FDA approves Xolair (omalizumab) for people with Chronic Idiopathic Urticaria, a form of chronic hives

- First biologic medicine approved for CIU, a burdensome skin condition that can cause hives and severe itch and may last many years
- Nearly 50 percent of patients have inadequate response to H1-antihistamines, previously the only approved therapy for CIU

Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that the U.S. Food and Drug Administration (FDA) approved Xolair (omalizumab) for the treatment of chronic idiopathic urticaria (CIU), a form of chronic hives. The new use is for people 12 years of age and older who remain symptomatic despite treatment with H1-antihistamine therapy. Until now, H1-antihistamines have been the only approved therapy for CIU, with about 50 percent of patients having an inadequate response.

“Chronic idiopathic urticaria can be difficult to manage because its causes are unknown, and other approved medicines aren’t effective enough for many patients,” said Sandra Horning, M.D., Chief Medical Officer and Head of Global Product Development. “We are pleased to have Xolair as a new option for people with this serious skin condition.”

CIU, also known as chronic spontaneous urticaria (CSU), is diagnosed when hives occur without an identifiable cause, spontaneously present and reoccur for more than six weeks. CIU can have burdensome symptoms including swelling, severe itch, pain and discomfort that may last for many months and even years. Approximately 1.5 million people in the U.S. develop CIU at some stage in their life. Women are twice as likely as men to experience CIU and most develop symptoms between the ages of 20 and 40.

Xolair is the first biologic medicine and first medicine approved by the FDA for CIU since non-sedating H1-antihistamines. The efficacy and safety profile of Xolair for the treatment of CIU was evaluated in two clinical studies called ASTERIA I and ASTERIA II. In these studies, patients 12 to 75 years old received doses of Xolair at 150 mg, 300 mg or placebo. Xolair or placebo was given every four weeks for 24 weeks (ASTERIA I) and 12 weeks (ASTERIA II). In addition, patients continued to receive H1-antihistamine medicines they
had been taking for CIU before starting treatment with Xolair.

**Efficacy and Safety Findings**

The efficacy of Xolair in patients 12 years and older who remained symptomatic despite taking H1-antihistamines was assessed using a scale known as the average (mean) weekly Itch Severity Score (ISS) at Week 12. The weekly ISS has potential scores ranging from 0 to 21. In ASTERIA I, Xolair 150 mg improved ISS from the starting measurement by 47 percent (-6.7) and Xolair 300 mg improved ISS from the starting measurement by 66 percent (-9.4) at Week 12, compared to a 25 percent (-3.6) score improvement for patients who received placebo. Also, a larger proportion of patients (36 percent) treated with Xolair 300 mg reported no itch and no hives at Week 12, compared to patients treated with Xolair 150 mg (15 percent), and patients in the placebo group (9 percent). Similar results were observed for the ASTERIA II study.

The most common side effects in patients treated with Xolair were nausea, headaches, swelling of the inside of the nose, throat or sinuses, cough, joint pain, and upper respiratory tract infection.

**About Xolair**

Xolair for subcutaneous use is an injectable prescription medicine used to treat adults and children 12 years of age and older with:

- moderate to severe persistent allergic asthma who have had a skin or blood test that is positive for allergic asthma and whose asthma symptoms are not controlled by asthma medicines called inhaled corticosteroids.
- chronic idiopathic urticaria (CIU; chronic hives without a known cause) who continue to have hives that are not controlled by H1-antihistamine treatment.

Xolair is not used to treat other allergic conditions, other forms of urticaria (hives), acute bronchospasm (serious and sudden breathing problems) or status asthmaticus (acute, severe, prolonged asthma attack that can be life threatening). Xolair is not for use in children less than 12 years of age.

Xolair is jointly developed by Genentech and Novartis Pharma AG and is co-promoted in the U.S. with Novartis Pharmaceuticals Corporation.

**Xolair in Allergic Asthma**

Xolair was originally approved in 2003 for people 12 years and older with moderate to severe persistent
allergic asthma caused by year-round allergens in the air and not controlled by asthma medicines called inhaled steroids. Xolair should not be used to treat other allergic conditions. Xolair is not a rescue medicine and should not be used to treat sudden asthma attacks. Xolair should not be used in children under 12 years of age.

About Roche in Immunology
The Roche Group’s immunology medicines include rheumatoid arthritis treatments MabThera/Rituxan (rituximab) and ACTEMRA/RoACTEMRA (tocilizumab), XOLAIR (omalizumab) for asthma and Pulmozyme (dornase alfa) for cystic fibrosis. In addition to its approved portfolio of immunology medicines, Roche’s late stage pipeline products include etrolizumab, being studied in ulcerative colitis, and lebrikizumab for severe asthma.

About Roche
Headquartered in Basel, Switzerland, Roche is a leader in research-focused healthcare with combined strengths in pharmaceuticals and diagnostics. Roche is the world’s largest biotech company, with truly differentiated medicines in oncology, immunology, infectious diseases, ophthalmology and neuroscience. Roche is also the world leader in in vitro diagnostics and tissue-based cancer diagnostics, and a frontrunner in diabetes management. Roche’s personalised healthcare strategy aims at providing medicines and diagnostics that enable tangible improvements in the health, quality of life and survival of patients. Founded in 1896, Roche has been making important contributions to global health for more than a century. Twenty-four medicines developed by Roche are included in the World Health Organisation Model Lists of Essential Medicines, among them life-saving antibiotics, antimalarials and chemotherapy.

In 2013 the Roche Group employed over 85,000 people worldwide, invested 8.7 billion Swiss francs in R&D and posted sales of 46.8 billion Swiss francs. 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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References

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2. American Academy of Allergy Asthma & Immunology (AAAAI) website. "Skin Allergy Overview."
5. Xolair® Full Prescribing Information. Genentech, Inc. (Date TBD)