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‘Leclaza could change Tagrisso-led lung cancer drug market’

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Yuhan's Leclaza (ingredient: lazertinib), Korea's 31st novel drug that treats lung cancer, has reached the commercialization stage, raising expectations for a new treatment option.

Professor Cho Byoung-chul of Yonsei Cancer Center explains the benefits of Yuhan's lung cancer treatment, Leclaza, during a news conference held at Four Seasons Hotel, downtown Seoul, on Friday.

The drug received approval from the Ministry of Food and Drug Safety on Jan. 18, on the condition that the company submits phase-3 trial data after the market release.

Hospitals can use the drug for treating non-small cell lung cancer (NSCLC) patients with positive EGFR T790M (epidermal growth factor receptor threonine at amino acid position 790) mutation.

Researchers in the anticancer field predict a major change in the lung cancer prescription market, currently dominated by AstraZeneca's Tagrisso (Ingredient: Osimertinib), as clinical results of Leclaza has shown that it can provide new options for NSCLC patients.

"In the clinical trials of existing third-generation EGFR TKI first-line treatments, the drug's efficacy was lower in Asians compared to the non-Asians population," Professor Ahn Myung-ju at the Department of Hematology-Oncology at Samsung Medical Center said during a news conference on Friday. "Therefore, it was necessary to verify the efficacy of NSCLC drugs in Koreans, including Asians."

Ahn added that researchers believe that the approval of Leclaza will resolve such concerns and address the unmet demand for EGFR TKI (tyrosine kinase inhibitor) as the drug showed excellent effects in terms of resistance and brain metastasis, she added.

Professor Cho Byoung-chul of Yonsei Cancer Center, who participated in the Leclaza study as principal investigator, stressed the importance of Leclaza's approval.

"Leclaza's product license is good news for Yuhan and Korean patients and patients worldwide as well," Professor Cho said. "Leclaza is the only third-generation EGFR mutant therapeutic agent that has been on the same level in terms of effectiveness as Tagrisso."

He stressed that Leclaza's approval is important because a Korean pharmaceutical company obtained approval for Korean patients.

Cho explained the mechanism, efficacy, and safety of Leclaza based on its non-clinical and clinical trials' main results.

"Researchers have high expectations as compared to other EGFR TKI treatments, Leclaza has excellent selectivity in distinguishing between normal and mutant EGFR, and exhibits excellent effects on brain metastasis tumors," Cho said.

According to Cho, the LASER201 clinical trials showed that the objective response rate (ORR) according to the independent central review and investigator evaluation of 76 T790M mutation-positive patients is 78 patients assigned to the 240mg dose group was 58 and 72 percent. At the same time, the median progression-free survival was 11 and 13.2 months.

Researchers also observed drug-related adverse reactions of CTCAE (common terminology criteria for adverse events) grade 3 or higher in only 5 percent of the test subjects. At the same time, cardiac safety results were also excellent.

"As a result, we could confirm that Leclaza showed a significant therapeutic effect and safety profile as a second-line treatment for EGFR T790M mutation-positive NSCLC," Cho said. "Starting with the local approval, I hope that Leclaza will become a symbol of hope for lung cancer patients around the world as Yuhan plans to conduct a global phase 3 clinical trial."

According to a company official, Yuhan has almost completed recruiting participants for the global phase 3 clinical trial, despite the ongoing Covid-19 epidemic.

"We still need to recruit additional Westerners to participate in the trial, but have reached our goal to recruit patients in Asia," the official said.

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