March 31, 2021

Dear Healthcare Provider,

We are writing to provide you with information on the status of the NATPARA recall in the U.S. and a supply update for patients receiving NATPARA® (parathyroid hormone) for Injection through the Special Use Program (SUP).

While we have made progress on the original issue that led to the U.S. recall, which was the issue of rubber particulates originating from the rubber septum of the NATPARA cartridge, we have not yet reached a resolution. We continue to face complex challenges in bringing NATPARA back to the broader patient community in the U.S.

As we have communicated previously, we continue to monitor all doses of NATPARA within the Special Use Program based on the extraordinary supply demands of the Program. As part of our rigorous quality and manufacturing processes, we have experienced a delay that has affected the manufacturing and release of NATPARA 100-mcg. This is separate from the issue of rubber particulates originating from the rubber septum of the NATPARA cartridge that led to the U.S. recall in September 2019.

The manufacturing delay that is currently affecting NATPARA 100-mcg within the SUP has further impacted our timelines, and at this time we do not expect a return to market before March 31, 2022. Patients who are enrolled in the SUP continue to have access to therapy, and we will keep the community informed of relevant updates as we progress. We regret that we are anticipating an interruption in supply of the 100-mcg strength and we are working with urgency to maintain supply continuity for all SUP patients.

Reporting Adverse Events
Healthcare providers and patients are encouraged to report adverse events in patients taking NATPARA to Takeda at 1-800-828-2088. You are encouraged to report negative side effects of prescription drugs to the U.S. Food & Drug Administration (FDA). Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Medical Information
You may also contact our medical information department at 1-877-TAKEDA-7 (1-877-825-3327) if you have any questions about the information contained in this message or the safe and effective use of NATPARA.

This letter is not intended as a complete description of the benefits and risks related to the use of NATPARA. Please refer to the enclosed full Prescribing Information and Medication Guide. For additional information, please call Takeda at 1-877-TAKEDA-7 (1-877-825-3327) or visit www.natpara.com.

We realize this update may be difficult for those who have been eagerly awaiting information about our anticipated timelines for bringing back NATPARA, and we are disappointed there is not better news to share.

Sincerely,

Tom Koutsavlis
Head, US Medical

Enclosure: NATPARA Full Prescribing Information

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