Prograf® (tacrolimus) – Expanded indication

- On July 16, 2021, the FDA approved Astellas Pharma's Prograf (tacrolimus), for the prophylaxis of organ rejection, in adult and pediatric patients receiving lung transplant in combination with other immunosuppressants.
    - Prograf is also approved for the prophylaxis of organ rejection, in adult and pediatric patients receiving allogeneic kidney transplant, liver transplant, or heart transplant.
- The efficacy and safety of Prograf-based immunosuppression in primary lung transplantation were assessed in a noninterventional (observational) study using data from the U.S. Scientific Registry of Transplant Recipients. The study analyzed outcomes based on discharge immunosuppression treatment regimen in recipients of a primary lung transplant between 1999 and 2017 who were alive at the time of discharge.
    - In adult patients receiving tacrolimus immediate-release products in combination with mycophenolate mofetil (MMF) (n = 15,478) or tacrolimus immediate-release products in combination with azathioprine (AZA) (n = 4,263), the one-year graft survival estimates from time of discharge were 90.9% and 90.8%, respectively.
    - In pediatric patients receiving tacrolimus immediate-release products in combination with MMF (n = 450) or tacrolimus immediate-release products in combination with AZA (n = 72), the one-year graft survival estimates from time of discharge were 91.7% and 84.7%, respectively.
- Prograf carries a boxed warning for malignancies and serious infections.
- Refer to the Prograf drug label for complete dosing and administration recommendations in lung transplant as well as its other uses.