EU Approves Roche's ATEZOLIZUMAB to Treat Non-small Cell Lung Cancer ALK+

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The European Commission (EC) granted marketing authorization to Roche for Tecentriq (atezolizumab) as a monotherapy for patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) after prior treatment with chemotherapy, the company announced in a press release.

Tecentriq can be administered regardless of PD-L1 status, and patients that have EGFR-activating mutations or ALK-positive tumor mutations must have received targeted therapy prior to administration of Tecentriq . This approval is based on the positive results obtained from a

large randomized Phase III OAK study, which demonstrated that treatment with Tecentriq can help patients survive to a median of 13.8 months, which is 4.2 months longer than patients on docetaxel chemotherapy (9.6 months).

The EC also granted Tecentriq with marketing authorization for locally advanced or metastatic urothelial carcinoma as a monotherapy after patients have undergone treatment with a platinum-containing chemotherapy or are ineligible for cisplatin chemotherapy, regardless of PD-L1 status. The results from both the Phase II IMvigor210 and the Phase III IMvigor211 studies were the basis for approval in this indication.

The Phase II study demonstrated that Tecentriq achieved a median overall survival of 15.9 months in a specific cohort. The Phase III study did not increase overall survival compared to patients undergoing chemotherapy. However, the median duration of response, which was the secondary endpoint, was 21.7 months in the Tecentriq cohort compared to 7.4 months in chemotherapy cohort. Additionally, 63% of patients continuously responded to Tecentriq treatment compared to only 21% of chemotherapy patients.

Tecentriq is an antibody that was developed to bind PD-L1, a protein that is present on tumor cells. By binding to PD-L1, the antibody blocks interaction with PD-1 and B7.1 receptors, which in turn enable the activation of cancer-destroying T-cells. In the U.S., it is approved for treatment of metastatic NSCLC as well as for locally advanced or metastatic urothelial carcinoma for patients.

“The totality of the data for Tecentriq across all indications including long-term responses in advanced bladder cancer and the overall survival advantage observed in our phase III advanced lung cancer study means that we are able to extend the benefits of Tecentriq to people living with these types of cancer regardless of their levels of PD-L1 expression,” said Sandra Horning, MD, Roche’s chief medical officer and head of global product development