FDA accepts supplemental biologics license application for Xolair (omalizumab) for the treatment of nasal polyps

- **The submission is based on positive results from the Phase III POLYP 1 and POLYP 2 studies of Xolair in adults with chronic rhinosinusitis with nasal polyps with inadequate response to intranasal corticosteroids**
- **If approved, Xolair would become the first antibody to help reduce the size of nasal polyps and help improve symptoms through targeting and blocking immunoglobulin E**
- **Frequently co-occurring with other respiratory conditions, nasal polyps is a chronic condition and causes a range of symptoms impacting patients' lives including loss of sense of smell and nasal congestion**

Basel, 11 December 2019 - Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that the U.S. Food and Drug Administration (FDA) has accepted the company's supplemental Biologics License Application (sBLA) for Xolair® (omalizumab) for the treatment of nasal polyps in adult patients 18 years of age and older with inadequate response to intranasal corticosteroids. If approved, Xolair would become the first antibody to help reduce the size of nasal polyps and help improve symptoms through targeting and blocking immunoglobulin E (IgE). The FDA is expected to make a decision on approval for this indication by Q3 2020.

"Nasal polyps may limit patients' ability to breathe and smell normally and causes other symptoms that can negatively impact their lives. There is a critical need for new treatment options for the millions of people living with this condition," said Levi Garraway, M.D., Ph.D., Roche's Chief Medical Officer and Head of Global Product Development. "Results from our two Phase III studies in nasal polyps add to our understanding of Xolair as a potential treatment option across allergic respiratory conditions and associated comorbidities."

Nasal polyps is a common and potentially debilitating condition in adults, impacting 13 million people in the U.S. Currently, there are limited treatment options available and many patients opt for nasal surgery or systemic steroids, which often cannot effectively control symptoms over time due to nasal polyps regrowth. Nasal polyps presents as noncancerous lesions on the lining of the nasal sinuses or nasal cavity associated with irritation and inflammation, which can block normal airflow. Frequently co-occurring with other respiratory conditions, nasal polyps impacts approximately 45% of people with adult-onset asthma and approximately 30% of people with chronic rhinosinusitis, resulting in chronic rhinosinusitis with nasal polyps (CRSwNP) if the nasal polyps and sinusitis symptoms are present for 12 weeks or longer. After sinus surgery, nasal polyps recurs in up to 80% of people, with approximately 40% requiring at least one further surgery.

This sBLA is based on results from the Phase III POLYP 1 and POLYP 2 trials, which showed Xolair met

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both co-primary and multiple secondary endpoints in treating adult patients with CRSwNP who have not adequately responded to intranasal corticosteroids. The co-primary endpoints were change from baseline in Nasal Polyp Score (NPS) and change from baseline in average daily Nasal Congestion Score (NCS) at 24 weeks. Key secondary endpoints that were met included improvement in the Sino-Nasal Outcome Test-22 (SNOT-22) health-related quality of life assessment, improvement in sense of smell, post-nasal drip (posterior rhinorrhea), and runny nose (anterior rhinorrhea). The safety profile in these trials were consistent with the known safety profile for Xolair, with no new unexpected safety signals identified. Full results from the POLYP 1 and POLYP 2 studies were recently presented during an oral session at the 2019 American College of Allergy, Asthma and Immunology (ACAAI) Annual Meeting (abstract #D450).

Xolair is an injectable biologic medicine designed to target and block IgE. Xolair is currently 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 chronic idiopathic urticaria (CIU) in people 12 years of age and older who continue to have hives that are not controlled by H1 antihistamines. In the U.S., Genentech and Novartis Pharmaceuticals Corporation work together to develop and co-promote Xolair.

About POLYP 1 and POLYP 2
POLYP 1 and POLYP 2 are replicate Phase III studies designed to determine the efficacy and safety of Xolair compared with placebo in adult patients with CRSwNP who have had an inadequate response to intranasal corticosteroids. Both trials were randomized, multicenter, double-blind and placebo-controlled. POLYP 1 included 138 patients and POLYP 2 included 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 intranasal corticosteroid.

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 several investigational medicines in clinical development for immunological diseases including autoimmune disorders, 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 2018 employed about 94,000 people worldwide. In 2018, Roche invested CHF 11 billion in R&D and posted sales of CHF 56.8 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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