Keytruda® (pembrolizumab) – New warnings

- On July 27, 2017, the FDA approved updates to the *Warnings and Precautions* section of the Keytruda (pembrolizumab) drug label regarding immune-mediated skin adverse reactions and other immune-mediated adverse reactions to include solid organ transplant rejection.

- Keytruda is approved to treat melanoma, non-small cell lung cancer, head and neck squamous cell cancer, classical Hodgkin lymphoma, urothelial carcinoma, and microsatellite instability-high cancer. Refer to the Keytruda drug label for more specific indication information.

- Immune-mediated rashes, including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN) (some cases with fatal outcome), exfoliative dermatitis, and bullous pemphigoid, can occur.

    — Patients should be monitored for severe skin reactions and exclude other causes.
    — Based on the severity of the adverse reaction, Keytruda should be withheld or permanently discontinued and corticosteroids administered.
    — For signs or symptoms of SJS or TEN, Keytruda should be withheld and the patient should be referred for specialized care for assessment and treatment.
    — If SJS or TEN is confirmed, Keytruda should be permanently discontinued.

- Solid organ transplant rejection has been reported in the post-marketing setting in patients treated with Keytruda.

    — Treatment with Keytruda may increase the risk of rejection in solid organ transplant recipients.
    — The benefit of treatment with Keytruda should be considered versus the risk of possible organ rejection in these patients.

- In addition, information regarding the adverse skin reactions and possible organ transplant rejection has been added to the *Patient Counseling Information*.