FDA Approves Xolair (omalizumab) Prefilled Syringe for Self-Injection Across All Indications

- **Xolair for self-injection offers healthcare providers and appropriate patients another administration option for more flexibility in managing their treatment**

Basel, 13 April 2021 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that the U.S. Food and Drug Administration (FDA) has approved the company's supplemental Biologics License Application for Xolair® (omalizumab) prefilled syringe for self-injection across all approved U.S. indications.[1] Xolair is the only FDA-approved biologic designed to target and block immunoglobulin E (IgE) for the treatment of moderate to severe persistent allergic asthma, chronic idiopathic urticaria (CIU) and nasal polyps.

"Today's approval reflects our commitment to continued innovation with Xolair to address the critical needs of people living with allergic and inflammatory conditions," said Levi Garraway, M.D., Ph.D., Roche's Chief Medical Officer and Head of Global Product Development. "Appropriate patients will now have the flexibility to administer Xolair from home, which is particularly important for those who are considered high-risk during the COVID-19 pandemic."

Before starting self-injection with Xolair prefilled syringe, the patient must have no prior history of anaphylaxis and be closely observed by a healthcare provider for at least three injections with no hypersensitivity (allergic reactions). After Xolair therapy has been initiated and safely established in a healthcare setting, a healthcare provider may determine whether self-injection with Xolair prefilled syringe by the patient or a caregiver is appropriate. The healthcare provider must train the patient or caregiver on the correct subcutaneous injection technique, how to recognize the signs and symptoms of anaphylaxis and how to treat anaphylaxis appropriately, before the first self-injection outside a healthcare setting.

"Expanding treatment options for personalised care and self-management is always welcome news for the patient community," said Kenneth Mendez, CEO and President, Asthma and Allergy Foundation of America. "The possibility of administering FDA-approved treatment outside of the healthcare provider's office, but still guided by that healthcare provider, may reduce barriers to care for patients and their caregivers."

Approximately 460,000 patients have been treated in the U.S. with Xolair since its initial approval in 2003.[2] The use of Xolair across allergic asthma, CIU and nasal polyps is based on its well-established efficacy and safety profile and supported by a robust clinical development program, including 10 Phase III studies.[1]

In the U.S., Genentech, a member of the Roche group, and Novartis Pharmaceuticals Corporation work together to develop and co-promote Xolair.

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About Xolair
Xolair is the only approved antibody designed to target and block immunoglobulin E (IgE). By reducing free IgE, down-regulating high-affinity IgE receptors and limiting mast cell degranulation, Xolair minimizes the release of mediators throughout the allergic inflammatory cascade.

About Roche in Immunology
The Roche Group's immunology medicines include: Actemra®/RoActemra® (tocilizumab) for rheumatoid arthritis, polyarticular juvenile idiopathic arthritis (pJIA), systemic juvenile idiopathic arthritis (sJIA) and giant cell arteritis (GCA) and for the treatment of severe or life-threatening chimeric antigen receptor (CAR) T cell-induced cytokine release syndrome (CRS); Rituxan®/MabThera® (rituximab) for rheumatoid arthritis granulomatosis with polyangiitis and microscopic polyangiitis and for pemphigus vulgaris (PV); Xolair® (omalizumab) for allergic asthma and chronic idiopathic urticaria (CIU); Pulmozyme® (dornase alfa) for cystic fibrosis; and Esbriet® (pirfenidone) for idiopathic pulmonary fibrosis (IPF). Roche has more than 15 investigational medicines in clinical development for immunological diseases that include asthma, autoimmune diseases, rheumatoid arthritis, ulcerative colitis and Crohn's disease.

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. More than 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. Moreover, for the twelfth consecutive year, Roche has been recognised as one of the most sustainable companies in the Pharmaceuticals Industry by the Dow Jones Sustainability Indices (DJSI).

The Roche Group, headquartered in Basel, Switzerland, is active in over 100 countries and in 2020 employed more than 100,000 people worldwide. In 2020, Roche invested CHF 12.2 billion in R&D and posted sales of CHF 58.3 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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References

[1] Xolair® Full Prescribing Information. Genentech, Inc.; November 2020.
[2] Data on file. Genentech, Inc.

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