BERLIN 2025 ESMO congress

LBA105

A phase II, open-label, single-arm, multi-center study of rivoceranib in patients with metastatic thymic epithelial tumor, KCSG LU23-09 (THRIVE)

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Background

Metastatic thymic epithelial tumors (TETs) are rare and aggressive malignancies with limited treatment options beyond cytotoxic chemotherapy. Multi-target tyrosine kinase inhibitors (TKIs) with anti-angiogenic activity have shown benefit but limited efficacy. Rivoceranib, a selective VEGFR-2 inhibitor, was evaluated in patients with metastatic TET after prior therapy.

Methods

This open-label, multicenter, prospective, single-arm phase II study enrolled patients with histologically confirmed metastatic TET across 11 centers in South Korea. Rivoceranib 700 mg orally once daily was administered as second- or later-line therapy. Primary endpoint: objective response rate (ORR). Secondary endpoints: progression-free survival (PFS), disease control rate (DCR), duration of response (DoR), and safety.

Results

Forty patients were enrolled (median age 60 years, range 29–82); thymic carcinoma (60.0%) was most common. Median follow-up was 3.7 months (95% CI 2.7–4.5); 70.0% remain on treatment. Among 36 evaluable patients, ORR was 38.9% (14 partial responses), and DCR was 94.4% including 20 stable disease. Median PFS was not reached (95% CI 2.7 months–NR), with 7 PFS events (5 progressions, 2 deaths). Median DoR was 1.7 months (range 0.2–4.8 months), with 92.9% of responses ongoing. Dose modification occurred in 62.5%. Common drug-related adverse events were hypertension (47.5%), proteinuria (42.5%), and stomatitis (35.0%), mostly grade 1–2. Grade 3 events included hypertension (n=7), proteinuria (n=4), stomatitis (n=4), anemia (n=3), cardiac failure (n=2), and one case each of palmar-plantar erythrodysaesthesia, ALT elevation, myalgia, and one grade 4 proteinuria. Three patients discontinued treatment due to the drug-related adverse events. All were manageable with supportive care.

Conclusions

Rivoceranib showed meaningful clinical efficacy with durable disease control and an acceptable safety profile in metastatic TET. These findings support rivoceranib as a potential systemic treatment option and warrant further investigation.

Clinical trial identification

NCT06200233.

Editorial acknowledgement

This work was supported by HLB by providing rivoceranib and funds for this study. The source of funding had no role in the study design, data collection, data analysis, data interpretation, or writing of the report.

Legal entity responsible for the study

Myung-Ju Ahn.

Funding

HLB.

Disclosure

All authors have declared no conflicts of interest.