 5.6 mg/kg, and 6.4 mg/kg.

Treatment-related adverse events (TRAEs) occurred in 26 (92.9%) patients, with nausea, anorexia, anemia, and weakness occurring most frequently. Nine (32.1%) patients experienced TRAEs of grade 3 or higher, and of those grade ≥3 TRAEs, seven were instances of hematological toxicity. No TRAEs led to treatment discontinuation or death, and no patients experienced interstitial lung disease, ocular toxicity, or febrile neutropenia, Zhu said.

After a median follow-up of 2.2 months, nine patients had a partial response at various dose levels. Two of these partial responses occurred in patients who had no detectable CLDN6 expression.

Across all dose levels, 18 evaluable patients experienced an objective response rate of 50% and a disease control rate of 94.4%. When calculated for the 17 evaluable patients who had received dose levels ≥3.2 mg/kg, the objective response rate and disease control rate rose to 52.9% and 100%, respectively. These responses to QLS5132 occurred irrespective of patients' CLDN6 expression levels at baseline.

"The most encouraging finding from our study was that QLS5132 demonstrated compelling antitumor activity in patients with platinum-resistant ovarian cancer, with an objective response rate exceeding 50%," said Zhu. "Equally important, at the potential recommended phase II dose, we observed a favorable safety profile with no reported cases of interstitial lung disease, ocular toxicity, oral mucositis, or febrile neutropenia."

Zhu also noted that, though more research would be needed to confirm, preliminary data indicated antitumor activity from QLS5132 regardless of CLDN6 expression levels—which, he said, could expand its potential as a treatment option to a broad cohort of patients with platinum-resistant ovarian cancer.

Zhu acknowledged that further research would be needed to fully understand why QLS5132 can have anticancer effects in patients with undetectable CLDN6 tumoral expression. But he suggested the phenomenon may have a few explanations, including tumor heterogeneity, as well as a potent bystander effect resulting in antitumor efficacy even in cells with low or no CLDN6 expression.

"These findings support the advancement of QLS5132 into phase III studies, with the goal of providing a much-needed new treatment option for these patients," said Zhu.

Limitations of this study include a small sample size and an exploratory single-arm design.

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