FDA approves Xolair® (omalizumab) for adults with nasal polyps

- **Xolair is the first biologic for the treatment of nasal polyps that targets and blocks immunoglobulin E (IgE), a key driver of inflammation**
- **Xolair is now FDA-approved across three diseases and in two formulations, continuing to build on the medicine's 17 years of patient experience since its initial approval for allergic asthma**

Basel, 01 December 2020 - 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 (sBLA) for Xolair® (omalizumab) for the add-on maintenance treatment of nasal polyps in adult patients 18 years of age and older with inadequate response to nasal corticosteroids.[1] Nasal polyps can lead to a loss of smell and nasal congestion, and frequently co-occur with other respiratory conditions, such as allergies and asthma. With this approval, Xolair is now the first biologic for the treatment of nasal polyps that targets and blocks immunoglobulin E (IgE), a key driver of inflammation.

"With Xolair, we observed significantly reduced nasal polyps and congestion symptoms in adults who had nasal polyps in two pivotal Phase III studies," said Joseph Han, M.D., Chief of the Division of Rhinology and the Division of Allergy at Eastern Virginia Medical School and study investigator of the POLYP 1 and POLYP 2 trials. "Xolair provides a new option for treating these patients, who often have other respiratory and allergic conditions that may further worsen symptoms."

The FDA's approval is based on results from the Phase III POLYP 1 and POLYP 2 trials. Both trials showed that adult patients with nasal polyps who had an inadequate response to nasal corticosteroids and received Xolair had statistically significant greater improvement from baseline at Week 24 in Nasal Polyp Score (NPS) and weekly average Nasal Congestion Score (NCS) than patients who received placebo.[1] The greater improvements in NPS and NCS in the Xolair group compared to the placebo group were observed as early as the first assessment at Week 4 in both studies. All patients received background nasal mometasone therapy during both the treatment period and a five-week run-in period. The safety profile in POLYP 1 and POLYP 2 was consistent with the established safety profile for Xolair.

"With today's approval, people living with nasal polyps now have a treatment option that targets IgE, an underlying driver of various allergic conditions," said Levi Garraway, M.D., Ph.D., Roche's Chief Medical Officer and Head of Global Product Development. "We are committed to understanding the full potential of Xolair across the spectrum of allergic diseases and are excited to provide this important treatment for people living with nasal polyps."

Xolair is an injectable biologic medicine that is also FDA-approved for the treatment of moderate to severe persistent allergic asthma in people 6 years of age or older whose asthma symptoms are not controlled by inhaled corticosteroids, and for chronic idiopathic urticaria (CIU) in people 12 years of age and older who continue to have hives that are not controlled by H1 antihistamines. Approximately 460,000 patients have been treated in the U.S. with Xolair since its initial approval for allergic asthma in 2003.[2] In the U.S.,

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Genentech and Novartis Pharmaceuticals Corporation work together to develop and co-promote Xolair.

About Nasal Polyps
Nasal polyps is a commonly occurring and potentially debilitating condition in adults, impacting 13 million people in the U.S.[3,4] Currently, there are limited treatment options available and many patients opt for nasal surgery or systemic steroids. However, polyps may regrow over time. Nasal polyps present as noncancerous lesions on the lining of the nasal sinuses or nasal cavity associated with irritation and inflammation, which can block normal airflow.[5] Nasal polyps may co-occur with other respiratory conditions, such as allergies and asthma.

About POLYP 1 and POLYP 2
In POLYP 1 and POLYP 2, the mean change from baseline at Week 24 for Xolair compared to placebo were: NPS, -1.1 versus 0.1 (95% CI: -1.6, -0.7) and -0.9 versus -0.3 (95% CI: -1.1, -0.1); NCS, -0.9 versus -0. 4 (95% CI: -0.8, -0.3) and -0.7 versus -0.2 (95% CI: -0.8, -0.2).1 POLYP 1 and POLYP 2 are the ninth and tenth Phase III trials for Xolair, respectively. Results from POLYP 1 and POLYP 2 were recently published in the Journal of Allergy and Clinical Immunology. No new or unexpected safety signals were identified in patients treated with Xolair, with over 95% of patients completing each safety arm of POLYP 1 and POLYP 2.[6] The most common adverse reactions (≥3% of patients) included headache, injection site reaction, arthralgia, upper abdominal pain and dizziness.

POLYP 1 and POLYP 2 are replicate Phase III pivotal studies designed to determine the efficacy and safety of Xolair compared with placebo in adult patients with nasal polyps who had an inadequate response to nasal corticosteroids. Both trials were randomized, multicenter, double-blind and placebo-controlled. POLYP 1 involved 138 patients, and POLYP 2 involved 127 patients. The co-primary outcomes for both trials were change from baseline to Week 24 in average daily Nasal Congestion Score and Nasal Polyp Score. Patients in the studies were administered either Xolair or placebo by subcutaneous injection every two to four weeks in addition to background nasal mometasone therapy during both the treatment period and a five-week run-in period.[1]

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 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.

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