BioSpectrum
the business of Bi
24 years of leveraging the business of Bio
www.biospectrumindia.co

AstraZeneca Pharma receives CDSCO approval for oncology drug Durvalumab

17 March 2026 | News

CDSCO decision is supported by results from the HIMALAYA Phase III trial



AstraZeneca Pharma India has announced that Central Drugs Standard Control Organisation (CDSCO) has approved an additional indication for Durvalumab solution for infusion (120 mg/2.4 mL and 500 mg/10 mL), for the treatment of patients with unresectable hepatocellular carcinoma (uHCC),who have not received prior systemic therapy.

Worldwide, hepatocellular carcinoma (HCC) is the sixth most common cancer and the third leading cause of cancer death. In India, according to GLOBOCAN 2022, more than 38,000 new cases of HCC are diagnosed annually, making it the 11th most common cancer. HCC's high mortality rate makes it the 8th leading cause of cancer-related deaths in the country, underscoring the urgent need for effective treatment options.

Durvalumab in combination with single dose of tremelimumab (STRIDE) has been approved in patients with uHCC based on the HIMALAYA global Phase III trial, where the STRIDE regimen showed superior outcomes over sorafenib. While immunotherapy combinations and antiâ??VEGF tyrosine kinase inhibitors are available for unresectable HCC, an estimated 25–30% of patients are not eligible for these therapies. In HIMALAYA, durvalumab monotherapy demonstrated nonâ??inferior overall survival versus sorafenib and demonstrated a favourable benefit risk profile for these patient groups with unresectable HCC.

The approved regimen, known as the durvalumab monotherapy regimen, comprises of fixed dose of single agent Durvalumab, an anti-PDL-1 immunotherapy agent 1500 mg given every four weeks until disease progression or unacceptable toxicity.

The CDSCO decision is supported by results from the HIMALAYA Phase III trial, in which durvalumab monotherapy achieved nonâ??inferior overall survival versus sorafenib with a favourable benefit risk profile in patients with unresectable HCC who had not received prior systemic therapy and were not eligible for locoregional treatment.