August 8, 2025

Hoffman–La Roche, Ltd.
C/O Genentech, Inc.
Attention: Dhushy Thambipillai
Regulatory Program Manager
1 DNA Way, Building 45-1
South San Francisco, CA 94080

RE: Emergency Use Authorization 099

Dear Ms. Thambipillai:

This letter is to notify you of the revocation of the Emergency Use Authorization (EUA) authorizing the emergency use of Genentech, Inc's ("Genentech") Actemra (tocilizumab), issued initially on June 24, 2021, and amended on October 27, 2022 and December 21, 2022.

The authorization of a drug for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revised or revoked when the criteria under section 564(b)(1) of the Act no longer exist, the criteria under section 564(c) of the Act for issuance of such authorization are no longer met, or other circumstances make such revision or revocation appropriate to protect the public health or safety.

FDA has determined that the criteria for issuance of the authorization for Actemra under section 564(c) of the Act are no longer met. Under section 564(c)(3) of the Act, an EUA may be issued only if FDA concludes there is no adequate, approved[1], and available alternative to the product for diagnosing, preventing, or treating the disease or condition.

On August 8, 2025, the Agency approved a supplemental Biologics License Application (BLA) to BLA 125276, which expanded the approved indication for COVID-19 to the following:

[1] In the context of section 564, the term "approved" refers to a product that is approved, licensed, or cleared under section 505, 510(k), or 515 of the Act or section 351 of the Public Health Service Act. See section 564(a)(2) of the Act.

ACTEMRA® (tocilizumab) is an interleukin-6 (IL-6) receptor antagonist indicated for the treatment of:

Coronavirus Disease 2019 (COVID-19)

Hospitalized adult and pediatric patients aged 2 years and older with coronavirus disease 2019 (COVID-19) who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO).

Based on this approval, FDA has concluded that BLA 125276 for Actemra is an adequate, approved, and available alternative to Actemra's emergency use for the treatment of COVID-19 for the purposes of section 564(c)(3) of the Act.

Accordingly, FDA revokes EUA 099 for Actemra, pursuant to section 564(g)(2) of the Act. As of the date of this letter, the Actemra that was authorized by FDA for emergency use under EUA 099 is no longer authorized by FDA.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

George F Tidmarsh

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George F. Tidmarsh, M.D., Ph.D.
Director
Center for Drug Evaluation and Research
U.S. Food and Drug Administration