FDA Approves Treatment for Two Rare Types of Non-Hodgkin Lymphoma

Poteligeo approved for mycosis fungoides and Sézary syndrome.

August 9, 2018 By Food and Drug Administration (FDA)

The U.S. Food and Drug Administration today approved Poteligeo (mogamulizumab-kpkc) injection for intravenous use for the treatment of adult patients with relapsed or refractory mycosis fungoides (MF) or Sézary syndrome (SS) after at least one prior systemic therapy. This approval provides a new treatment option for patients with MF and is the first FDA approval of a drug specifically for SS.

“Mycosis fungoides and Sézary syndrome are rare, hard-to-treat types of non-Hodgkin lymphoma and this approval fills an unmet medical need for these patients,” said Richard Pazdur, M.D., director of the FDA’s Oncology Center of Excellence and acting director of the Office of Hematology and Oncology Products in the FDA’s Center for Drug Evaluation and Research. “We are committed to continuing to expedite the development and review of this type of targeted therapy that offers meaningful treatments for patients.”

Non-Hodgkin lymphoma is a cancer that starts in white blood cells called lymphocytes, which are part of the body’s immune system. MF and SS are types of non-Hodgkin lymphoma in which lymphocytes become cancerous and affect the skin. MF accounts for about half of all lymphomas arising from the skin. It causes itchy red rashes and skin lesions and can spread to other parts of the body. SS is a rare form of skin lymphoma that affects the blood and lymph nodes.

Poteligeo is a monoclonal antibody that binds to a protein (called CC chemokine receptor type 4 or CCR4) found on some cancer cells.

The approval was based on a clinical trial of 372 patients with relapsed MF or SS who received either Poteligeo or a type of chemotherapy called vorinostat. Progression-free survival (the amount of time a patient stays alive without the cancer growing) was longer for patients taking Poteligeo (median 7.6 months) compared to patients taking vorinostat (median 3.1 months).

The most common side effects of treatment with Poteligeo included rash, infusion-related reactions, fatigue, diarrhea, musculoskeletal pain and upper respiratory tract infection.

Serious warnings of treatment with Poteligeo include the risk of dermatologic toxicity, infusion reactions, infections, autoimmune problems (a condition where the immune cells in the body

attack other cells or organs in the body), and complications of stem cell transplantation that uses donor stem cells (allogeneic) after treatment with the drug.

The FDA granted this application Priority Review and Breakthrough Therapydesignation. Poteligeo also received Orphan Drug designation, which provides incentives to assist and encourage the development of drugs for rare diseases.

The FDA granted this approval to Kyowa Kirin, Inc.

View full prescribing information for Poteligeo

This announcement was originally published on the Food and Drug Administration website on August 8, 2018.
