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FDA grants priority review for Roche's MabThera/ Rituxan (rituximab) for pemphigus vulgaris

- **Pemphigus vulgaris (PV) is a life-threatening, autoimmune condition with limited treatment options[1]**
- **The FDA previously granted Breakthrough Therapy Designation and Orphan Drug Designation for MabThera/Rituxan in PV**

Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that the US Food and Drug Administration (FDA) has accepted the company's Supplemental Biologics License Application (sBLA) and granted Priority Review for the use of MabThera/Rituxan® (Rituximab) for the treatment of pemphigus vulgaris (PV), a rare, life-threatening condition characterized by progressive painful blistering of the skin and mucous membranes.[1]

The FDA previously granted Breakthrough Therapy Designation and Orphan Drug Designation to MabThera/Rituxan for the treatment of PV. Presently, there are limited approved treatment options available for patients with PV.[1]

"We are committed to developing medicines for rare diseases with limited treatment options, such as pemphigus vulgaris," said Sandra Horning, MD, Chief Medical Officer and Head of Global Product Development. "We look forward to continued work with the FDA to hopefully provide patients with a new treatment for this serious and potentially life-threatening disease."

The sBLA submission is based on data from a Roche-supported randomised trial conducted in France, which evaluated MabThera/Rituxan plus a tapering regimen of low dose oral corticosteroid (CS) treatment compared to a standard dose of CS alone as a first-line treatment in patients with newly diagnosed moderate to severe pemphigus.[2] Results of the study show that MabThera/Rituxan may provide substantial improvement in pemphigus vulgaris remission rates and successful tapering and/or cessation of CS therapy.[2]

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These results were published in The Lancet in March 2017. Genentech is currently conducting another Phase III study in PV which is evaluating MabThera/Rituxan plus a tapering regimen of CS compared to Cellcept (PEMPHIX, NCT02383589).[3]

About pemphigus vulgaris

Pemphigus vulgaris is an autoimmune, intraepidermal, blistering disease affecting the skin and mucous membranes.[1] This rare, life-threatening condition is the most common type of a group of autoimmune disorders collectively called pemphigus.[4] It is estimated that around three in every 100,000 people are diagnosed with this disease.[1]

About the PEMPHIX study

Phase III, randomised, double-blind, double-dummy, active-comparator, parallel-arm multicentre study (PEMPHIX, NCT02383589) was designed to evaluate the efficacy and safety of MabThera/Rituxan compared with mycophenolate mofetil (MMF) in patients with moderate to severe active pemphigus vulgaris requiring 60-120 mg/day oral prednisone (or equivalent).[3]

About MabThera/Rituxan

MabThera/Rituxan is approved to treat rheumatoid arthritis (RA) in combination with another prescription medicine called methotrexate, to reduce the signs and symptoms of moderate to severe active RA in adults, after treatment with at least one other medicine called a tumour necrosis factor (TNF) antagonist has been used and did not work well enough.

MabThera, in combination with glucocorticoids, is indicated for the induction of remission in adult patients with severe, active granulomatosis with polyangiitis (Wegener's, GPA) and microscopic polyangiitis (MPA).

People with serious infections should not receive MabThera/Rituxan. It is not known if MabThera/Rituxan is safe or effective in children.

About Roche

Roche is a global pioneer in pharmaceuticals and diagnostics focused on advancing science to improve people's lives. The combined strengths of pharmaceuticals and diagnostics under one roof have made Roche the leader in personalised healthcare – a strategy that aims to fit the right treatment to each patient in the best way possible.

Roche is the world's largest biotech company, with truly differentiated medicines in oncology, immunology, infectious diseases, ophthalmology and diseases of the central nervous system. Roche is also the world leader in in vitro diagnostics and tissue-based cancer diagnostics, and a frontrunner in diabetes management.

Founded in 1896, Roche continues to search for better ways to prevent, diagnose and treat diseases and make a sustainable contribution to society. The company also aims to improve patient access to medical innovations by working with all relevant stakeholders. Thirty medicines developed by Roche are included in the World Health Organization Model Lists of Essential Medicines, among them life-saving antibiotics, antimalarials and cancer medicines. Roche has been recognised as the Group Leader in sustainability within the Pharmaceuticals, Biotechnology & Life Sciences Industry nine years in a row by the Dow Jones Sustainability Indices (DJSI).

The Roche Group, headquartered in Basel, Switzerland, is active in over 100 countries and in 2017 employed about 94,000 people worldwide. In 2017, Roche invested CHF 10.4 billion in R&D and posted sales of CHF 53.3 billion. Genentech, in the United States, is a wholly owned member of the Roche Group. Roche is the majority shareholder in Chugai Pharmaceutical, Japan. For more information, please visit www.roche.com.

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