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CDSCO gives nod to AstraZenecaâ??s Durvalumab for metastatic biliary tract cancer treatment

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The current approval for the molecule is for its use in combination with chemotherapy



AstraZeneca India has announced additional indication approval from Central Drugs Standard Control Organisation (CDSCO) for Durvalumab to treat biliary tract cancer (BTC) in India.

BTC is a group of rare and aggressive gastrointestinal (GI) cancers that form in the cells of the bile ducts (cholangiocarcinoma), gallbladder or ampulla of Vater (where the bile duct and pancreatic duct connect to the small intestine). Apart from ampullary cancer, early-stage BTC often presents without clear symptoms and most new cases of BTC are therefore diagnosed at an advanced stage, when treatment options are limited, and the prognosis is poor.

More than 30,000 new cases of BTCs are seen in India every year with 90% of them diagnosed in the advanced stage. In fact, statistics show a high incidence of gall bladder cancer in the northern part of India.

The approval for AstraZeneca molecule is based on the findings of TOPAZ-1, a Phase-3 Global clinical trial with patients recruited from India as well, that evaluated Immunotherapy plus Chemotherapy as first line treatment for advanced BTCs.

Durvalumab is already approved for use in Stage-III locally advanced, unresectable Non-Small Cell Lung Cancer (NSCLC) post chemoradiotherapy as maintenance treatment and as first line treatment in combination with chemotherapy in Extensive-Stage Small Cell Lung Cancer (ES-SCLC). In July 2022, Durvalumab plus chemotherapy was added to the National Comprehensive Cancer Network‘s (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines) as a Category 1 preferred regimen as 1st-line therapy for locally advanced or metastatic BTC based on the data from TOPAZ-1.