December 22, 2020

Dear Hypoparathyroidism Association board members and community,

On behalf of Takeda, we are sharing a supply-status update to the information we provided during the week of December 14, regarding the potential for near-term supply interruptions of NATPARA® (parathyroid hormone) for Injection that may impact U.S. patients receiving NATPARA through the Special Use Program.

Since that supply update, the manufacturing disruption impacting the availability of NATPARA 100-mcg and NATPARA 75-mcg has now been mitigated. **This means that we are no longer expecting a near-term supply interruption for any NATPARA dose for patients receiving NATPARA through the Special Use Program.**

Takeda OnePath® Patient Support Managers plan to reach out to patients receiving NATPARA 100-mcg or NATPARA 75-mcg in the coming days to provide the update that we are no longer expecting near-term supply interruptions for NATPARA and to answer questions related to the patient's shipment schedule or the Special Use Program. If you need to reach a OnePath® Patient Support Manager, they are available at 866-888-0660 Monday through Friday 8:30 AM – 8:00 PM ET.

We recognize that we have been communicating about supply frequently since October 2020, and we are doing that to ensure that patients receiving NATPARA through the Special Use Program and their prescribers have time to discuss treatment plans in the event of actual NATPARA supply interruptions. This is especially important because any potential interruption or reduction in the daily dose of NATPARA can cause a sharp decrease in blood calcium levels (severe hypocalcemia) which can be dangerous.

At this time, we do not anticipate near-term supply interruptions for any NATPARA dose. However, we are closely monitoring all NATPARA doses based on the supply demands of the Special Use Program. We remain committed to supply continuity and will provide another update on all NATPARA doses by March 2021.

Wishing you and your family a happy and healthy holiday season,

Cheryl Schwartz
Head of US Rare Disease Business Unit

Tom Koutsavlis
Head of US Medical Affairs

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about NATPARA?

Warning: Possible bone cancer (osteosarcoma).

- During animal drug testing, NATPARA caused some rats to develop a bone cancer called osteosarcoma. It is not known if people who take NATPARA will have a higher chance of getting

osteosarcoma. Tell your doctor right away if you have pain in any areas of your body that does not go away, or any new or unusual lumps or swelling under your skin that is tender to touch.

NATPARA is only available through the NATPARA Risk Evaluation and Mitigation Strategy (REMS) Program. The purpose of the NATPARA REMS program is to inform patients about the potential risk of osteosarcoma associated with the use of NATPARA. For more information about this REMS program, call 1-855-NATPARA (628-7272) or go to **www.NATPARAREMS.com**.

NATPARA may cause other serious side effects, including:

High blood calcium (hypercalcemia)

- NATPARA can cause some people to have a higher blood calcium level than normal.
  - Your doctor should check your blood calcium before you start and during your treatment with NATPARA.
  - Tell your doctor if you have nausea, vomiting, constipation, low energy, or muscle weakness. These may be signs that you have too much calcium in your blood.

Low blood calcium (hypocalcemia)

- People who stop using or miss a dose of NATPARA may have an increased risk of severe low blood calcium levels.
- Tell your doctor if you have tingling of your lips, tongue, fingers and feet, twitching of face muscles, cramping of feet and hands, seizures, depression, or have problems thinking or remembering.

Tell your doctor right away if you have any of these signs and symptoms of **high or low blood calcium** levels.

Who should not use NATPARA?

- **Do not use NATPARA** if you are allergic to parathyroid hormone or any of the ingredients in NATPARA.

What should I tell my healthcare provider before using NATPARA?

- **Before you start using NATPARA, tell your doctor about all of your medical conditions. Tell your doctor about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

What are the possible side effects of NATPARA?

- **NATPARA may cause serious side effects like allergic (hypersensitivity) reaction, including anaphylaxis**. Tell your healthcare provider or get emergency medical help right away if you have any of the following symptoms of an allergic reaction:
  - swelling of your face, lips, mouth, or tongue
  - breathing problems
  - fainting, dizziness, feeling lightheaded (low blood pressure)
  - itching
  - rash
  - hives

- fast heartbeat

- **The most common side effects of NATPARA include:** tingling, tickling, or burning feeling of the skin, low or high blood calcium, headache, nausea, reduced sense of touch or sensation, diarrhea, vomiting, pain in joints, too much calcium in urine, and pain in limbs.

These are not all the possible side effects of NATPARA. For more information, talk with your doctor.

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.

Please go to **https://www.shirecontent.com/PI/PDFs/Natpara_USA_ENG.pdf for the Full Prescribing Information and Medication Guide.**

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