26 March 2020

Re: Actemra (Tocilizumab) use in treatment of rheumatoid arthritis (RA), juvenile idiopathic arthritis (pJIA), systemic juvenile idiopathic arthritis (sJIA) and considerations for coronavirus (COVID-19).

To Whom It May Concern:

At present, there is no published clinical evidence regarding the safety or efficacy of Actemra in treatment of COVID-19 associated viral pneumonia. Preliminary case study/series exploring the use of Actemra for treatment of patients with severe respiratory complications and COVID-19 have been reported from various parts of the world. A randomized, double-blind, placebo-controlled, multicenter study to evaluate the safety and efficacy of tocilizumab in patients with severe covid-19 pneumonia has recently been initiated. On March 3, 2020, Tocilizumab (Actemra) was included in the 7th updated diagnosis and treatment plan for COVID-19 issued by China National Health Commission (NHC).

In the setting of COVID-19 associated viral pneumonia, the IV formulation of Actemra has been used off label. The SC formulation is approved for the treatment of moderate to severe active rheumatoid arthritis (RA) in adult patients either who have responded inadequately to, or who were intolerant to, previous therapy with one or more disease modifying anti-rheumatic drugs (DMARDs) or tumour necrosis factor (TNF) antagonists. Currently in South Africa, 65% of patients are on SC formulation and 35% on the IV formulation in rheumatology.

Commitment to supply chain continuity

We would like to provide reassurance that there are provisions for all your patients currently on treatment as well as a normal increase in patient numbers based on our population incidence in both formulations.

In the interest of the pandemic and facilitating optimum clinical care, we would like to suggest that when the clinical indications are appropriate in adult RA patients, the SC formulation may be used and IV reserved for juvenile idiopathic arthritis (pJIA), systemic juvenile idiopathic arthritis (sJIA) and adults where SC is not suitable. This is a suggestion in order to ensure we accommodate the pandemic whose future local pattern cannot be predicted fully at this point.

Whilst we make this responsible provision, we would like to provide assurance that Roche continues its commitment in the management of and ensuring provisions for rheumatology patients. Roche will continue to assess the potential implications to its manufacturing and supply operations in real time. In line with Health Service Executive (HSE) regulations, Roche Products (South Africa) Ltd currently has at least 10 weeks or more of forecasted requirements of all of Actemra available in the Republic of South Africa with room for provisions.

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These medicines are on allocation, which means that Roche has control over what stock goes out and monitors this on a daily basis, in order to ensure there is no stock piling. Based on current demand forecasts, available stock, and the latest information from our suppliers, Roche is currently not facing any supply challenges in providing supplies for all patients in rheumatology as well as making provisions, together with our global supply chain system, for the arising need in the management of patients with Covid-19.

Yours truly,

Dr Nicholas Mangeya
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