Thymoglobulin® [anti-thymocyte globulin (rabbit)] – Expanded indication

- On April 24, 2017, Sanofi announced the FDA approval of Thymoglobulin [anti-thymocyte globulin (rabbit)] injection, for the prophylaxis of acute rejection in patients receiving a kidney transplant. Thymoglobulin is to be used in conjunction with concomitant immunosuppression.
    - Previously, Thymoglobulin was only approved for the treatment of acute rejection in patients receiving a kidney transplant in conjunction with concomitant immunosuppression.
- Kidney disease is the ninth leading cause of death in the U.S.; 468,000 patients are currently on dialysis for kidney failure, including an estimated 100,000 who are waiting for a kidney transplant.
- Kidney transplantation offers patients with end-stage renal disease a potential alternative to dialysis. With kidney transplantation, however, there is a risk of acute rejection, which can lead to graft complications and potential loss of the transplanted kidney.
- The approval of Thymoglobulin's expanded indication was based on two clinical studies of 508 patients at increased risk of acute rejection and/or delayed graft function randomized to Thymoglobulin or interleukin-2 receptor antagonists (IL2RA). The primary endpoint was treatment failure, defined as the occurrence of acute rejection, graft loss, death, or lost to follow-up within 12 months following transplantation.
    - The first study showed a significantly lower incidence of treatment failure in the Thymoglobulin group vs. the IL2RA group (25% vs. 38%; p = 0.02).
    - The second study demonstrated non-inferiority of Thymoglobulin to ILRA with treatment failure rates of 25% vs. 34%, with an estimated treatment group difference of -9% (95 % CI: -19.9% to 3.6%).
    - A pooled analysis of both studies showed a composite treatment failure rate of 25.1% with Thymoglobulin vs. 36% with the IL2RA group. The estimated between treatment group difference (Thymoglobulin to IL2RA) was -10.9% (95% CI: -18.8% to - 2.9%), which demonstrated superiority of Thymoglobulin for the prevention of acute rejection.
- Thymoglobulin carries a boxed warning for immunosuppression.
- The recommended dose of Thymoglobulin for the prophylaxis of acute rejection in patients receiving a kidney transplant is 1.5 mg/kg of body weight administered by intravenous (IV) infusion daily with the first dose initiated prior to reperfusion of the donor kidney. The usual duration of administration is 4 to 7 days.
    - The recommended dose of Thymoglobulin for treatment of acute rejection in patients receiving a kidney transplant is 1.5 mg/kg of body weight administered daily for 7 to 14 days.
    - Premedication with corticosteroids, acetaminophen, and/or an antihistamine 1 hour prior to each infusion of Thymoglobulin is recommended and may reduce the incidence and intensity of infusion-associated reactions.