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AstraZeneca receives approval for cancer drug combination in India

02 June 2023 | News

Tremelimumab in combination with Durvalumab is indicated for the treatment of patients with unresectable hepatocellular carcinoma



AstraZeneca Pharma India, a science-led biopharmaceutical company, has received approval from the Central Drugs Standard Control Organisation (CDSCO) for its cancer drug Tremelimumab Concentrate to be administered intravenously.

The approval for Tremelimumab in combination with Durvalumab is based on results from Phase III HIMALAYA clinical trial and is indicated for the treatment of patients with unresectable hepatocellular carcinoma (uHCC).

The trial was conducted in 181 centres across 16 countries, including in the US, Canada, Europe, South America and Asia including India. This approval paves way for the launch of Tremelimumab solution of 20 mg/ml (25 mg/1.25 ml and 300 mg/15 ml presentations in single dose vials) in India for the specified indication.

GLOBOCAN INDIA 2020 reports more than 30,000 new local cases of HCC are diagnosed every year, making it the 10th most common cause of cancer in India. It's high mortality rate makes it the 8th most common cause of cancer related deaths in the country.

The common causes and risk factors for HCC in India include- cirrhosis, hepatitis B infection, hepatitis C infection, alcohol, smoking, diabetes, NAFLD (Non-Alcoholic Fatty Liver Disease). The 5-year survival rate for HCC is about 18%; localised, regional and metastatic HCC have a 5-year overall survival (OS) of 33%, 10% & 2% respectively.