FDA Grants Priority Review to Tecentriq Combo for First-Line Treatment of Advanced Lung Cancer

MAY 15, 2018MAY 15, 2018

The U.S. Food and Drug Administration has granted priority review to Tecentriq (atezolizumab) in combination with Avastin (bevacizumab) and chemotherapy medications Taxol (paclitaxel) and carboplatin for first-line treatment of metastatic non-squamous non-small cell lung cancer (NSCLC).

Priority review of Roche's supplemental Biologics License Application means the FDA will decide whether or not to approve the therapy within six months instead of the standard 10 months. A decision is now expected by Sept. 5. To be granted priority review, a therapy candidate must show potential to provide significant benefits for the treatment, prevention, or diagnosis of a disease.

Roche's application is based on results from the IMpower150 Phase 3 clinical trial (NCT02366143). This multicenter, open-label, randomized study evaluated the safety and effectiveness of Tecentriq in combination with Taxol and carboplatin with or without Avastin in 1,202 patients with metastatic non-squamous NSCLC not previously treated with chemotherapy.

Patients received either Tecentriq plus carboplatin and Taxol; Tecentriq and Avastin plus carboplatin and Taxol; or Avastin plus carboplatin and Taxol, which was the control group.

They received an induction therapy and then maintenance treatment until their disease worsened or they died. Results indicated a delay in disease worsening, as well as better overall survival. The safety data of the combo therapy matched that of its individual components.

The company had reported the positive findings of IMpower150 in November 2017.

“Our phase 3 results showed Tecentriq in combination with Avastin, paclitaxel and carboplatin has the potential to provide a significant survival benefit in the initial treatment of metastatic non-squamous non-small cell lung cancer,” Sandra Horning, MD, Roche’s chief medical officer and head of global product development at Roche, said in a press release. “We are working closely with the FDA to bring this treatment regimen to people with this type of lung cancer as soon as possible.”

Tecentriq is a so-called checkpoint inhibitor, which targets the PD-L1 protein. Cancer cells use binding of their own PD-1 to immune T-cells’ PD-L1 to avoid attack. Checkpoint inhibitors block this binding, boosting immune response against tumor cells.

Tecentriq is already FDA-approved for second-line treatment of metastatic NSCLC after failed platinum-based chemotherapy. It is also approved for bladder cancer.

Besides IMpower150, Roche is conducting eight lung cancer clinical trials on Tecentriq alone or in combination with other medications.

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