Supplemental Approvals

Generic Name (Trade Nameâ€"Company)	**Uses**/Notes
June 8, 2018	
Rituximab ***(Rituxan—Genentech)*** **FDA approves first biologic therapy for pemphigus vulgaris**	Genentech announced FDA approval of rituximab to treat adults with moderate to severe pemphigus vulgaris (PV), a rare, serious, potentially life-threatening condition characterized by progressive painful blistering of the skin and mucous membranes. Rituximab is the first biologic therapy approved by FDA for PV and the first major advancement in treatment of the disease in more than 60 years. The agent is now approved to treat four autoimmune diseases. Approval was based on data from the Ritux 3 trial, a randomized, controlled trial conducted in France that used Roche-manufactured, European Union (EU)–approved rituximab product as the clinical trial material. The study compared the Ritux 3 regimen (EU-approved rituximab product plus short-term corticosteroids [CS]) to CS alone as a first-line treatment in patients with newly diagnosed moderate to severe pemphigus. The primary endpoint of the study was complete remission at month 24 without use of steroids for 2 or more months. Results of the study showed that 90% of patients with PV treated with the Ritux 3 regimen met the endpoint, compared with 28% of patients with PV who were treated with CS alone. These results supported rituximab's efficacy in treating patients with moderate to severe PV, while tapering off CS therapy. Rituxan can cause serious adverse effects that can lead to death, including severe skin and mouth reactions, hepatitis B virus reactivation, and progressive multifocal leukoencephalopathy. Common adverse effects include infusion reactions, infections (with fever and chills), body aches, tiredness, and nausea.

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