

Xolair (omalizumab) significantly reduced nasal polyps and congestion symptoms in adults with chronic rhinosinusitis with nasal polyps in two phase III studies

- **The Phase III POLYP 1 and POLYP 2 studies of Xolair in adults with chronic rhinosinusitis with nasal polyps (CRSwNP) with inadequate response to intranasal corticosteroids met both co-primary endpoints and key secondary endpoints**
- **In both studies, Xolair showed a safety profile consistent with previous FDA-approved indications**
- **CRSwNP impacts up to 4 percent of people worldwide, and the prevalence increases with age**

Basel, 03 June 2019 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced positive topline data from two Phase III multicenter studies evaluating Xolair® (omalizumab) for the treatment of adults with chronic rhinosinusitis with nasal polyps (CRSwNP) who have not adequately responded to intranasal corticosteroids. The POLYP 1 and POLYP 2 Phase III trials met both co-primary endpoints and key secondary endpoints. Xolair, an injectable biologic medicine designed to target and block immunoglobulin E (IgE), was shown to be well tolerated and the safety profile was consistent with that observed in previous studies in people with moderate to severe allergic asthma and chronic idiopathic urticaria.

“The results from these pivotal studies provided further support that IgE plays a role in inflammatory and respiratory conditions, and showed that Xolair reduced the size of nasal polyps and associated symptoms that impact these patients’ quality of life,” said Sandra Horning, M.D., chief medical officer and head of Global Product Development. “We plan to discuss these results with the FDA with the goal of bringing this new treatment option as soon as possible to people who do not experience relief with the current standard of care.”

The co-primary endpoints of POLYP 1 and POLYP 2 were change from baseline in Nasal Polyp Score (NPS) and change from baseline in average daily Nasal Congestion Score (NCS) over 24 weeks. Xolair demonstrated statistically significant and clinically relevant improvements in both of these co-primary outcomes. Patients enrolled in the studies included those with and without a history of surgery.

Key secondary endpoints were met, including improvement in smell, post-nasal drip (posterior rhinorrhea score), runny nose (anterior rhinorrhea score) and the Sino-Nasal Outcome Test-22 (SNOT-22) health-related quality of life assessment.

CRSwNP is the inflammation of the nose and paranasal sinuses with the presence of nasal polyps on the lining of the nasal sinuses or nasal cavity. Additional findings from these trials will be presented at an upcoming scientific congress.

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 standard of care treatment. Both trials were randomized, multicenter, double-blind and placebo-controlled. POLYP 1 involved 138 patients, and POLYP 2 involved 127 patients. The primary outcomes for both trials were change from baseline in average daily nasal congestion score at Week 24, and change from baseline in nasal polyp score to week 24. Patients in the studies were administered either Xolair or placebo by subcutaneous injection every two to four weeks.

About chronic rhinosinusitis with nasal polyps (CRSwNP)

Chronic rhinosinusitis with nasal polyps (CRSwNP) is the inflammation of the nose and paranasal sinuses with the presence of noncancerous lesions (nasal polyps) on the lining of the nasal sinuses or nasal cavity. It is possible to have a single polyp or several and the size of the polyps can vary from microscopic to several centimeters. Symptoms can include nasal blockage/obstruction, nasal congestion, nasal discharge, facial pain/pressure and reduction in or loss of smell. CRSwNP is diagnosed by physical examination with endoscopy. The condition is associated with asthma and Aspirin sensitivity.

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 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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