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Imfinzi (durvalumab) Injection
Clinical Update

Clinical Update: Imfinzi (durvalumab) Approved by FDA in the US for Extensive-Stage Small Cell Lung Cancer.
FDA approval date: March 30, 2020

Imfinzi (durvalumab) is a human monoclonal antibody that binds to PD-L1 and blocks the interaction of PD-L1 with PD-1 and CD80, countering the tumour's immune-evading tactics and releasing the inhibition of immune responses.

Imfinzi is approved in the curative-intent setting of unresectable, Stage III NSCLC after chemoradiation therapy in the US, Japan, China, across the EU and in many other countries, based on the Phase III PACIFIC trial. Imfinzi is approved for the 1st-line treatment of ES-SCLC in combination with SoC chemotherapy in the US and Singapore. Imfinzi is also approved for previously treated patients with advanced bladder cancer in the US and a small number of other countries.

As part of a broad development programme, Imfinzi is also being tested as a monotherapy and in combination with tremelimumab, an anti-CTLA4 monoclonal antibody and potential new medicine, as a treatment for patients with NSCLC, SCLC, bladder cancer, head and neck cancer, liver cancer, biliary tract cancer, cervical cancer and other solid tumours.

The approval by the Food and Drug Administration was based on positive results from the Phase III CASPIAN trial showing Imfinzi in combination with SoC platinum-etoposide demonstrated a statistically significant and clinically meaningful improvement in overall survival (OS) versus SoC alone.

CASPIAN: It was a randomised, open-label, multi-centre, global, Phase III trial in the 1st-line treatment of 805 patients with ES-SCLC. The trial compared Imfinzi in combination with etoposide and either carboplatin or cisplatin chemotherapy, or Imfinzi and chemotherapy with the addition of a second immunotherapy, tremelimumab, versus chemotherapy alone. In the experimental arms, patients were treated with four cycles of chemotherapy. In comparison, the control arm allowed up to six cycles of chemotherapy and optional prophylactic cranial irradiation. The trial was conducted in more than 200 centres across 23 countries, including the US, in Europe, South America, Asia and the Middle East. The primary endpoint was OS in each of the two experimental arms.