

FDA grants approval of Xolair (omalizumab) prefilled syringe formulation

- **Xolair, the only biologic approved for both allergic asthma and chronic idiopathic urticaria indications, is now also approved in a prefilled syringe (PFS) formulation**
- **More than 330,000 patients have been treated with Xolair in the last 15 years**
- **The 75 mg/0.5 mL and 150 mg/1 mL single-dose prefilled syringes are expected to be available by the end of 2018**

Basel, 1 October 2018 - Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that the U.S. Food and Drug Administration (FDA) has approved 75 mg/0.5 mL and 150 mg/1 mL single-dose prefilled syringes (PFS) for Xolair® (omalizumab) as an additional formulation for both allergic asthma and chronic idiopathic urticaria (CIU) indications. The new Xolair PFS formulation is expected to be available by the end of this year for the first time in the U.S. Xolair is currently available in a 150 mg single-dose vial with lyophilized, sterile powder for reconstitution.

“Xolair has long been an important treatment option for people with allergic asthma and CIU,” said Sandra Horning, M.D., chief medical officer and head of Global Product Development. “The prefilled syringe formulation reflects our continued commitment to provide healthcare professionals with choices to best support each patient's unique needs.”

The Xolair PFS eliminates the need for healthcare providers to procure Sterile Water for Injection (SWFI) and reconstitute Xolair before administering the medicine.

Xolair is approved for the treatment of moderate to severe persistent allergic asthma in people six years of age or older whose asthma symptoms are not controlled by inhaled corticosteroids, and for CIU in people 12 years of age and older who continue to have hives that are not controlled by H1 antihistamines. Over 330,000 people in the U.S. have been treated with Xolair since its initial approval for people 12 years and older with allergic asthma in 2003.

About allergic asthma and chronic idiopathic urticaria

Asthma is a serious and chronic lung disease affecting an estimated 26 million people in the U.S. It causes swelling and narrowing of the airways, making breathing difficult. Allergic asthma, the most common form of asthma, accounts for approximately 60 percent of asthma cases in adults.

Chronic idiopathic urticaria (CIU) is a skin condition that can cause hives and severe itch that can last many months and years. CIU is characterized 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 U.S. have CIU.

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.

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

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. 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 tenth consecutive year, Roche has been recognised as the most sustainable company 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 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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