

Crizotinib phase II study in East Asian Patients meets end point expectations

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OxOnc Development LP has announced that Study OO-1201, a phase II open-label, single-arm study of crizotinib in East Asian patients with ROS1-positive metastatic non-small cell lung cancer (NSCLC), met its primary objective of demonstrating a high overall response rate for crizotinib.

Study OO-1201 enrolled 127 ROS1-positive patients in the People's Republic of China (PRC), Japan, Taiwan and South Korea, and is claimed to be the largest ROS1-positive NSCLC cohort reported to date. The study was presented as a Poster Discussion at the 2016 American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago on Saturday, June 4, 2016.

Data from the study confirmed the clinical benefit of crizotinib in East Asian patients with ROS1-positive metastatic NSCLC with an objective response rate of 69 percent (95% CI, 61-77) by an independent radiology review. The safety profile of crizotinib in patients with ROS1-positive NSCLC was consistent with the known overall crizotinib safety profile.

"We are extremely pleased for the opportunity to collaborate with Pfizer on this important project. Patients with ROS1-positive metastatic NSCLC are in acute need of biomarker-driven treatment options, and the data collected from this trial in East Asian patients brings us one step closer to fulfilling that need. We want to thank the investigators, patients and other partners for their participation and support," said Wenn Sun, PhD, managing partner, OxOnc Development LP.

Recruitment for Study OO-1201 was conducted in collaboration with the Lung Cancer Genomic Screening Project in Japan and Chinese Thoracic Oncology Group in the PRC, two leading academic consortia in lung cancers and precision medicine. For the companion diagnostic development, OxOnc collaborated with Amoy Diagnostics and Riken Genesis in the PRC and Japan, respectively.

ROS1 rearrangements occur when the ROS1 gene attaches to another gene and changes the way each gene normally functions, which can contribute to cancer-cell growth. Epidemiology data suggest that ROS1 rearrangements occur in approximately 2.4 percent of Asian patients with NSCLC. It is estimated that 1.5 million new cases of NSCLC will be diagnosed worldwide each year.