Statement

Roche statement on global supply constraints of Actemra/RoActemra

Basel, 16 August 2021

Actemra/RoActemra has been widely used to treat hospitalised patients with severe or critical COVID-19 around the world, and demand for this medicine has increased to unprecedented levels globally.

Whilst not approved for the treatment of COVID-19 in any country, Actemra/RoActemra (tocilizumab), has recently been granted a U.S. FDA Emergency Use Authorization for hospitalized adults and pediatric patients (2 years of age and older) who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO). Additionally, tocilizumab has also now been included in the WHO Therapeutics and COVID-19 living guideline, based on the body of evidence that has been generated throughout the last 18 months.

Our teams have been working around the clock to make Actemra/RoActemra available as quickly and widely as possible since the beginning of the pandemic. Our largest manufacturing facility is dedicated exclusively to producing treatments for patients with COVID-19. In 2020, ahead of data on Actemra/RoActemra in COVID-19 becoming available, we ramped up our own manufacturing network and contracted with all available large-scale manufacturers around the world to transfer our technologies and maximise production. We have also worked with distributors globally to flexibly manage product supply to enable both Roche and our partners to quickly fulfil requests to meet patient needs. As a result, in 2021 we have supplied Actemra/RoActemra at levels that have increased by more than 100% compared to before the pandemic. So far, approximately 60% of our estimated COVID-19 supply has gone to upper-middle and lower-middle income countries, following the urgent need and representing 300% growth compared to the pre-pandemic supply to these countries.

In addition, Roche and Chugai (who are both holders of Actemra/RoActemra-related patents) have decided not to assert any patents against the use of Actemra/RoActemra in COVID-19 in low- and middle-income countries (LMICs) during this current pandemic, which will provide legal certainty for biologic manufacturers.

Despite all these efforts, the unfortunate reality is that due to the unprecedented surge in worldwide demand - with US demand spiking to well-beyond 400% of pre-COVID levels over the last two weeks alone - we will experience shortages of Actemra/RoActemra globally over the weeks and months ahead. This is due to global manufacturing capacity limits, raw material supply constraints, the complex, labour-intensive process of manufacturing biologics and the dynamically evolving nature of the pandemic.

We have been doing everything possible to minimise the impact of supply constraints and have a controlled distribution strategy in place for people with conditions for which Actemra/RoActemra is approved. We will

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continue to work closely with global health authorities and our partners to help these patients, as well as patients with COVID-19, as quickly as possible.

We are also investigating other treatment approaches to help minimise the impact of COVID-19, including a direct acting antiviral, that may help prevent patients from progressing to severe illness and a monoclonal antibody combination. The antibody combination known as Ronapreve has been authorised for emergency use or temporary pandemic use in territories and regions, including in the European Union, United States, India, Switzerland and Canada, and has been approved in Japan.

Roche stands together with society, governments, healthcare providers and all those working towards the common goal of overcoming the COVID-19 pandemic.

About the Emergency Use Authorization (EUA) for Actemra/RoActemra
Actemra/RoActemra has not been approved by the U.S. FDA in this setting, but the U.S. FDA has made Actemra/RoActemra available under an emergency access mechanism called an EUA as a treatment for certain patients with COVID-19. There is limited information known about the safety or effectiveness of using Actemra/RoActemra to treat people in the hospital with COVID-19. The EUA is supported by a Secretary of Health and Human Services (HHS) declaration that circumstances exist to justify the emergency use of drugs and biological products during the COVID-19 pandemic. The authorisation is temporary and does not replace the formal review and approval process. Actemra/RoActemra is authorised under the EUA only for the duration of the declaration that circumstances exist justifying the authorisation of the emergency use of Actemra/RoActemra under Section 564(b)(1) of the Act, 21 U.S.C.§ 360bbb-3(b)(1), unless the authorisation is terminated or revoked sooner. Roche has existing distribution channels established to ship Actemra/RoActemra to hospitals across the United States.

Please see additional information in Fact Sheet for Healthcare Providers, Fact Sheet for Patients and Parents/Caregivers, and FDA Letter of Authorization.

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, as well as growing capabilities in the area of data-driven medical insights help Roche deliver truly personalised healthcare. Roche is working with partners across the healthcare sector to provide the best care for each person.

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. In recent years, Roche has invested in genomic profiling and real-world data partnerships and has become an industry-leading partner for medical insights.

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 twelfth 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 2020 employed more than 100,000 people worldwide. In 2020, Roche invested CHF 12.2 billion in R&D and posted sales of CHF 58.3 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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