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ASIA EDITION

FDA gives nod to treat rare non-Hodgkin lymphoma

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The U.S. Food and Drug Administration 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.

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 FDA granted this application Priority Review and Breakthrough Therapy designation.

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.