

## Icotinib Active in Previously Treated Non-Small Cell Lung Cancer

Icotinib, an epidermal growth factor receptor (EGFR) inhibitor, shows efficacy and safety as second-line therapy for patients with previously treated advanced non-small cell lung cancer, as confirmed by results of a recent study.

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January 16, 2015 – In patients with non-small cell lung cancer (NSCLC), icotinib treatment showed efficacy and favorable safety as second-line treatment in a recent single arm, multi-center, prospective study.

Xingsheng Hu, MD, with the Chinese Academy of Medical Sciences and Peking Union Medical College, Beijing, China, and colleagues reported their findings in the November 24, 2015 issue of *PLOS One*.

Icotinib is an epidermal growth factor receptor tyrosine kinase inhibitor (EGFR-TKI). A previous randomized, double-blind, head-to-head phase 3 trial (ICOGEN) showed comparable safety and efficacy of icotinib and gefitinib as second-line treatment for advanced NSCLC.

The current study evaluated a total of 124 patients from 15 facilities. Participants had cytology confirmed stage IIIB/IV NSCLC with tumor(s) measurable by RECIST 1.0. Eligible patients had previously received platinum-based chemotherapy and experienced clinical progression. Patients received 125 mg of icotinib orally 3 times daily until disease progression or unacceptable adverse events (AE) occurred. Tumor response was evaluated after 4 weeks of treatment and then every 6 weeks using RECIST 1.0.

The length of progression-free survival (PFS) while receiving icotinib treatment served as the primary endpoint for this study. Median PFS was 5.0 months (95% CI 2.9-6.6 m) in icotinib treated patients.

Multiple secondary endpoints were evaluated including overall survival (OS), overall response rates (ORR), disease-control rate (DCR), time-to-progression (TTP), and safety. Median OS was calculated at 17.6 months (95% CI 14.2-NA). However, follow-up OS data collection is ongoing. ORR was calculated at 25.8% while DCR was 67.7%. TTP was similar to PFS at 5.4 months.

AEs occurred in 89 (70.2%) of patients, most commonly rash, elevated transaminase, and diarrhea. Although a 5 deaths were recorded, researchers attributed only one fatal AE of interstitial lung disease (ILD) to the treatment drug. The researchers reported that the AEs recorded in this study, including ILD, were congruent with the safety profile of other currently approved EGFR-TKIs such as gefitinib.

According to the authors, in this patient population with NSCLC resistant to platinum-based chemotherapy, icotinib “provided favorable clinical outcome benefits”. These results were “consistent with that in the confirmatory phase 3 ICOGEN study” which showed a median PFS of 4.6 months. The authors concluded that, based on safety and efficacy, “icotinib is a potential option for pretreated NSCLC population” as second-line therapy.

This study was sponsored by Betta Pharmaceuticals Co, Ltd., the manufacturer of icotinib. Betta Pharmaceuticals Co, Ltd. provided financial, organizational and data collection support as well as provided salary for several authors.

PLoS One. 2015 Nov 24;10(11):e0142500. doi: 10.1371/journal.pone.0142500. eCollection 2015

