**Background**

Microsatellite instability-high (MSI-H)/mismatch repair-deficient (dMMR) tumors share common histopathologic characteristics that may make them susceptible to immune checkpoint-directed therapies that generally work well for colorectal cancers (CRC) and other solid tumors with high levels of cancer-specific neoantigens.

**Objectives**

- To evaluate the safety and antitumor activity of tislelizumab monotherapy for patients with gynecological MSI-H/dMMR tumors.
- To assess the prevalence of durable clinical benefit and immune-related adverse events (AEs) in these patients.
- To report the updated safety and efficacy results from the RATIONALE 209 trial.

**Methods**

- **Study Design:** Tislelizumab (NCT03736889) is an ongoing single-arm, non-randomized, open-label, multicenter study conducted at 26 sites in China.
- **Patient Selection:** Eligible patients were adults with histologically-confirmed MSI-H/dMMR tumors of any histology except CRC.
- **Treatment:** Tislelizumab was administered at a dose of 200 mg intravenously every 3 weeks.
- **Endpoints:** Safety variables including extent of exposure to study treatments and incidence of AEs were assessed among responders using descriptive statistics.

**Findings**

- **Safety Analysis:** One hundred and ninety patients (N=190) were treated with tislelizumab, including 17 patients with gynecological MSI-H/dMMR tumors. The most common Grade ≥ 3 TEAEs were urinary tract infection (3/17 [17.6%]), abdominal pain (3/17 [17.6%]), and fatigue (3/17 [17.6%]).
- **Efficacy Analysis:** The tumor type, n (%): cervical cancer 15 (88.2), endometrial cancer 1 (5.9), and others 1 (5.9).
- **Clinical Outcomes:** Among 17 patients with gynecological tumors, ORR was 10% (95% CI: 0.0–20.0), including 1 CR (6.0%) and 6 SD (35.3%) patients, and the disease control rate was 53.0% (95% CI: 28.4–75.6).
- **Survival Analysis:** The median follow-up duration was 4.9 months, and no new safety signals were observed.

**Conclusions**

This phase 2 study demonstrated that tislelizumab was clinically active in patients with gynecological MSI-H/dMMR tumors and was generally well tolerated with no new safety signals.

**Disclosures**

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**References**