Congress: WCLC 2022, August 6-9, 2022, Vienna, Austria	
Submission Deadline: Initial submission: March 16, 2022 (23:59 PST)= March 17, 16:00 Final LBA May 27, 2022 (23:59 PST)= May 28 15:00 BJ	**Submission type:** LBA
LBA notification date: April 20 2022	
Category: NSCLC	**ClinicalTrials.gov Identifier:** NCT03728556
Character Limit: **Word Limit:** 500 words (does not include title and authors) Abstracts should be organized in different sections based on the selected abstract type. Please refer to the 'Abstract Type' section on this page for further information. **Title Word Limit:** 125 characters total (including spaces) **Tables:** No limit; each table counts as 100 words **Images:** 2 maximum; each image counts as 100 words	**Current character count:** Title: 122 (containing space) Body 485 words

Title:

Sugemalimab vs placebo after cCRT or sCRT in pts with unresectable stage III NSCLC: final PFS analysis of a phase 3 study

Background

Sugemalimab is a full-length, fully human IgG4 monoclonal antibody targeting PD-L1. GEMSTONE-301 is an ongoing phase 3 trial to evaluate sugemalimab as a consolidation treatment in patients(pts) with stage III NSCLC without disease progression following chemoradiotherapy (CRT). This is the first phase 3 trial in this setting to include pts who received either concurrent or sequential chemoradiotherapy (cCRT or sCRT). In the PFS interim analysis, sugemalimab showed a statistically significant and clinically meaningful improvement in PFS compared with placebo. Here, we report the results from the pre-planned PFS final analysis, and preliminary results of OS.

Methods

Eligible pts ≥18 years of age with an ECOG performance status (PS) of 0 or 1 were randomized 2:1 to receive a fixed IV dose of sugemalimab 1200 mg or matching placebo once every 3 weeks as consolidation therapy for up to 24 months. Stratification factors included ECOG PS (0 vs 1), CRT type (cCRT vs sCRT), and total radiotherapy dose (<60 Gy vs ≥60 Gy). The primary endpoint was PFS by blinded independent central review (BICR) according to RECIST v1.1. Secondary endpoints included OS, investigator-assessed PFS, ORR, DoR, et al.

Result

A total of 381 pts were randomized. As of PFS final analysis (1 Mar 2022), treatment was ongoing for 62 (24.3%) pts in the sugemalimab group and 26 (20.6%) pts in the placebo group. The median follow-up duration was 27.1 and 23.5 months, respectively. The PFS assessed by BICR was longer in the sugemalimab group vs placebo (stratified HR 0.65; 95% CI 0.50–0.84; mPFS 10.5 vs 6.2 months). The 24- and 36-month PFS rates were 38.6% vs 23.1% and 26.1% vs 0, respectively. Consistent PFS benefit was observed with sugemalimab vs placebo, regardless of whether pts received prior sCRT (HR 0.57, mPFS 8.1 vs 4.1 months) or cCRT (HR 0.71, mPFS 15.7 vs 8.3 months). Median OS was not reached with sugemalimab vs 25.9 months with placebo (HR 0.69; 95% CI 0.49–0.97) and results were consistent in pts who received prior sCRT (HR 0.60, mOS not reached vs 24.1 months) or cCRT (HR 0.75, mOS not reached vs 32.4 months). The 24- and 36-month OS rates were 67.6% vs 55.0% (sCRT 70.7% vs 53.7%; cCRT 66.3% vs 57.6%) and 55.8% vs 29.5% (sCRT 59.0% vs 43.7%; cCRT 54.1% vs 19.8%), respectively. BICR-assessed ORR

was 24.5% in the sugemalimab group and 25.2% in the placebo group, median DoR was 24.1 months and 6.9 months, respectively. Grade ≥3 TRAE occurred in 11.4% vs 5.6% of pts treated with sugemalimab or placebo, respectively. No new safety signals were identified.

Conclusion

Sustained PFS benefits of sugemalimab and well-tolerated safety profile were observed in this PFS final analysis, preliminary overall survival data showed a trend for benefit favoring sugemalimab. The results provide evidence that sugemalimab is a safe and effective consolidation therapy for pts with unresectable stage III NSCLC without disease progression after either cCRT or sCRT.