ERS
INTERNATIONAL CONGRESS 2021
virtual

Late Breaking Abstract - Randomized phase III study of erlotinib compared to intercalated erlotinib with cisplatin and pemetrexed as first-line therapy for advanced EGFR mutated non-small cell lung cancer, the NVALT 17 study.

R. Gijtenbeek (Leeuwarden, Netherlands), V. Van Noort (Leeuwarden, Netherlands), J. Aerts (Rotterdam, Netherlands), J. Staal - Van Den Brekel (Almelo / Hengelo, Netherlands), E. Smit (Amsterdam, Netherlands), F. Krouwels (Hoofddorp, Netherlands), F. Wilschut (Ede, Netherlands), T. Hilterman (Groningen, Netherlands), W. Timens (Groningen, Netherlands), E. Schuuring (Groningen, Netherlands), J. Janssen (Endhoven / Veldhoven, Netherlands), M. Goosens (Zutphen, Netherlands), P. Van De Berg (Willemstad, Curaçao), A. De Langen (Amsterdam, Netherlands), J. Stigt (Zwolle, Netherlands), B. Van Den Borne (Eindhoven, Netherlands), H. Groen (Groningen, Netherlands), W. Van Geffen (Leeuwarden, Netherlands), A. Van Der Wekken (Groningen, Netherlands)

Introduction
To delay tyrosine kinase inhibitor (TKI) resistance in epidermal growth factor receptor (EGFR) mutated non-small cell lung cancer (NSCLC), we designed a multicenter randomized phase III trial to demonstrate superiority of combining cisplatin-pemetrexed with intercalated erlotinib (day 2-16)(CPE) for a total of four cycles followed by pemetrexed and erlotinib maintenance compared to daily erlotinib (E) until disease progression or intolerable toxicity.

Methods
Treatment-naïve patients with stage IV NSCLC with an activating EGFR mutation, ECOG performance score of 0-3 and adequate organ function, were randomly assigned 1:1 to either arm. The primary endpoint was progression free survival (PFS). Secondary endpoints were overall survival (OS), objective response rate (ORR) and toxicity.

Results
After inclusion of 22 patients from April 2014 to September 2016, the trial was terminated due to slow enrollment. Median follow up was 64 months. Median PFS for E was 10.3 months (95%CI 7.1-15.5) and 13.7 months (95%CI 5.2-19.9) for CPE (HR 0.62 (95%CI 0.25-1.57)). Median OS and 1-year OS were 17.2 months (95%CI 11.5-45.5) and 73% (95%CI 46-99) for E compared to 31.7 months (95%CI 21.8-61.9) and 100% (95%CI 59-100) for CPE (HR 0.58 (95%CI 0.23-1.49)). ORR was 55% versus 64% for E and CPE, respectively. Patients treated with CPE reported higher rates of treatment related fatigue (45 vs. 18%), anorexia (55 vs. 0%), weight loss (18 vs. 0%) and renal toxicity (27 vs. 0%).

Conclusion
Although underpowered, CPE shows a trend to a better PFS and OS than E but was associated with more toxicity.