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Final analysis of first-line serplulimab plus chemotherapy with or without HLX04 in advanced nonsquamous non-small cell lung cancer: The ASTRUM-002 phase III study

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Background

Interim analysis of ASTRUM-002 study demonstrated a significant improvement in progression-free survival (PFS) for serplulimab (PD-1 inhibitor) plus chemotherapy (chemo) versus chemo alone in patients with advanced nonsquamous non-small cell lung cancer (nsqNSCLC). Here, we present the overall survival (OS) results for the first time and the updated results of efficacy and safety.

Methods

This was a three-arm, randomised, double-blind, multicentre, phase 3 study. Patients with locally advanced or metastatic nsqNSCLC without *EGFR* sensitizing mutations or *ALK*/*ROS1* rearrangements and no prior systemic therapy were randomised 1:1:1 to receive serplulimab + HLX04 + chemo (group A), serplulimab + chemo (group B), or chemo (group C). The primary endpoint was the BICR-assessed PFS per RECIST version 1.1. The key secondary endpoint was OS.

Results

Between Nov. 25, 2019 to Jun. 15, 2022, 636 patients were recruited across 72 hospitals in China. They were randomised to group A (n=212), B (n=214), or C (n=210). As of the data cutoff, Aug 07, 2025, median follow-up time was 48.4, 45.4, and 45.7 months for the respective groups. Median OS was 23.7 (95% CI 20.5–27.5), 26.8 (95% CI 21.2–30.9), and 20.3 months (95% CI 16.2–24.6), in group A, B, and C, respectively. A significant reduction in risk of death for group B compared to C was observed (HR=0.66, 95% CI 0.52–0.83, p=0.0004), while no statistical difference was observed for group A compared to B (HR=1.12, p=0.3628). Subgroup analysis of median OS was consistent with that of the primary findings. Median PFS and tumour response continued to be improved for group B compared to group C. Treatment-related adverse events leading to death occurred in 10 (4.7%), 5 (2.3%), and 7 (3.3%) patients, in groups A, B, and C, respectively.

Conclusions

The combination of serplulimab to chemo significantly prolonged OS and continued to confer significant PFS and clinical benefits compared to chemo alone, making it a promising first-line treatment option for patients with locally advanced or metastatic nsqNSCLC. The addition of HLX04 to serplulimab and chemo did not lead to a further improvement. Both investigated treatment regimens had manageable safety profiles.

Clinical trial identification

NCT03952403.

Legal entity responsible for the study

Shanghai Henlius Biotech, Inc.

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Disclosure

H. Yu, J. Li, Q. Wang: Financial Interests, Personal, Full or part-time Employment: Shanghai Henlius Biotech, Inc. All other authors have declared no conflicts of interest.