ANLOTINIB AS THIRD-LINE TREATMENT IN PATIENTS WITH REFRACTORY ADVANCED NON-SMALL CELL LUNG CANCER: A MULTICENTRE, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, PHASE II TRIAL (NCT01924195)

B. Han1, K. Li2, Y. Zhao1, B. Li3, Y. Cheng4, J. Zhou5, Y. Lu6, Y. Shi7, Z. Wang8, L. Jiang1

1Department of Pulmonary Medicine, Shanghai Chest Hospital, Shanghai, China
2Oncology Medicine, Tianjin Medical University Cancer Institute and Hospital, Tianjin, China
3Department of Oncology, Beijing Chest Hospital, Beijing, China
4Department of Oncology, Jilin Province Cancer Hospital, Changchun, China
5Department of Pulmonary, 1st Affiliated Hospital of Zhejiang University School of Medicine, Hangzhou, China
6Department of Oncology, West China Hospital, Huaxi, Sichuan University, Chengdu, China
7Department of Oncology, Cancer Institute and Hospital, Chinese Academy of Medical Sciences (CAMS), Beijing, China
8Department of Oncology, Shandong Cancer Hospital, Jinan, China

Aim: The aim of this randomised, double-blind, placebo-controlled, anlotinib study was to investigate its efficacy and safety in patients with refractory non-small-cell lung cancer.

Methods: Patients aged ≥18 years with histologically or cytological confirmed, metastatic or recurrent advanced non-squamous NSCLC and an ECOG performance status of 0–1 were randomised 1:1 to receive anlotinib or placebo (anlotinib 12mg/day, po, day 1-14 each 3-week) until progression or unacceptable toxicity, withdrawal of patient consent or death. Patients had received first and second line prior treatment for advanced NSCLC. The primary endpoint was PFS in the intent-to-treat (ITT) population; secondary endpoints included objective response rate (ORR), OS, exploratory biomarkers and safety.

Results: Between 08, 2010 to 05, 2014, we enrolled 117 patients from 13 centres, 60 patients with anlotinib arm and 57 patients with placebo. Baseline characteristics were similar in both groups. PFS was prolonged with anlotinib 4.83 months versus placebo 1.23 months; HR 0.32(CI 0.20–0.51); p < 0.0001 (TTP population). ORR was anlotinib13.3% versus 0% with placebo (p < 0.006). Disease control rate was 93.3% with anlotinib versus 30% with placebo (p < 0.0001), respectively. OS data are not yet mature. Adverse events occurred more frequently with anlotinib (grade 1-2) than with...