December 20, 2021

Dear Healthcare Provider,

The purpose of this communication is to provide a year-end update for NATPARA® (parathyroid hormone) for Injection in the US. No action is required by you, however we are sharing this information for your awareness because your patient(s) enrolled in the Special Use Program (SUP), as well as many patients previously prescribed NATPARA, will also be receiving this update.

As announced in September 2021, Takeda filed a Prior Approval Supplement (PAS) with the US Food & Drug Administration (FDA). The NATPARA PAS submission proposes device component changes that include a new septum and new needle. These proposed changes are intended to address the issue of rubber particulates originating from the rubber septum of the NATPARA cartridge that led to the US recall in 2019.

FDA has communicated to Takeda that this PAS submission is associated with a six-month review timeline. Once the FDA completes their review, there are two potential regulatory outcomes of FDA's review: 1) FDA approval of the PAS, or 2) regulatory feedback that may require significant changes to our proposed approach, or lead to a revised approach. If the FDA requests additional data or alternative proposals during or at the end of the review process, a new submission will be required, and the review/approval timelines will be extended.

While the NATPARA PAS submission represents an important step to address the original issue that led to the US recall, the manufacturing and supply issue that we have previously shared will also impact the timeline for bringing NATPARA back in the US. At this time, those issues remain complex.

Given the serious risks associated with abrupt discontinuation of NATPARA, we would not bring NATPARA back to the broader US hypoparathyroidism patient population without being able to ensure reliable and consistent supply. Takeda continues to work with urgency to test and evaluate approaches to best address these complex manufacturing and supply issues. Patients who are enrolled in the SUP continue to have access to NATPARA through that program.

All of us at Takeda remain committed to keeping the hypoparathyroidism community informed in the coming months and will provide another regulatory status update in March or April of 2022.

Reporting Adverse Events
Healthcare providers and patients are encouraged to report adverse events in patients taking NATPARA to Takeda at 1-877-TAKEDA-7 (1-877-825-3327). 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 communication is not intended as a complete description of the benefits and risks related to the use of NATPARA. Please visit www.natpara.com for the 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.

PAS Submission Announcement: www.takeda.com/4a620b/siteassets/en-us/home/newsroom/natpara/natpara_pas_submission_statement.pdf
Manufacturing and Supply Call Summary: www.takeda.com/49bb7d/siteassets/en-us/home/newsroom/natpara/natpara-callsummary.pdf

Sincerely,

Tom Koutsavlis, Head, US Medical