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AstraZeneca Pharma India receives CDSCO approval for treatment of muscle-invasive bladder cancer

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Bladder cancer is the amongst the top 10 most common cancer worldwide



AstraZeneca Pharma India has received approval from the Central Drugs Standard Control Organisation (CDSCO), to import and distribute Durvalumab solution for infusion for an additional indication in India.

The newly approved indication allows the use of Durvalumab in combination with gemcitabine and cisplatin as neoadjuvant treatment, followed by single agent Durvalumab as adjuvant treatment following radical cystectomy, for the treatment of adult patients with muscle invasive bladder cancer (MIBC).

Bladder cancer is the amongst the top 10 most common cancer worldwide, with over 600,000 new cases and 220,000 deaths reported globally in 2022. In India, 22,500 new cases and over 12,000 deaths were recorded in the same year.

Praveen Akkinepally, Country President and Managing Director, AstraZeneca Pharma India Limited said, “This approval reflects AstraZeneca’s unwavering commitment to science-led innovation and to bringing transformative medicines to patients in India. Introducing the first perioperative immunotherapy for muscle-invasive bladder cancer marks a significant step forward in improving outcomes and redefining standards of care. At AstraZeneca, we firmly believe that where a person lives should not determine the quality of treatment they receive. We are deeply focused on closing gaps in access and accelerating the availability of cutting-edge therapies in high-burden countries like India. This milestone is a continuation of our ambition to bring the right medicine to patients in need at the right time, helping them live longer, healthier lives.”

Durvalumab is currently approved in India for the treatment of non-small cell lung cancer, small cell lung cancer, biliary tract cancers, hepatocellular carcinoma and endometrial cancer. This latest approval further strengthens AstraZeneca’s oncology portfolio and reinforces its commitment to delivering innovative therapies that improve patient outcomes.