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Roche receives EU approval of TECENTRIQ

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TECENTRIQ provides a new treatment option for people with previously treated locally advanced or metastatic non-small cell cancer (NSCLC). TECENTRIQ is a new treatment option for people with metastatic urothelial carcinoma (mUC) who have been previously treated with a platinum-based chemotherapy and for people who are ineligible to receive cisplatin chemotherapy.

Roche has announced that the European Commission (EC) has granted a marketing authorisation for TECENTRIQ (atezolizumab) as a monotherapy for the treatment of people with locally advanced or metastatic non-small cell lung cancer (NSCLC) after they have been previously treated with chemotherapy regardless of PD-L1 status.

People with EGFR-activating mutations or ALK-positive tumour mutations should also have received targeted therapy before receiving TECENTRIQ. This approval is based on results from the large randomised Phase III OAK study and the randomised Phase II POPLAR study.

The Phase III OAKstudy showed that TECENTRIQ helped people in the overall study population live a median of 13.8 months–4.2 months longer than those treated with docetaxel chemotherapy (median OS: 13.8 vs 9.6 months; hazard ratio [HR] = 0.73, 95% confidence interval [CI]: 0.62, 0.87).

The EC has also granted marketing authorisation for TECENTRIQ as a monotherapy for the treatment of people with locally advanced or metastatic urothelial carcinoma (mUC) who have been previously treated with a platinum-containing chemotherapy or who are considered ineligible for cisplatin chemotherapy, regardless of PD-L1 status.

This approval is based on results from the randomised Phase III IMvigor211 study and cohorts 1 and 2 from the single-arm Phase II IMvigor210 study. The Phase III IMvigor211 study did not meet its primary endpoint of OS, compared with chemotherapy. However, the study showed that the median duration of response (mDOR), a secondary endpoint, for those receiving TECENTRIQ was 21.7 months (95% CI: 13.0, 21.7) in the overall study population, compared with 7.4 months (95% CI: 6.1, 10.3) for those receiving chemotherapy.

At the time of data cutoff, the majority (63%) of people who responded to treatment with TECENTRIQ continued to respond,

compared with 21% of people treated with chemotherapy. Results from cohort 1 of the Phase II IMvigor210 study showed that TECENTRIQ achieved a median OS of 15.9 months (10.4, NE) in the overall study population.

“We are delighted that the European Commission has approved TECENTRIQ, the first anti-PD-L1 cancer immunotherapy approved in the EU, as a monotherapy in both advanced bladder and advanced lung cancer”, said Sandra Horning, MD, Roche’s Chief Medical Officer and Head of Global Product Development in a press release. “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.”

TECENTRIQ is already approved in the USA and in several other countries for people with metastatic NSCLC – and for people with locally advanced or mUC who are not eligible for cisplatin chemotherapy, or who have had disease progression during or following platinum-containing therapy.