August 16, 2023

Notice Regarding BAXJECT® II Reconstitution Devices Packaged with RECOMBINATE™ [Antihemophilic Factor (Recombinant)] and RIXUBIS® [Coagulation [Factor IX (Recombinant)]

The purpose of this letter is to inform you of a potential issue with some BAXJECT® II reconstitution devices produced by Baxter, the contract manufacturer organization (CMO), between October 2021 and January 2022 for use in conjunction with RECOMBINATE™ [Antihemophilic Factor (Recombinant)] and RIXUBIS® [Coagulation Factor IX (Recombinant)] in the U.S.

Takeda notified the U.S. Food and Drug Administration (FDA) of reports of plastic particles originating near the luer port of the BAXJECT II device. All reported complaints to date were observed prior to administration, either when the luer port cap was removed as part of the preparation process or in the syringe after the drug was reconstituted. There have been no reported adverse events attributable to the BAXJECT II device in our Global Safety databases. **It is important to note there is no quality issue with RECOMBINATE and/or RIXUBIS**.

The European Medicine Agency has issued a recommendation based upon the BAXJECT II situation for European countries. Takeda is working closely with the FDA for a timely resolution to determine the appropriate course of action and will communicate next steps as soon as possible. Since learning of this situation, we have actively collaborated with Baxter, our CMO, to fully resolve the particle issue. **Please do not contact Baxter, as Takeda is the market authorization license holder.**

Patients should be advised that they continue to prepare and administer their RECOMBINATE and/or RIXUBIS using the BAXJECT II devices in their possession according to the Instructions for Use contained with the product packaging. Instructions for Use should be followed carefully, including routine inspection for particles prior to administration. The reconstituted solution should look colorless to faint yellow, and free from foreign particles. In the event particles are identified in the reconstituted product, please do not administer the product. Patients should contact their pharmacy provider or health care provider with any questions related to administration of product or this device issue. **The safety and efficacy profiles of RECOMBINATE and RIXUBIS remain consistent with the product Prescribing Information**.

Please contact Takeda at **1-877-TAKEDA-7 (1-877-825-3327)** with any questions related to information contained in this communication.

Reporting Adverse Events
Healthcare providers and patients are encouraged to report adverse reactions and/or quality problems related to the BAXJECT II reconstitution device, RECOMBINATE and/or RIXUBIS to Takeda at 1-877-TAKEDA-7 (1-877-825-3327). You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

This statement is not intended as a complete description of the benefits and risks related to the use of RECOMBINATE and/or RIXUBIS. Please refer to the product full Prescribing Information and Medication Guide.

US-XMP-2568v1.0 08/23

Appendix

BAXJECT II Reconstitution Device:

Luer Port on BAXJECT II Reconstitution Device: