Introduction

- In the Phase 3 HIMALAYA study (NCT03308451) in uHCC, a single priming dose of tremelimumab (anti-CTLA-4) and multiple doses of durvalumab (anti-PD-L1), administered every 4 weeks in combination, significantly improved OS versus sorafenib: durvalumab monotherapy was not superior to OS for OS.

- STRIDE has been approved in many regions across the world for the treatment of adults with uHCC, including in the United States, the European Union, and Japan.

- Long-term survivors were defined as all participants surviving >12 months beyond randomization.

- Statistical analysis of the 4-year updated data was performed in the same manner as the primary analysis, except it was exploratory in nature and there was no control for alpha.

Results and interpretation

- The data cut-off for this updated analysis was January 23, 2023.

- In total, 1171 participants were randomized to STRIDE (n=393), durvalumab (n=389), and sorafenib (n=399).

- Follow-up duration was approximately 4 years across the three treatment arms for OS.

- There was 79% OS at 4 years for STRIDE (Figure 3).

- The OS hazard ratio versus sorafenib (0.78; 95% confidence interval [CI], 0.67–0.90) and estimated 36-month OS (45.4% vs 36.6%) for STRIDE were consistent with the primary analysis.

- Long-term OS benefit was demonstrated in one-in-four survival rates at 4 years (Figure 2A).

- STRIDE maintained OS benefit in sorafenib survivors consistent with the primary analysis (Figure 2B).

- Baseline demographic, clinical characteristics, and subsequent therapies in patients treated with STRIDE were similar to those in the primary analysis.

- STRIDE is a treatment that combines a single dose of tremelimumab with multiple doses of durvalumab, administered every 4 weeks in combination.

- Patients in the STRIDE regimen received tremelimumab 10 mg/kg and 400 mg BID durvalumab.

- Patients in the sorafenib arm received 400 mg BID sorafenib.

- Long-term survival is an important efficacy measure both for IC1 studies and for patients with uHCC.

- In the current analysis, 1171 participants were randomized to STRIDE (n=393), durvalumab (n=389), and sorafenib (n=399).

- Follow-up duration was approximately 4 years across the three treatment arms for OS.

- There was 79% OS at 4 years for STRIDE (Figure 3).

- The OS hazard ratio versus sorafenib (0.78; 95% CI, 0.67–0.90) and estimated 36-month OS (45.4% vs 36.6%) for STRIDE were consistent with the primary analysis.

- Long-term OS benefit was demonstrated in one-in-four survival rates at 4 years (Figure 2A).

- STRIDE maintained OS benefit in sorafenib survivors consistent with the primary analysis (Figure 2B).

- Baseline demographic, clinical characteristics, and subsequent therapies in patients treated with STRIDE were similar to those in the primary analysis.

- STRIDE is a treatment that combines a single dose of tremelimumab with multiple doses of durvalumab, administered every 4 weeks in combination.

- Patients in the STRIDE regimen received tremelimumab 10 mg/kg and 400 mg BID durvalumab.

- Patients in the sorafenib arm received 400 mg BID sorafenib.

- Long-term survival is an important efficacy measure both for IC1 studies and for patients with uHCC.