(PS1880) REAL-WORLD OUTCOMES OF ZEVORCABTAGENE AUTOLEUCEL, A FULLY HUMAN BCMA-TARGETED CAR-T THERAPY, IN 136 PATIENTS WITH MULTIPLE MYELOMA (MM): A MULTICENTER EXPERIENCE FROM CHINA

Topic: 14. Myeloma and other monoclonal gammopathies - Clinical

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Background

Zevorcabtagene Autoleucel (Zevor-cel) is a fully human BCMA-targeted CAR-T therapy. Based on its pivotal registrational clinical study (LUMMICAR-1), it received NMPA approval in February 2024 for adults with relapsed/refractory multiple myeloma (RRMM) after ≥3 prior therapies.

Aims

This study presents, for the first time, the efficacy and safety of Zevor-cel in a real-world study in China, providing evidence-based support for its application in clinical practice.

Methods

We conducted analysis on data from 136 patients who received infusion therapy across 51 centers between April 1, 2024 and December 31, 2025. Median follow-up was 7.5 months. All patients received a single infusion of Zevor-cel at the dose of 1.5×10^8 CAR-T cells/kg. Responses were evaluated per IMWG criteria, and the overall response rate (ORR) was defined as at least ≥PR.

Results

All 136 patients underwent leukapheresis followed by Zevor-cel infusion. Median age was 63.5 years (range: 22–83), with 30.1% aged ≥70. Disease characteristics included high-risk cytogenetics (58.3%, 67/115; 21 of 136 patients had no available FISH results), extramedullary myeloma (EMM) (60.3%, 82/136), plasma cell leukemia (PCL) (14.7%, 20/136), and central nervous system (CNS) involvement (5.1%, 7/136). The median prior therapy lines were 3 (range:1–11).
In the efficacy-evaluable population (n=120; excluding 6 deaths and 1 lost to follow-up), the ORR was 90.8% (109/120), with 68.3% (82/120) achieving complete response (CR) or better. Among these patients, 8 had prior exposure to BCMA-targeted therapies, including CAR-T, BiTE, or ADC. One patient relapsed after GPRC5D-directed CAR-T therapy. Among these 9 patients, the ORR also reached 77.8% (7/9). In the EMM subgroup, ORR was 90.5% vs 95.7% in the non-EMM subgroup, with ≥CR rates 60.8% and 80.4% respectively. The ORR and CR rates varied between treatment lines, with early-line therapy (1–3 prior lines) achieving an ORR of 97.9% and a CR of 72.9%, compared to 86.1% ORR and 65.3% CR in late-line settings (3rd line or later). Patients without high-risk cytogenetics had a higher ORR rate (94% vs 87.8%).
The most common zevor-cel-related treatment-emergent adverse events (TEAEs) were cytopenias, with at least 1 grade ≥3 haematological toxicity in all patients. Hematotoxicity resolved within 30 days in most patients. Regarding the incidence of prolonged hematotoxicity, the proportions of grade 3/4 neutropenia, lymphopenia, anemia, and thrombocytopenia were 38.2%, 27.6%, 33.3%, and 34.1%, respectively. CRS of any grade was reported in 88 (73.3%) patients, with the majority classified as grade 1 and grade 2. Only 1 patient experienced grade 3 cytokine release syndrome (CRS). Immune effector cell-associated neurotoxicity syndrome (ICANS) was 5.8% (7/120), with 6 patients classified as grade 1 and 1 patient as grade 3.

Summary/Conclusion

Zevor-cel, as a fully human BCMA-targeted CAR-T therapy, demonstrated high efficacy in 120 evaluable patients. Despite high-risk features including high-risk cytogenetics (58.3%)、EMM (60.3%), PCL (14.7%), and CNS infiltration (5.1%), outcomes aligned with the pivotal LUMMICAR STUDY1(NCT03975907) trial. Safety profiles showed predominantly low-grade CRS and an extremely low incidence of ICANS. These results validate Zevor-cel as an effective therapeutic option with a potential superior safety profile, although longer follow-up is required to evaluate survival outcomes and long-term safety profiles.