Clinical Benefit of Mirvetuximab Soravtansine in Ovarian Cancer Patients With High Folate Receptor
Alpha Expression: Results From the Soraya Study


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BACKGROUND AND OBJECTIVE

Mirvetuximab soravtansine (MIRV) is an antibody-drug conjugate (ADC) targeting folate receptor alpha (FRα) in patients with platinum-refractory advanced ovarian cancer. The results of the phase 3 SORAYA trial (NCT04296890) showed that MIRV demonstrated clinical benefit and a manageable safety profile. This analysis presents updated safety and efficacy results from the SORAYA study.

METHODS

SORAYA is a global, single-arm, phase 3 study that evaluated MIRV for the treatment of patients with platinum-resistant ovarian cancer. The primary endpoint was overall survival, and the secondary endpoints included response rate, disease control rate, progression-free survival, and safety. Patients were recruited from multiple centers across the globe.

RESULTS

The safety population contained 106 patients who received ≥1 dose of MIRV. The efficacy-evaluable population consisted of 105 patients who had measurable disease and were treated with ≥1 dose of MIRV. Treatment with MIRV demonstrated clinically meaningful antitumor activity, and disease control was observed in 51% of patients (95% CI, 40.3–61.4). In the efficacy-evaluable population, the disease control rate was 51% (95% CI, 40.3–61.4). Median duration of response was 12.0 months (range, 6.7–24.1 months). Median overall survival had not been reached (95% CI, 15.8–Not Reached).

The most frequently reported adverse events were neutropenia, fatigue, nausea, anemia, and vomiting. The incidence of adverse events with a grade ≥3 was 11% (n=12). There were 16 treatment-related deaths, 9 of which were classified as possibly related to study drug. One death was recorded as related to study drug, and 5 of the 16 deaths were classified as not related to study drug.

CONCLUSIONS

The results from the SORAYA study confirm the clinical benefit and manageable safety profile of MIRV in patients with platinum-resistant ovarian cancer. These findings support the continued evaluation of MIRV in this patient population, and further studies are needed to explore the potential of MIRV as a frontline treatment option.

For more information, please visit: https://clinicaltrials.gov/ct2/show/NCT04296890