Dr Harald Enzmann
European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

Basel, 13 September 2023

Subject: Withdrawal of RoActemra (tocilizumab)Type II Variation- **EMEA/H/C/000955/II/0114**

Dear Dr Enzmann,

I would like to inform you that, at this point in time, Roche Registration GmbH has taken the decision to withdraw the application for a new indication for RoActemra for slowing the rate of decline in pulmonary function in adult patients with systemic sclerosis-associated interstitial lung disease (SSc-ILD).

This withdrawal is based on the feedback from the CHMP that indicates that while the safety profile of tocilizumab observed was consistent with the established safety profile, the submitted efficacy data are not sufficient for the Committee to conclude on a positive benefit-risk balance for the proposed indication.

This withdrawal does not have any impact on ongoing clinical trials with tocilizumab as monotherapy or in combination with other agents.

Roche is committed to further advance the standard of care for patients and reserves the right to make further submissions at a future date in this or other therapeutic indication(s).

Roche Registration GmbH would like to sincerely thank the (Co-)Rapporteurs, EMA, PRAC and CHMP members for the time dedicated to reviewing this application and the support provided during the procedure.

I agree for this letter to be published on the EMA website.

Yours sincerely,

On behalf of the Marketing Authorization Holder, Roche Registration GmbH