Aim: Switch maintenance is an effective strategy in advanced NSCLC treatment. Pz is an orally active, multi-targeted tyrosine kinase inhibitor (TKI), potentially effective in lung cancer. EORTC 08092 evaluated Pz given as maintenance following standard first line platinum-based chemotherapy (CT) in pts with advanced NSCLC.

Methods: Pts with non-progressive disease after 4-6 cycles of CT were randomized to receive either Pz 800 mg/day or matched placebo until progression or unacceptable toxicity. The primary endpoint was overall survival (OS) and secondary endpoints were progression-free survival (PFS) and safety. Assuming 80% power and 5% 2-side type I error and taking into account an Interim Analysis (IA) for futility based on PFS, 587 pts had to be randomized in order to improve median overall survival (OS) from 9.7 to 12.7 months.

Results: After 102 pts were randomized to Pz (n = 50) or P (n = 52), the trial was prematurely stopped due to an early IA. Median age was 64 years in both arms.

Baseline characteristics for Pz and P arms (%): male/female: 57/43 and 55/45; squamous/non-squamous-cell: 78/22 and 82/18; ECOG PS 0/1/2: 21/75/4 and 36/64/0; Prior Chemotherapy Response CR-PR/SD: 27/73 and 32/68; current/former/never smoker/NA: 8/67/19/6 and 22/52/22/4. OS was not significantly different, median 17.4 months (m) for Pz vs. 12.3 m for P (adjusted HR was 0.72 [95% CI 0.40-1.28]; p = 0.257). Median PFS was 4.3 m vs. 3.2 m (HR 0.67, [95% CI 0.43,1.03]), p = 0.068. PFS rates at 4 months were 56% and 45% respectively. Pz was well tolerated: the majority of treatment-related adverse events (AEs) were grade 1/2. Reported grade 3/4 AEs (% Pz vs. P) were neutropenia (8% vs. 0%), hypertension (38% vs. 8%) and elevated SGPT (6% vs. 0%). Only 22% of pts receiving Pz withdrew due to a treatment-related AE.

Conclusions: Switch maintenance with Pazopanib following platinum-based chemotherapy in pts with advanced NSCLC was well tolerated. This study was stopped for futility following an IA due to lack of efficacy judging by a stringent criteria for PFS.

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