Novel ADC Shows Antitumor Activity in Patients With Advanced Ovarian Cancer

More than half of patients taking a higher dose of Rina-S had confirmed objective responses, including two complete responses.

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Elizabeth K. Lee, MD, a medical oncologist in the gynecologic oncology program at Dana-Farber, presented results from a phase 1/2 clinical trial reporting that rinatabart sesutecan (Rina-S), an investigational, novel antibody-drug conjugate directed at folate receptor alpha (FRα), showed encouraging preliminary antitumor activity as a single agent in a dose expansion cohort of patients with advanced ovarian cancer.

Ovarian cancer is the fifth leading cause of cancer-related mortality in women with most patients presenting with advanced disease at the time of diagnosis.

The findings from the B1 cohort of the RAINFOL-01 study were presented by Lee today at the Society for Gynecologic Oncology (SGO) Annual Meeting, the foremost scientific gathering for professionals dedicated to the treatment and care of individuals with gynecologic cancer.

The open-label, multicenter phase 1/2 study tested Rina-S in a cohort of 42 patients with heavily treated advanced ovarian cancer. Patients received one of two doses of Rina-S (100 mg/m2 or 120 mg/m2) every three weeks.

After a median of 24 weeks of follow-up, 22.7% of patients taking the lower dose and 55.6% of patients taking the higher dose had confirmed objective responses, with 2 complete responses in the higher dose group. Side effects included low blood counts and gastrointestinal distress. The results support further testing of single-agent Rina-S at 120mg/m2; enrollment of patients with platinum resistant ovarian cancer is ongoing in a phase 2 study (RAINFOL-OV1) and in a randomized phase 3 study (RAINFOL-OV2/GOG-3107, NCT06619236).

“Rina-S, a novel FRa-directed antibody drug conjugate, demonstrated encouraging activity in patients with ovarian cancer, across FRa expression levels,” said Lee. “These findings presented at SGO today support the further study of Rina-S in ovarian cancer.”

The RAINFOL-01 study consists of multiple parts including Part A dose-escalation cohorts; Part B tumor-specific monotherapy dose-expansion cohorts; Part C platinum-resistant ovarian cancer (PROC) cohort; and Part D combination therapy cohorts.

Part B of the trial includes the B1 cohort. Initial results from Part B of this trial were presented by Lee during a mini-oral session at the European Society of Medical Oncology Congress 2024 (ESMO).

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