January 16, 2025

Baxter Healthcare Corporation
Attention: Ximena Semensato
Senior Manager, Global Regulatory Affairs
Acute Therapies
1 Baxter Parkway
DF64E-087
Deerfield, IL 60015

Re: Revocation of EUA 068

Dear Ms. Semensato:

This letter is in response to the request from Baxter Healthcare Corporation (Baxter) that the U.S. Food and Drug Administration (FDA) revoke the EUA for REGIOCIT. This EUA was issued initially on August 13, 2020. Baxter has informed the FDA that it does not intend to offer REGIOCIT under the EUA in the United States anymore. FDA understands that Baxter will issue a communication to notify healthcare facilities and providers that have received REGIOCIT under the EUA of this revocation and to stop using REGIOCIT with instructions for product return for any product that remains in distribution.

The authorization of a drug for emergency use under section 564 of the Act (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revoked when circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). While there is no new safety concern with REGIOCIT, the Agency recognizes that FDA-approved replacement solutions are in sufficient supply to meet the public health need. Accordingly, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization.

FDA hereby revokes EUA 068 for REGIOCIT pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, REGIOCIT is no longer authorized for emergency use by FDA.

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

Sincerely,

Patrizia A. Cavazzoni -S

Digitally signed by Patrizia A. Cavazzoni -S
Date: 2025.01.16 11:11:41 -05'00'

Patrizia Cavazzoni, M.D.
Director
Center for Drug Evaluation and Research
U.S. Food and Drug Administration