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FDA breakthrough status for Merck's KEYTRUDA

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Merck, known as MSD outside the United States and Canada, has announced that the US Food and Drug Administration (US FDA) has granted Breakthrough Therapy Designation to KEYTRUDA (pembrolizumab), the company's anti-PD-1 therapy, for the treatment of patients with relapsed or refractory classical Hodgkin lymphoma (cHL). This is the fourth Breakthrough Therapy Designation granted for KEYTRUDA.

"Merck has launched an ambitious clinical development program examining the efficacy of KEYTRUDA in a broad range of solid and blood cancers, and our studies of relapsed or refractory classical Hodgkin lymphoma are quite promising," said Dr Roger M Perlmutter, president, Merck Research Laboratories. "The FDA's Breakthrough Designation for this blood cancer provides an important mechanism to assist us in bringing this immunotherapy to patients who could benefit from its use."

The FDA's Breakthrough Therapy Designation is intended to expedite the development and review of a candidate that is planned for use, alone or in combination, to treat a serious or life-threatening disease or condition when preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. KEYTRUDA was previously granted breakthrough status for specific patients with advanced melanoma, advanced non-small cell lung cancer (NSCLC), and advanced colorectal cancer.

The Breakthrough Therapy Designation in cHL is based on data from the ongoing Phase 1b KEYNOTE-013 and Phase 2 KEYNOTE-087 studies evaluating single agent KEYTRUDA in patients with cHL. Findings from the KEYNOTE-013 study were presented at the 2015 American Society of Hematology (ASH) Annual Meeting and data from KEYNOTE-087 will be presented at an upcoming medical meeting.

The KEYTRUDA clinical development program includes patients with more than 30 tumor types in more than 250 clinical trials, including more than 100 trials that combine KEYTRUDA with other cancer treatments.

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Registration-enabling trials of KEYTRUDA are currently enrolling patients in melanoma, NSCLC, head and neck cancer, bladder cancer, gastric cancer, colorectal cancer, esophageal cancer, breast cancer, ovarian cancer, Hodgkin lymphoma, non-Hodgkin lymphoma, multiple myeloma, and other tumors, with further trials in planning for other cancers.

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