MO2 – 5 – 6 Palbociclib (PAL) + cetuximab (CET) vs CET in patients (pts) with head and neck cancer: Asian subgroup analysis

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Background: The double-blind, randomized, phase 2 PALATINUS trial found a trend in prolongation of median overall survival (OS) with PAL+CET vs CET in CET-naive pts with platinum-resistant, HPV-unrelated HNSCC (median OS: 9.7 mo vs 7.8 mo, stratified by performance status [PS] hazard ratio [HR]=0.82, 95%CI: 0.54-1.25, P = 0.18). This subgroup analysis evaluated the efficacy and safety of PAL+CET in Asian pts enrolled in PALATINUS in Japan, Korea, and China.

Methods: Pts were treated with CET+PAL (arm A) or placebo (arm B) and stratified by PS and prior immunotherapy (IT). 120 pts were required for 1:1 randomization to have ≥80% power to detect an HR of 0.6 (corresponding to a median OS of 10 mo in arm A and 6 mo in arm B) using a 1-sided log-rank test at α = 0.10. Secondary endpoints included progression-free survival (PFS), objective response rate (ORR; complete or partial response per RECIST v1.1), and adverse events (AEs).

Results: Of 125 pts randomized in PALATINUS, 28 were enrolled from Asian countries (arm A: 15; arm B: 13). PS and prior IT were balanced between groups. Unbalanced primary sites included hypopharynx (arm A: 9; arm B: 1) and oral cavity (arm A: 3; arm B: 7). Other pt characteristics were similar between the 2 arms. Median OS was 7.1 mo (95%CI: 3.1-8.8) in arm A and 7.0 mo (95%CI: 4.1-9.5) in arm B (stratified by PS: HR = 0.72, 95%CI: 0.3-1.8, P = 0.24). Median PFS was 3.2 mo in arm A and 3.0 mo in arm B (stratified by PS: HR = 1.22, 95%CI:0.5-3.0, P = 0.3). ORR was 13.3% (95%CI: 1.7-40.5) in arm A and 15.4% (95%CI: 1.9-45.4) in arm B. Hematologic AEs were reported primarily in arm A. No difference in safety profile was shown in the Asian vs overall populations.

Conclusions: Although PAL+CET showed a trend toward prolongation of median OS vs CET in the overall PALATINUS population, no significant difference in OS or PFS was apparent with PAL+CET vs CET in the subgroup of Asian pts, possibly due to the limited cohort size.

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