ESMO 2018: CTONG 1103 Finds Benefit With Neoadjuvant Erlotinib in Some *EGFR*-Mutated NSCLCs

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Key Points

- The objective response rate for neoadjuvant erlotinib vs gemcitabine plus cisplatin chemotherapy was 54.1%.
- Median progression-free survival was significantly longer with erlotinib at 21.5 months vs gemcitabine plus cisplatin chemotherapy at 11.9 months.
- Grade 3 and 4 toxicities were fewer in the erlotinib arm (0%) compared to the gemcitabine plus cisplatin arm (29.4%).

Neoadjuvant erlotinib (Tarceva) benefits selected patients with epidermal growth factor receptor (*EGFR*)-mutated non–small cell lung cancer (NSCLC) who undergo complete resection of stage IIIA-N2 disease, according to a randomized study comparing erlotinib with gemcitabine plus cisplatin as neoadjuvant treatment. The findings were presented by Zhong et al at the European Society for Medical Oncology (ESMO) 2018 Congress (Abstract LBA48_PR).

"Our results suggest promise for the use of biomarker-guided neoadjuvant EGFR tyrosine kinase inhibitor treatment strategies in stage IIIA-N2 NSCLC," said **Yi-Long Wu, MD**, Tenured Professor at Guangdong Lung Cancer Institute in Guangzhou, China, and principal investigator of the CTONG 1103 study. "This is the first study to demonstrate progression-free survival superiority for erlotinib over gemcitabine plus cisplatin chemotherapy in the neoadjuvant/adjuvant setting of stage IIIA-N2 *EGFR*-mutated NSCLC," Dr. Wu added.

CTONG 1103 Results

A total of 386 patients from 17 centers in China were screened, and 72 were randomly assigned 1:1 to therapy and included in the intention-to-treat population. The objective response rate (ORR) for neoadjuvant erlotinib vs gemcitabine plus cisplatin chemotherapy was 54.1% (95% confidence interval [CI] = 37.2%–70.9%) vs 34.3% (95% CI = 17.7%–50.8%) with an odds ratio of 2.26 (95% CI = 0.87–5.84; *P* = .092). After neoadjuvant therapy, 83.8% of patients in the erlotinib group and 68.6% in the gemcitabine-plus-cisplatin group underwent surgery.

Median progression-free survival was significantly longer with erlotinib at 21.5 months (95% CI = 19.3–23.6) vs gemcitabine-plus-cisplatin chemotherapy at 11.9 months (95% CI = 9.1–14.7) with a hazard ratio of 0.42 (95% CI = 0.23–0.76; *P* = .003). Overall survival is too immature to report, said Dr Wu.

Grade 3 and 4 toxicities were fewer in the erlotinib arm (0%) compared to the gemcitabine/cisplatin arm (29.4%).

Current treatment strategies for resected stage IIIA-N2 *EGFR*-mutated NSCLC are controversial, explained Dr Wu, but EGFR tyrosine kinase inhibitors have been shown to improve the prognosis of patients with advanced *EGFR*-mutant NSCLC.

“Cisplatin-based doublet chemotherapy as neoadjuvant treatment for stage IIIA-N2 NSCLC only gives patients [a] 5% 5-year overall survival benefit,” said Dr. Wu, explaining the unmet medical need in this patient population. “Recently, the CTONG 1104 trial [published by Zhong et al in *Lancet Oncology*] showed for the first time that adjuvant … gefitinib [Iressa] could improve disease-free survival by 10 months compared to adjuvant chemotherapy (28.7 vs 18.0 months) in N1–N2 resected NSCLC. This raises the possibility that EGFR tyrosine kinase inhibitors may play a beneficial role in the neoadjuvant setting for this subgroup.”