

FDA accepts application for Xolair (omalizumab) prefilled syringe for self-administration across all indications

- **If approved, Xolair self-administration would offer a more flexible option to help select patients manage their treatment needs**
- **Filing acceptance is based on the well-established efficacy and safety profile of Xolair in allergic asthma and chronic idiopathic urticaria**

Basel, 13 August 2020 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that the US Food and Drug Administration (FDA) accepted the company's supplemental Biologics License Application (sBLA) for a new self-administration option for Xolair[®] (omalizumab) across all approved US indications. If approved, Xolair prefilled syringe would become available for either self-administration by select patients or administration by their caregivers. A decision on approval is anticipated by Q1 2021. In the US, Xolair is currently approved for administration by a healthcare provider in a healthcare setting, and is the only approved biologic designed to target and block immunoglobulin E (IgE) for the treatment of patients with moderate to severe persistent allergic asthma and chronic idiopathic urticaria (CIU).

“Due to the COVID-19 pandemic, there is an urgent need to provide self-administration of Xolair to our patients, particularly those who are considered high-risk for severe illness,” said Levi Garraway, M.D., Ph.D., Roche's Chief Medical Officer and Head of Global Product Development. “We look forward to working closely with the FDA to make Xolair self-administration available as quickly as possible to provide patients with greater flexibility to manage their treatment needs.”

If approved, once Xolair therapy has been established and closely observed by a healthcare provider, self-administration of Xolair prefilled syringe outside of a healthcare setting by a patient or caregiver may be deemed appropriate by the healthcare provider for select patients. In those instances, the patient or caregiver would be trained by a healthcare provider in the correct subcutaneous injection technique and recognition of the early signs and symptoms of anaphylaxis.

Approximately 460,000 patients have been treated in the US with Xolair since its initial approval for allergic asthma in 2003. The use of Xolair in allergic asthma and CIU is supported by a robust clinical development programme, including eight phase III studies. Independent clinical studies involving patients with allergic asthma and CIU on Xolair treatment suggest that Xolair may be self-administered with proper training and monitoring.

In the US, Genentech and Novartis Pharmaceuticals Corporation work together to develop and co-promote Xolair.

About Allergic Asthma and Chronic Idiopathic Urticaria (CIU)

Asthma is a serious and chronic lung disease affecting an estimated 24 million people in the US. It causes swelling and narrowing of the airways, making breathing difficult. Allergic asthma, the most common form of asthma, accounts for approximately 60% of asthma cases in adults.

CIU is a skin condition that can cause hives and severe itch that can last many months and years. CIU is characterised by hives that spontaneously occur without an identifiable cause, and recur for six weeks or more. It is estimated that approximately 1.5 million people in the US have CIU.

About Xolair® (omalizumab)

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 minimises 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 eleventh 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 2019 employed about 98,000 people worldwide. In 2019, Roche invested CHF 11.7 billion in R&D and posted sales of CHF 61.5 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.

All trademarks used or mentioned in this release are protected by law.

Roche Investor Relations

Dr. Karl Mahler
Phone: +41 61 68-78503
e-mail: karl.mahler@roche.com

Dr. Sabine Borngräber
Phone: +41 61 68-88027
e-mail: sabine.borngraeber@roche.com

Dr. Birgit Masjost
Phone: +41 61 68-84814
e-mail: birgit.masjost@roche.com

Investor Relations North America

Loren Kalm
Phone: +1 650 225 3217
e-mail: kalm.loren@gene.com

Jon Kaspar Bayard
Phone: +41 61 68-83894
e-mail: jon_kaspar.bayard@roche.com

Dr. Bruno Eschli
Phone: +41 61 68-75284
e-mail: bruno.eschli@roche.com

Dr. Gerard Tobin
Phone: +41 61 68-72942
e-mail: gerard.tobin@roche.com

Dr. Lisa Tuomi
Phone: +1 650 467 8737
e-mail: tuomi.lisa@gene.com