FDA approves subcutaneous formulation of Actemra for use in active systemic juvenile idiopathic arthritis (sJIA), a rare form of juvenile arthritis

Basel, 13 September 2018 - Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that the US Food and Drug Administration (FDA) has approved the subcutaneous (SC) formulation of Actemra® (tocilizumab) for the treatment of active systemic juvenile idiopathic arthritis (sJIA) in patients two years of age and older. Actemra can be given alone or in combination with methotrexate (MTX) in patients with sJIA. In 2011, FDA approved the intravenous (IV) formulation of Actemra for patients two years of age and older with active sJIA.

"Systemic juvenile idiopathic arthritis is a rare, debilitating disease with limited treatment options," said Sandra Horning, MD, Chief Medical Officer and Head of Global Product Development. "We are pleased to now offer physicians the flexibility to prescribe for children two years of age and older either Actemra IV, administered in a medical office, or Actemra subcutaneous, a prefilled syringe that can be injected at home."

sJIA is the rarest form of juvenile idiopathic arthritis (JIA), a chronic arthritic disease affecting children.\(^1\) JIA affects nearly 300,000 children in the US, of which sJIA accounts for around 10 percent. sJIA is characterised by inflammation in one or more joints, and a daily, spiking fever for at least two weeks, which may be accompanied by a skin rash.\(^1\) Other symptoms may include anemia, enlargement of the liver or spleen, and inflammation of the lining of the heart and/or lungs.\(^1\)

The approval is based on data from the JIGSAW-118 study, a 52-week, open-label, multicenter, phase 1b pharmacokinetic (PK)/pharmacodynamic (PD) bridging study designed to determine the appropriate dosing regimen of Actemra SC across a range of body weights (BW) in children with sJIA.\(^2\) The study enrolled 51 patients aged one to 17 years with sJIA and previous inadequate response or intolerance to methotrexate who were either Actemra naive or were receiving Actemra IV with adequate disease control. Actemra SC was administered open label according to a body weight–based dosing regimen: sJIA patients weighing <30 kg received 162 mg of Actemra every two weeks or 10 days and sJIA patients weighing ≥30 kg received 162 mg of Actemra every week for 52 weeks. Model-computed PK and PD parameters, and safety were assessed.

In general, the safety observed for Actemra SC was consistent with the known safety profile of Actemra IV, with the exception of injection site reactions (ISRs). A higher frequency of Actemra SC patients experienced ISRs, 41 percent (21/51) compared to patients treated with Actemra SC for other approved indications. All ISRs reported were non-serious, and none required patient withdrawal from treatment or dose interruption.

The efficacy of Actemra SC in children two to 17 years of age is based on PK exposure and extrapolation of established efficacy of Actemra IV in sJIA patients and Actemra SC in patients with RA.
About Actemra /RoActemra (tocilizumab)
Actemra/RoActemra is the first approved anti-IL-6 receptor biologic available in both intravenous (IV) and subcutaneous (SC) formulations for the treatment of adult patients with moderate-to-severe active rheumatoid arthritis (RA). Actemra/RoActemra can be used alone or with methotrexate (MTX) in adult RA patients who are intolerant to, or have failed to respond to, other disease-modifying anti-rheumatic drugs (DMARDs). In Europe, RoActemra IV and SC are also approved for use in adult patients with severe, active and progressive RA who previously have not been treated with MTX. Actemra/RoActemra IV and SC are approved globally for polyarticular juvenile idiopathic arthritis (pJIA) and IV approved for systemic juvenile idiopathic arthritis (sJIA) in children two years of age and older. Actemra/RoActemra SC injection is also the first approved therapy for the treatment of giant cell arteritis (GCA) in more than 40 countries, including the US and Europe. Actemra was granted Breakthrough Therapy Designation for GCA by the FDA in October 2016. In the US and Europe, Actemra/RoActemra IV injection is approved for the treatment of chimeric antigen receptor (CAR) T-cell-induced severe or life-threatening cytokine release syndrome (CRS) in people two years of age and older. Actemra is the first approved treatment for CRS in this setting. In Japan, Actemra is also approved for the treatment of Castleman’s Disease and Takayasu Arteritis. Actemra/RoActemra is part of a co-development agreement with Chugai Pharmaceutical Co., Ltd and has been approved in Japan since April 2005. Actemra/RoActemra is approved in more than 110 countries worldwide.

About Roche in rheumatology and beyond
For more than 50 years, Roche has followed the science to pioneer medicines for immune-mediated rheumatic diseases. First-in-class anti-IL-6 receptor therapy Actemra®/RoActemra® (tocilizumab) has treated more than one million people with debilitating conditions, such as rheumatoid arthritis (RA), polyarticular and systemic juvenile idiopathic arthritis, giant cell arteritis and chimeric antigen receptor T-cell-induced cytokine release syndrome. Rituxan®/MabThera® (rituximab), which targets CD20, has significant clinical and real-world experience treating rheumatic conditions including RA, granulomatosis with polyangiitis and microscopic polyangiitis. Roche aims to provide solutions for people that need new treatments most, particularly those with severe or life-threatening conditions and limited treatment options. Our pipeline consists of treatments designed to target immune pathways including a Bruton’s tyrosine kinase inhibitor, which is being studied in RA, lupus erythematosus and chronic spontaneous urticaria, a cadherin-11 antibody in RA, and a glycoengineered type II anti-CD20 antibody in lupus nephritis.

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. Roche has been recognised as the Group Leader in sustainability within the Pharmaceuticals, Biotechnology & Life Sciences Industry nine years in a row by the Dow Jones Sustainability Indices (DJSI).

The Roche Group, headquartered in Basel, Switzerland, is active in over 100 countries and in 2017 employed about 94,000 people worldwide. In 2017, Roche invested CHF 10.4 billion in R&D and posted sales of CHF 53.3 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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References

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