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Risvutatug rezetecan (Ris-Rez) versus gemcitabine and docetaxel (GD) in heavily pretreated patients (pts) with relapsed or refractory (R/R) osteosarcoma: Primary results from the phase 3 ARTEMIS-011 study

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Background

Ris-Rez (HS-20093/GSK5764227), a B7-H3-directed antibody-drug conjugate (ADC), previously showed promising antitumor activity with manageable toxicity in heavily pretreated pts with R/R sarcomas. Here, we report the primary results from a phase 3 ARTEMIS-011 study (NCT06935409) comparing Ris-Rez with GD in Chinese pts with R/R osteosarcoma.

Methods

ARTEMIS-011 was a multi-center, open-label, randomized phase 3 trial. Eligible pts should have progressed or relapsed after ≥2 prior lines of systemic therapy. Pts (≥12 years) were randomized (2:1) to receive either Ris-Rez 12.0 mg/kg every 3 weeks (Q3W) or GD Q3W. The primary endpoint was progression-free survival (PFS) assessed by Blinded Independent Central Review (BICR).

Results

As of data cutoff (June 17, 2026), a total of 122 pts were randomized to receive Ris-Rez (n=80) or GD (n=42), the median (m) follow-up time was 7.1 months (mo). The median age was 21.0 years, 31 pts (25.4%) were adolescents (12-18 years). Ris-Rez demonstrated a statistically significant and clinically meaningful improvement in BICR-assessed PFS compared with GD (mPFS, 5.5 vs. 1.4 mo; HR, 0.33; p<0.0001), consistent with Investigator-assessed mPFS (5.6 vs. 1.0 mo). OS data were immature, but a favorable trend was observed toward Ris-Rez (HR, 0.51). Ris-Rez showed a manageable safety profile. Grade ≥3 TEAEs were reported in 92.5% with Ris-Rez vs. 83.3% with GD. Incidence of treatment-related SAE was numerically higher with Ris-Rez than with GD (63.8% vs. 28.6%), mainly driven by hematologic toxicities. Treatment discontinuation due to TRAE was similar between the groups (3.8% vs. 2.4%). One treatment-related interstitial lung disease was reported (CTCAE grade 2, resolved) in Ris-Rez group. No treatment-related deaths or new safety signals were observed.

Conclusions

In the ARTEMIS-011 study, Ris-Rez demonstrated a statistically significant and clinically meaningful improvement in BICR-assessed PFS, accompanied by a favorable trend in OS and a manageable safety profile, highlighting its potential as a new treatment standard for patients with R/R osteosarcoma.

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Legal entity responsible for the study

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Disclosure

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