Rituxan® (rituximab) – New orphan indication

- On June 7, 2018, Genentech announced the FDA approval of Rituxan (rituximab) intravenous (IV) infusion, for the treatment of adult patients with moderate to severe pemphigus vulgaris (PV).

- Rituxan is also approved to treat non-Hodgkin's lymphoma, chronic lymphocytic leukemia (CLL), rheumatoid arthritis, granulomatosis with polyangiitis (Wegener's granulomatosis), and microscopic polyangiitis.

- PV is an autoimmune, potentially life-threatening, blistering disease affecting the skin and mucous membranes. It affects 30,000 to 40,000 people in the U.S.

- The efficacy of Rituxan in PV was demonstrated in an open-label study enrolling 90 newly-diagnosed adults with pemphigus. Patients received rituximab and prednisone or prednisone alone. The primary endpoint was complete remission (complete epithelialization and absence of new and/or established lesions) at month 24.

    — For PV, 90% of Rituxan and prednisone-treated patients vs. 28% of prednisone-treated patients met the primary endpoint.

- Rituxan carries a boxed warning for fatal infusion reactions, severe mucocutaneous reactions, hepatitis B virus reactivation and progressive multifocal leukoencephalopathy.

- The most common adverse reactions (≥ 15%) with Rituxan use in PV were infusion reactions and depression. Other important adverse reactions are infections.

- The recommended dosage of Rituxan for PV is as follows: administer Rituxan as two-1,000 mg IV infusions separated by 2 weeks in combination with a tapering course of glucocorticoids.

    — For maintenance treatment, administer Rituxan as a 500 mg IV infusion at month 12 and every 6 months thereafter or based on clinical evaluation.
    — For treatment of relapse, administer Rituxan as a 1,000 mg IV infusion on relapse, and consider resuming or increasing the glucocorticoid dose based on clinical evaluation.
    — Consult the Rituxan drug label for further information and for dosing recommendations for all other indications.