Abstract 1950

# GEMSTONE-301: A randomized, double-blind, placebo-controlled, phase 3 study of sugemalimab in patients with unresectable stage III non-small cell lung cancer (NSCLC) who had not progressed after concurrent or sequential chemoradiotherapy (CRT)

Type: Late-Breaking Abstract

Category: NSCLC, locally advanced

Authors: Y.-L. Wu[1], Q. Zhou[1], M. Chen[2], O. Jiang[3], D. Hu[4], Q. Lin[5], G. Wu[6], J. Cui[7], J. Chang[8], Y. Cheng[9], C. Huang[10], A. Liu[11], N. Cui[12], J. Wang[12], Q. Wang[12], M. Qin[12], R. Zhang[12], J. Yang[12]; [1]Department of Oncology, Guangdong Lung Cancer Institute, Guangdong Provincial People's Hospital, and Guangdong Academy of Medical Sciences, Guangzhou, China, [2]Department of Oncology, Zhejiang Cancer Hospital, Hangzhou, China, [3]Oncology center, The Second People's Hospital of Neijiang, Neijiang, China, [4]Department of Radiation Oncology, Hubei Cancer Hospital, Wuhan, China, [5]Department of Radiation Oncology, The First Affiliated Hospital of Xiamen University, Xiamen, China, [6]Oncology center, Union Hospital, Tongji Medical College, Huazhong University of Science and Technology, Wuhan, China, [7]Oncology center, The First Hospital of Jilin University, Changchun, China, [8]Department of Medical Oncology, Fudan University Shanghai Cancer Center, Shanghai, China, [9]Department of Radiation Oncology, Qilu Hospital of Shandong University, Jinan, China, [10]Department of Oncology, Fujian Medical University - Fujian Provincial Cancer Hospital, Fuzhou, China, [11]Department of Oncology, The Second Affiliated Hospital of Nanchang University, Nanchang, China, [12]Clinical Department, CStone Pharmaceuticals (Su Zhou) Co., Ltd., Shanghai, China

**Background**

Concurrent CRT (cCRT) followed by immunotherapy is the standard of care for patients (pts) with unresectable stage III NSCLC. However, nearly half of this population cannot tolerate cCRT, and thus sequential CRT (sCRT) is commonly utilized. We conducted a phase 3 trial to evaluate sugemalimab, a full-length, fully human IgG4 monoclonal antibody targeting PD-L1, as a consolidation treatment in pts with stage III NSCLC who had not progressed following cCRT or sCRT. This is the first phase 3 trial including both populations in this setting.

**Methods**

Eligible pts were randomized 2:1 to receive sugemalimab 1200 mg or placebo Q3W, stratified by ECOG performance status (0 vs 1), CRT type (cCRT vs sCRT), and total RT dose (<60 Gy vs ≥60 Gy). The primary endpoint was progression-free survival (PFS) by blinded independent central review according to RECIST v1.1.

**Results**

Of 381 pts randomized from 50 sites, 33.3% received prior sCRT, 69.6% had an ECOG performance status of 1, 69.0% had squamous cell carcinoma, and 28%/55%/16% had stage IIIA/IIIB/IIIC disease. At the pre-planned interim analysis with a median follow-up of 14 months, median PFS was 9.0 months with sugemalimab vs 5.8 months with placebo (HR 0.64; 95% CI 0.48–0.85; P=0.0026). The 12- and 18-month PFS rates were 45% vs 26% and 39% vs 23%, respectively. Consistent PFS benefit was observed regardless of whether pts received prior sCRT (median PFS 8.1 vs 4.1 months, HR 0.59) or cCRT (median PFS 10.5 vs 6.4 months, HR 0.66). Overall survival (OS) data were immature, but a trend favouring sugemalimab was observed (HR 0.44; 95% CI 0.27–0.73). The 12- and 18-month OS rates were 89% vs 76% and 82% vs 60%, respectively. Grade ≥3 treatment-emergent adverse events occurred in 24.3% of pts in the sugemalimab group and in 23.8% in the placebo group.

**Conclusions**

A statistically significant and clinically meaningful improvement in PFS was observed with sugemalimab vs placebo, with a well-tolerated safety profile. These results provide evidence for sugemalimab as a consolidation treatment

for pts with unresectable stage IIIA–C NSCLC who have not progressed following cCRT or sCRT.

**Clinical trial identification**

NCT03728556

**Editorial acknowledgement**

Editorial assistance was provided by Muge Qile of CStone Pharmaceuticals, and Ward A. Pedersen with Mary Lawrence of Parexel, funded by CStone Pharmaceuticals (Suzhou) Co., Ltd, Suzhou, China.

Print