

Transcript Details

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Updated Overall Survival From Stage 1 of PRESERVE-003: Gotistobart vs Docetaxel in Metastatic Squamous NSCLC After Anti-PD-(L)1 Progression

Announcer:

You're listening to GLC on ReachMD. This activity, titled 'Updated Overall Survival From Stage 1 of PRESERVE-003: Gotistobart vs Docetaxel in Metastatic Squamous NSCLC After Anti-PD-(L)1 Progression,' is provided by Global Learning Collaborative.

Dr. Cho:

Hello, I'm Dr. Byoung Chul Cho from Yonsei Cancer Center in Seoul. I will briefly review the updated results from stage 1 of PRESERVE-003 presented at WCLC 2026 and discuss their clinical implications.

PRESERVE-003 is an international randomized two-stage phase 3 trial comparing gotistobart with docetaxel in patients previously treated with platinum-based chemotherapy whose disease had progressed on PD-1 or PD-L1 inhibitors. Gotistobart is a next-generation pH-sensitive anti-CTLA-4 antibody designed to enhance depletion of regulatory T cells within the tumor.

Stage 1 enrolled 217 patients across squamous and non-squamous NSCLC. This update focused on the squamous cohort; 45 patients received the selected gotistobart regimen, and 42 received docetaxel. The primary endpoint is overall survival, with response, progression-free survival, and safety as the secondary endpoints.

The key finding is that survival advantage remains evident with longer follow-up. At a median follow-up of 25.4 months, median overall survival was 18.5 months with gotistobart versus approximately 10 months with docetaxel, with a hazard ratio of 0.56. What stands out to me is the magnitude of this difference in patients whose disease has already progressed after immunotherapy.

The pharmacology findings also support the loading-dose regimen which achieves higher exposure early in the treatment. Higher drug exposure was associated with better survival. On safety, grade 3 or higher treatment-related adverse events occurred in approximately 44% versus 49% of patients. However, serious treatment-related events and discontinuation were more frequent with gotistobart. In my view, this reinforces the importance of careful management of immune-related toxicity.

For me, these results suggest that a different immunotherapy approach may still provide benefit after progression on PD-1 or PD-L1 treatment. However, this was a small non-pivotal cohort. I would view the finding as an encouraging randomized signal rather than practice-changing evidence.

The pivotal stage 2 study, which focuses exclusively on squamous NSCLC, has reached its enrollment target. Confirmation in that study will be essential. If confirmed, gotistobart could offer a chemotherapy-free option for a population with a substantial unmet need. An important next step, in my view, will be identifying which patients are most likely to derive durable benefit.

I hope this brief review has been helpful. Thank you for listening.

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