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AstraZeneca’s Imfinzi (Durvalumab) receives US FDA accelerated approval

02 May 2017 | News

IMFINZI is approved under the FDA’s accelerated approval pathway, based on tumor response rate and durability of response.

AstraZeneca and its global biologics research and development arm, MedImmune, announced that the US Food and Drug Administration (FDA) has granted accelerated approval to IMFINZI™ (durvalumab). IMFINZI is indicated for the treatment of patients with locally advanced or metastatic urothelial carcinoma (mUC) who have disease progression during or following platinum-containing chemotherapy, or whose disease has progressed within 12 months of receiving platinum-containing chemotherapy before (neoadjuvant) or after (adjuvant) surgery.

IMFINZI is approved under the FDA’s accelerated approval pathway, based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

IMFINZI is also under investigation in the Phase III DANUBE trial as first-line treatment in urothelial carcinoma as monotherapy and in combination with tremelimumab.

Clinical trials have demonstrated that patients with PD-L1 high-expressing tumors have a higher likelihood of response through blockade of the programmed cell death or PD-1/PD-L1 pathway. PD-L1 expression testing may be a useful tool to help guide physicians in their treatment decisions, but it is not required for use of IMFINZI.