GENENTECH'S ALECENSA (ALECTINIB) SUPERIOR TO XALKORI IN NEWLY DIAGNOSED ALK+ ADVANCED NSCLC PATIENTS

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Patients with ALK-positive advanced non-small cell lung cancer (NSCLC) who receive Genentech's Alecensa (alectinib) as first-line therapy have significantly higher progression-free survival rates compared to those treated with the standard of care Xalkori (crizotinib).

The findings mean that the global, randomized Phase 3 ALEX trial (NCT02075840) met its primary endpoint of reduced risk of disease worsening or death.

The U.S. Food and Drug Administration (FDA) granted Alecensa, an ALK inhibitor, accelerated approval in December 2015 for treatment of patients with ALK+ metastatic NSCLC who have progressed on, or are intolerant to, Xalkori

treatment. Now Genentech is evaluating Alecensa as first-line therapy for newly diagnosed ALK+ metastatic NSCLC.

“Our goal is to transform the standard of care and we are excited to share these results with the lung cancer community,” Sandra Horning, MD, chief medical officer and head of global product development at Genentech, said in a press release. “As part of its Breakthrough Therapy Designation, we hope to bring Alecensa as an initial treatment for people with ALK+ NSCLC as soon as possible and will discuss these data with global health authorities.”

The ALEX Phase 3 trial was a randomized, multicenter, open-label study designed to assess the safety and efficacy of Alecensa versus Xalkori in newly diagnosed patients with ALK-positive NSCLC. The study included 303 patients from 161 cancer centers across 31 countries. Researchers evaluated participants’ ALK status using Roche’s VENTANA ALK (D5F3) CDx Assay.

The study’s main efficacy objective was investigator-assessed progression-free survival (PFS). Secondary objectives included independent review committee-assessed PFS, time to cancer progression to the central nervous system, objective response rate (defined as the percentage of patients whose tumor shrank or disappeared after treatment), duration of response and overall survival. Scientists also measured safety and health-related quality of life.

Full data from the ALEX trial will be presented at an upcoming medical meeting and will submitted to global health authorities for Alecensa approval.

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