1461P ASTRIS: A real world treatment study of osimertinib in patients (pts) with EGFR T790M-positive non-small cell lung cancer (NSCLC) - European subset

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Background: Osimertinib is a third-generation, CNS-active EGFR-TKI that potently and selectively inhibits both EGFR-TKI sensitising and EGFR T790M resistance mutations. We report results from the European subset of the ongoing global ASTRIS study (NCT02474355).

Methods: Eligible pts receive osimertinib 80 mg once daily. Inclusion criteria: Stage IIIB/IV T790M-positive NSCLC; T790M status confirmed locally by validated test, not restricted by sample type; prior EGFR-TKI therapy received; WHO performance status (PS) 0 – 2; acceptable organ and bone marrow function and no history of interstitial lung disease (ILD) or QTc prolongation. Asymptomatic, stable CNS metastases are permitted. The primary efficacy outcome is overall survival (OS). Second interim data cut-off (DCO) 20 Oct 2017.

Results: From Sept 18 2015, 759 pts were enrolled across 8 European countries and received ≥1 dose of osimertinib: median follow-up 10.9 months (mo) (range <1 – 24), median age 66 yrs (32–92), 24% ≥75 yrs, 69% female, 97% White, 14% WHO PS 2, 44% prior chemotherapy. T790M-positive status was identified from tissue in 290 pts (38%), plasma ctDNA in 415 pts (55%) and from other sources in 53 pts (7%). At DCO, 545 pts (72%) had discontinued treatment (214 [28%] ongoing); 442 pts (58%) had withdrawn from the study, including 268 deaths (35%); median duration of exposure 9.7 mo (<1–25). In pts evaluable for response, investigator-assessed clinical response rate was 55.3% (381/689; 95% CI 51.5, 59.1). Estimated median progression-free survival (PFS) was 9.7 mo (95% CI 8.5, 10.8), with 470 (62%) progressions/deaths. OS data are not mature (OS at 12 mo was 67.4%; 95% CI 63.7, 70.8). Adverse events (AEs) leading to dose modification and treatment discontinuation were reported in 149 pts (20%) and 53 pts (7%), respectively. Serious AEs were reported in 147 pts (19%). ILD / pneumonitis-like events were reported in 22 pts (3%), and QTc prolongation in 7 pts (1%).

Conclusions: In this European dataset from ASTRIS, clinical activity (response and PFS) with osimertinib in patients with T790M-positive NSCLC is similar to that observed in the global ASTRIS population and the wider osimertinib clinical trial programme with no new safety signals.

Clinical trial identification: NCT02474355.

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