Immune Response, Safety, and Survival Impact from CMB305 in NY-ESO-1+ Recurrent Soft Tissue Sarcomas (C131 Study)

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Abstract 2951

Efficacy Outcomes with CMB305 in Soft Tissue Sarcoma

Objective: To report safety, immune response, and anti-tumor activity from CMB305 in NY-ESO-1+ recurrent soft tissue sarcoma (STS) patients from the C131 clinical trial.

Patients: Patients with NY-ESO-1+ RT/AT or metastatic synovial sarcoma (SS) were eligible. Randomized: patients received 2 cycles of CMB305 + trabectedin (Arm A) or 4 cycles of G305 + trabectedin (Arm B). Median follow-up: 11 months. 14 patients in Arm A and 7 in Arm B. 22 patients evaluable for overall survival (OS), 18 evaluable for disease control.

Results: Median OS was 14 months (95% CI: 0.1785, 0.9955) in Arm A. Median OS was not reached in Arm B (95% CI: 10.57, 20.67). Median PFS was 7 months (95% CI: 3.70, 11.67) in Arm A. Median PFS was not reached in Arm B (95% CI: 1.66, Not Reached). 8 myxoid/round cell sarcoma patients; 12 pleomorphic sarcoma patients; 1 synovial sarcoma patient. No Grade 4 or 5 events. The best tumor response was partial response (PR) in 11 patients. Disease control was achieved in 12 patients (56%); 9 patients (39%) had a stable disease (SD) response. 

Conclusion: CMB305 monotherapy was well tolerated and demonstrated anti-tumor activity in NY-ESO-1+ sarcoma patients. Median OS of 14 months in Arm A is substantially longer than historical controls for advanced sarcoma disease. Further study is warranted in NY-ESO-1+ sarcoma patients.