Media & Investor Release

FDA grants priority review to Xolair (omalizumab) for children and adults with food allergies based on positive National Institutes of Health phase III study results

- **If approved, Xolair would be the first medicine to reduce allergic reactions to multiple foods following an accidental exposure**
- **Interim analysis results from first-of-its-kind phase III OUtMATCH study showed Xolair significantly increased the amount of peanut, milk, egg and cashew it took to cause an allergic reaction**
- **17 million people in the U.S. have confirmed food allergies and more than 40% of children and more than half of adults with food allergies have experienced a severe reaction at least once[1,2,3]**

Basel, 19 December 2023 - Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that the U.S. Food and Drug Administration (FDA) has accepted, under Priority Review, the company's supplemental Biologics License Application (sBLA) for Xolair® (omalizumab) for the reduction of allergic reactions, including anaphylaxis, that may occur with an accidental exposure to one or more foods in adult and paediatric patients aged 1 year and older with food allergy. If approved, people taking Xolair would still need to avoid foods they are allergic to (commonly referred to as "food avoidance"). The filing acceptance is based on positive interim analysis results from stage 1 of the National Institutes of Health (NIH)-sponsored pivotal phase III OUtMATCH study evaluating Xolair in patients allergic to peanuts and at least two other common foods. If approved, Xolair would be the first medicine to reduce allergic reactions to multiple foods following an accidental exposure. The FDA is expected to make a decision on approval in the first quarter of 2024.[4]

"Despite the significant and growing health burden from food allergies, treatment advances have been limited," said Levi Garraway, M.D., Ph.D., Roche's Chief Medical Officer and Head of Global Product Development. "We are proud to partner with the National Institutes of Health and leading research institutions on this groundbreaking study. The FDA's Priority Review designation acknowledges the unmet need for these patients, and we hope to make Xolair available to as many people as possible living with food allergies in the U.S."

At a pre-planned interim analysis, an independent Data and Safety Monitoring Board (DSMB) examined the data on the first 165 children and adolescents aged 1 to 17 years who participated in the first stage of the trial and determined the study met its primary endpoint and key secondary endpoints. These interim results showed that, compared to placebo, Xolair significantly increased the amount of peanut (primary endpoint) and milk, egg and cashew (key secondary endpoints) it took to cause an allergic reaction in children and adolescents

with food allergies. Safety findings were consistent with the known benefit-risk profile of Xolair across its approved indications and in previous clinical trials.[5]

The phase III OUtMATCH study is being sponsored and funded by the National Institute of Allergy and Infectious Diseases (NIAID), part of the NIH, and conducted by the NIAID-funded Consortium of Food Allergy Research (CoFAR) across 10 clinical sites throughout the U.S. The study is also supported by Genentech, a member of the Roche Group, and Novartis Pharmaceuticals Corporation. Detailed results from the OUtMATCH study have been submitted by NIAID and CoFAR to a peer-reviewed journal.

Food allergies affect up to 17 million children and adults in the U.S. and food allergy prevalence has been on the rise for the past 20 years.[1,2,3] Allergic reactions can range from mild to moderate, including hives and swelling, to severe and life-threatening, such as anaphylaxis.[6] More than 40% of children and more than half of adults with food allergies have experienced a severe reaction at least once, and it is estimated that food-related anaphylaxis results in 30,000 medical events treated in emergency rooms in the U.S. each year.[1,3,6]

In August 2018, the FDA granted Breakthrough Therapy Designation for Xolair for the prevention of severe allergic reactions following accidental exposure to one or more foods in people with allergies.[7] The FDA's Breakthrough Therapy Designation is designed to expedite the development and review of drugs that are intended to treat serious conditions. Xolair is currently FDA-approved for the treatment of moderate to severe persistent allergic asthma, chronic spontaneous urticaria (CSU) and chronic rhinosinusitis with nasal polyps (CRSwNP).[5] Since its initial approval in 2003, more than 700,000 patients have been treated with Xolair in the U.S.[8]

In the U.S., Genentech, a member of the Roche Group, and Novartis Pharmaceuticals Corporation work together to develop and co-promote Xolair.

About the OUtMATCH Study[4]

The Omalizumab as Monotherapy and as Adjunct Therapy to Multi-Allergen Oral Immunotherapy in Food Allergic Children and Adults (OUtMATCH; NCT03881696) study is an NIH-sponsored, three-stage, multicentre, randomised, double-blind, placebo-controlled study evaluating Xolair safety and efficacy in patients aged 1 to 55 years who are allergic to peanuts and at least two other common foods. The study includes three stages, of which only stage 1 has been completed.

Stage 1 patients were randomised to receive placebo or Xolair injections either every two weeks or every four weeks for 16 to 20 weeks. The Xolair dose and dosing interval were determined by total serum immunoglobulin E (IgE) level and body weight.

About Xolair

Xolair is the only approved antibody designed to target and block IgE. By reducing free immunoglobulin E (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

Founded in 1896 in Basel, Switzerland, as one of the first industrial manufacturers of branded medicines, Roche has grown into the world's largest biotechnology company and the global leader in in-vitro diagnostics. The company pursues scientific excellence to discover and develop medicines and diagnostics for improving and saving the lives of people around the world. We are a pioneer in personalised healthcare and want to further transform how healthcare is delivered to have an even greater impact. To provide the best care for each person we partner with many stakeholders and combine our strengths in Diagnostics and Pharma with data insights from the clinical practice.

In recognising our endeavour to pursue a long-term perspective in all we do, Roche has been named one of the most sustainable companies in the pharmaceuticals industry by the Dow Jones Sustainability Indices for the fifteenth consecutive year. This distinction also reflects our efforts to improve access to healthcare together with local partners in every country we work.

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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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