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EC approves Roche's MabThera for a rare autoimmune disease

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MabThera is the first biologic treatment approved for moderate to severe cases of the rare autoimmune disease pemphigus vulgaris (PV), and the first major advancement in the treatment of the disease in more than 60 years

Roche announced that the European Commission has approved MabThera® (rituximab) for the treatment of adults with moderate to severe pemphigus vulgaris (PV), a rare condition characterised by progressive painful blistering of the skin and/or mucous membranes. Extensive blistering can lead to serious, life-threatening fluid loss, infection and/or death.

MabThera is the first biologic therapy approved by the European Commission for PV and the first major advancement in the treatment of the disease in more than 60 years. Following approval by the US Food and Drug Administration (FDA) in June 2018 and current decision, MabThera is now approved to treat four autoimmune diseases in the US and Europe.

The European approval is based on data from the phase III Ritux 3 trial, a Roche-supported randomised controlled study, conducted in France, which evaluated MabThera plus a tapering regimen of oral corticosteroids (CS) compared to a standard dose of CS alone, as a first-line treatment in patients with newly diagnosed moderate to severe pemphigus.

Recently, an international panel of experts, the International Bullous Disease Group, published new recommendations on the diagnosis and management of pemphigus in the Journal of the American Academy of Dermatology, and recommended the use of an anti-CD20 monoclonal antibody, such as MabThera combined with a tapering regimen of oral CS, as a first-line therapy option for moderate to severe pemphigus.