

Poteligeo[®] (mogamulizumab-kpkc) – New orphan drug approval

- On August 8, 2018, the [FDA announced](#) the approval of [Kyowa Kirin's Poteligeo \(mogamulizumab-kpkc\)](#) for the treatment of adult patients with relapsed or refractory mycosis fungoides (MF) or Sézary syndrome (SS) after at least one prior systemic therapy.
- MF and SS are rare, hard-to-treat forms of non-Hodgkin lymphoma (NHL), a cancer that begins in lymphocytes.
 - 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 form of skin lymphoma that affects the blood and lymph nodes.
- Poteligeo is a monoclonal antibody that binds to CC chemokine receptor type 4, which is found on some cancer cells.
- The efficacy and safety of Poteligeo were based on an open-label study in 372 adult patients with MF or SS after at least one prior systemic therapy. Patients were given either Poteligeo or [Zolinza[®] \(vorinostat\)](#). The primary endpoint was progression-free survival (PFS).
 - The median PFS was 7.6 months with Poteligeo vs. 3.1 months with vorinostat (HR = 0.53 [95% CI: 0.41, 0.69, p < 0.001]).
 - In addition, the overall response rate was 52% with Poteligeo vs. 9% with vorinostat (p < 0.001).
- Warnings and precautions of Poteligeo include dermatologic toxicity, infusion reactions, infections, autoimmune complications, and complications of allogeneic hematopoietic stem cell transplantation after Poteligeo.
- The most common adverse reactions (≥ 20%) with Poteligeo use were rash, infusion related reactions, fatigue, diarrhea, musculoskeletal pain, and upper respiratory tract infection.
- The recommended dose of Poteligeo is 1 mg/kg administered as an intravenous infusion on days 1, 8, 15, and 22 of the first 28-day cycle, then on days 1 and 15 of each subsequent 28-day cycle until disease progression or unacceptable toxicity.
 - Premedication should be administered with [diphenhydramine](#) and [acetaminophen](#) for the first Poteligeo infusion.
- Kyowa Kirin plans to launch Poteligeo in the fourth quarter of 2018. Poteligeo will be available as a 20 mg/5 mL solution in a single-dose vial.