FDA approves Imfinzi for Extensive-Stage Small-Cell Lung Cancer

Additions of the checkpoint inhibitor led to improved survival compared with chemotherapy alone.

April 1, 2020 By Food and Drug Administration (FDA)

On March 27, 2020, the Food and Drug Administration approved durvalumab (Imfinzi, AstraZeneca) in combination with etoposide and either carboplatin or cisplatin as first-line treatment of patients with extensive-stage small cell lung cancer (ES-SCLC).

Efficacy of this combination in patients with previously untreated ES-SCLC was investigated in CASPIAN, a randomized, multicenter, active-controlled, open-label, trial (NCT03043872). The evaluation was based on the comparison of patients randomized to durvalumab plus chemotherapy vs. chemotherapy alone. The major efficacy outcome measure was overall survival (OS). Additional efficacy outcome measures were investigator-assessed progression-free survival (PFS) and objective response rate (ORR), per RECIST v1.1.

Median OS was 13.0 months (95% CI: 11.5, 14.8) in the durvalumab plus chemotherapy arm compared with 10.3 months (95% CI: 9.3, 11.2) in the chemotherapy alone arm (hazard ratio 0.73; 95% CI: 0.59, 0.91; p=0.0047).

Investigator-assessed PFS (96% of total planned events) showed a HR of 0.78 (95% CI: 0.65, 0.94), with median PFS of 5.1 months (95% CI: 4.7, 6.2) in the durvalumab plus chemotherapy arm and 5.4 months (95% CI: 4.8, 6.2) in the chemotherapy alone arm. The investigator-assessed confirmed ORR was 68% (95% CI: 62%, 73%) in the durvalumab plus chemotherapy arm and 58% (95% CI: 52%, 63%) in the chemotherapy alone arm.

The most common adverse reactions (≥20%) in patients with ES-SCLC were nausea, fatigue/asthenia, and alopecia.

For ES-SCLC, durvalumab is to be administered prior to chemotherapy on the same day. The recommended durvalumab dose when administered with etoposide and either carboplatin or cisplatin is 1500 mg every 3 weeks prior to chemotherapy and then every 4 weeks as a single agent.

View full prescribing information for Imfinzi.

This review used the Assessment Aid, a voluntary submission from the applicant to facilitate the FDA's assessment.

FDA granted this application priority review and granted durvalumab orphan drug designation for this indication. A description of FDA expedited programs is in the Guidance for Industry: Expedited Programs for Serious Conditions-Drugs and Biologics.

Healthcare professionals should report all serious adverse events suspected to be associated with the use of any medicine and device to FDA's MedWatch Reporting System or by calling 1-800-FDA-1088.

For assistance with single-patient INDs for investigational oncology products, healthcare professionals may contact OCE's Project Facilitate at 240-402-0004 or email OncProjectFacilitate@fda.hhs.gov.

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