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Ivonescimab plus chemotherapy as first-line treatment in recurrent/metastatic thymic carcinoma: Results from the iTHYM phase II study

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Background

Recurrent or metastatic thymic carcinoma is a rare and aggressive malignancy with limited prospective evidence for systemic treatment. Platinum-based chemotherapy remains a standard first-line option, but durable disease control remains suboptimal. This study aimed to evaluate ivonescimab, a PD-1/VEGF bispecific antibody, combined with chemotherapy as first-line treatment for this population.

Methods

iTHYM is a prospective, multi-center, single-arm phase II study of ivonescimab plus carboplatin and paclitaxel or nab-paclitaxel as first-line treatment for recurrent/metastatic thymic carcinoma, followed by ivonescimab maintenance until progression or unacceptable toxicity. The primary endpoint was 6-month progression-free survival rate (PFS_{6m}); secondary endpoints included ORR, DCR, DoR, PFS, OS, and safety. Simon's two-stage design defined success as no more than 10 progression events at 6 months among 24 treated patients (NCT06750952).

Results

As of July 31, 2026, 24 patients were enrolled and treated. Among 24 evaluable for response, 20 achieved partial response and 4 had stable disease, yielding an ORR of 83.3% and a DCR of 100.0%. Nineteen patients were evaluable for the primary endpoint, and all 19 remained progression-free at 6 months. After a median follow-up of 10.2 months, four patients experienced progression at 7.0, 8.1, 10.8, and 18.2 months. Based on the pre-specified Simon decision rule, the study met its primary endpoint of PFS6m. Median PFS and OS were not reached. Safety was manageable and consisted mainly of chemotherapy-related hematologic toxicities; ivonescimab-related adverse events were mostly low-grade, including hemorrhage (oral hemorrhage and epistaxis) (9/24, 37.5%), rash/pruritus (8/24, 33.3%), and proteinuria (3/24, 12.5%). Grade 3 proteinuria occurred in 2/24 (8.3%); Grade 3 acute coronary syndrome occurred in 1/24 (4.2%), leading to permanent discontinuation of ivonescimab.

Conclusions

Ivonescimab plus taxanes and carboplatin showed encouraging antitumor activity and manageable safety as first-line treatment for recurrent/metastatic thymic carcinoma. The iTHYM study met its pre-specified primary endpoint of 6-month PFS rate. Longer follow-up is ongoing to define the final PFS_{6m} estimate, durability of benefit, and long-term outcomes.

Clinical trial identification

NCT06750952.

Legal entity responsible for the study

Sun Yat-sen University Cancer Center.

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Disclosure

All authors have declared no conflicts of interest.

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