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Keytruda (pembrolizumab) for Injection
Clinical Update

Clinical update: FDA Approves Merck's Keytruda (pembrolizumab) for First-Line Treatment of Patients With Unresectable or Metastatic MSI-H or dMMR Colorectal Cancer.
FDA approval date: June 29, 2020

Keytruda is an anti-PD-1 therapy that works by increasing the ability of the body's immune system to help detect and fight tumor cells. Keytruda is a humanized monoclonal antibody that blocks the interaction between PD-1 and its ligands, PD-L1 and PD-L2, thereby activating T lymphocytes which may affect both tumor cells and healthy cells.

The approval is based on results from the Phase 3 KEYNOTE-177 trial, in which Keytruda significantly reduced the risk of disease progression or death by 40% (HR=0.60 [95% CI, 0.45-0.80; p=0.0004]) compared with chemotherapy, the current standard of care. In the study, treatment with KEYTRUDA also more than doubled median progression-free survival (PFS) compared with chemotherapy (16.5 months [95% CI, 5.4-32.4] versus 8.2 months [95% CI, 6.1-10.2].
Immune-mediated adverse reactions, which may be severe or fatal, can occur with Keytruda, including pneumonitis, colitis, hepatitis, endocrinopathies, nephritis and renal dysfunction, severe skin reactions, solid organ transplant rejection, and complications of allogeneic hematopoietic stem cell transplantation (HSCT). Based on the severity of the adverse reaction, Keytruda should be withheld or discontinued.
Keytruda can cause fetal harm when administered to a pregnant woman.