November 16, 2020

Dear Healthcare Provider,

The purpose of this letter is to provide an update on the information we provided in October 2020 regarding the potential for a near-term supply interruption of NATPARA® (parathyroid hormone) for Injection that may impact U.S. patients receiving NATPARA 100-mcg through the Special Use Program (SUP). We are also notifying you that we are now anticipating a near-term supply interruption of NATPARA 25-mcg, as well.

Please see the following time-sensitive information should you wish to consider alternative treatment plans for patients receiving those doses of NATPARA. Supply status updates for all other NATPARA doses are also included in this letter.

Time-Sensitive Information Regarding Patients Receiving NATPARA 25-mcg or NATPARA 100-mcg

As we communicated in October, we have been monitoring supply of NATPARA to prepare for potential supply interruptions. Based on our current assessments, we are anticipating supply interruptions for NATPARA 25-mcg, as early as **December 8, 2020**, as well as NATPARA 100-mcg as early as **January 2, 2021.**

Takeda cannot make dosing recommendations beyond those reflected in the NATPARA Full Prescribing Information. However, if in your best independent clinical judgement, you would like to have a contingency plan in place that includes modifying the patient's current dose of NATPARA, please complete and return the enclosed prescription form. **Any changes to your patient's NATPARA dose, as indicated on this form, will only be processed if a supply disruption occurs**. **If you have already completed a new prescription form and faxed it to us, there is nothing more you need to do.** If you need to make an immediate prescription change, please contact OnePath® at 866-888-0660, Monday through Friday 8:30 AM – 8:00 PM ET, to be connected to the pharmacy dispensing the medication for this program.

For any of your patients who may be affected by a NATPARA dose interruption, please review Section 2.6 (NATPARA Dose Interruption or Discontinuation) and Section 5.4 (Warnings and Precautions: Hypocalcemia) in the attached NATPARA Full Prescribing Information. It is very important to closely monitor serum calcium levels and observe for signs and symptoms of hypocalcemia in these patients while carefully adjusting active vitamin D and supplemental calcium doses. Some patients may require higher doses of active vitamin D and supplemental calcium than doses required prior to starting NATPARA. Additional guidance regarding NATPARA treatment interruption was previously issued in a joint statement by the Endocrine Society and the American Society for Bone and Mineral Research (ASBMR) at the following URL: https://endocrinenews.endocrine.org/endocrine-society-asbmr-issue-joint-statement-on-natpara-recall/.

Update Regarding NATPARA 50-mcg and 75-mcg:
At this time, we do **not** expect SUP-enrolled patients who are receiving **NATPARA 50-mcg** or **NATPARA 75-mcg** to be impacted by supply interruptions before the end of 2020. However, we are closely monitoring these NATPARA doses (50-mcg and 75-mcg). We are committed to supply continuity and will provide another update on all NATPARA doses by mid-December. We have communicated this information to patients who are receiving NATPARA through the

Special Use Program, and we have emphasized to patients receiving NATPARA 50-mcg or NATPARA 75-mcg that there is nothing they need to do at this time.

Compliance with Special Use Program Terms & Conditions
It is important to remind SUP-enrolled patients that each NATPARA cartridge under the Special Use Program (single dose use) is intended for one use only, and that used cartridges with remaining product are to be returned to Takeda in accordance with the Special Use Program (single dose use) instructions. Non-compliance with the rules under the Special Use Program (single dose use) could result in termination of the patient's ability to receive NATPARA product through the program.

Reporting Adverse Events
Heath care 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 1-800-828-2088 if you have any questions about the information contained in this letter 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 1-800-828-2088 or visit www.natpara.com.

We recognize the important medical need that NATPARA fills for your hypoparathyroidism patients. While we focus on mitigating these supply interruptions for SUP-enrolled patients, we continue to prioritize the goal of safely bringing NATPARA back to the broader patient community with U.S. Regulatory Authority oversight.

Sincerely,

Tom Koutsavlis
Head, US Medical

Enclosures: NATPARA Full Prescribing Information
Special Use Program Updated Prescription Form

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