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ASIA EDITION

Merck’s Keytruda wins FDA approval for invasive bladder cancer treatment

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Keytruda Is the First Anti-PD-1 therapy approved for certain patients with high-risk, non-muscle invasive bladder cancer

Merck, known as MSD outside the United States and Canada, has announced that the U.S. Food and Drug Administration (FDA) has approved KEYTRUDA, Merck’s anti-PD-1 therapy, as monotherapy for the treatment of patients with Bacillus Calmette-Guerin (BCG)-unresponsive, high-risk, non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors who are ineligible for or have elected not to undergo cystectomy.

“Today’s approval of KEYTRUDA reinforces our company’s commitment to expanding existing treatment options for certain patients with high-risk, non-muscle invasive bladder cancer,” said Dr. Scot Ebbinghaus, vice president, clinical research, Merck Research Laboratories. “As the first anti-PD-1 therapy approved in this setting, KEYTRUDA will be a new clinical option for a patient population that previously had limited FDA-approved therapies available.”

“High-risk, non-muscle invasive bladder cancer is a serious disease, characterized by frequent recurrences and progression,” said Arjun V. Balar, M.D., associate professor of Medicine and director of Genitourinary Medical Oncology at NYU Langone Health’s Perlmutter Cancer Center. “Historically, patients with high-risk, non-muscle invasive bladder cancer with CIS whose cancer is unresponsive to BCG treatment had limited non-surgical treatment options. As a physician who specializes in the management of bladder cancer, it is encouraging to now have a new treatment option for these patients.”