Better Health, Brighter Future

March 25, 2020

Dear Hypoparathyroidism Association board members and community,

On behalf of Takeda, I wanted to reach out during this uncertain time to answer some of the questions we have heard from people living with hypoparathyroidism related to the Coronavirus (COVID-19) outbreak.

One of the most frequently-asked questions we have heard from NATPARA patients, in regards to COVID-19, is whether or not COVID-19 will impact supply for patients who have been prescribed NATPARA® (parathyroid hormone) for injection as part of the Special Use Program (SUP). Based on our current assessments, we do not anticipate supply disruption to the SUP in the near-term due to the COVID-19 outbreak. While it is not yet possible to predict precisely what the impact may be on individual products in the longer term, we will continue to monitor the evolving COVID-19 situation. If there are material changes in status, we will keep patients, their prescribing healthcare providers and patient advocacy organizations – including the Hypoparathyroidism Association – informed.

For those patients enrolled in the SUP program, they will continue to receive their NATPARA directly from Theracom. As we have previously communicated to patients enrolled in the SUP, each shipment of NATPARA will now include two weeks of single-use vials instead of one week of treatment to ensure greater program efficiency. All other program elements, including retrieval of product, will continue.

We have also heard questions asking if we will stop reviewing new applications to the SUP in the event that COVID-19 infections lead to a greater number of new applications to the Program. I can confirm that we will continue to evaluate new applications from healthcare professionals to the SUP, which is focused on supporting patients who are at extreme risk of life-threatening complications as a result of discontinuation of NATPARA. Currently, 399 people are receiving NATPARA through this program.

We want to assure the hypoparathyroidism community that returning NATPARA to patients who need it remains a high priority for Takeda. Work on this program has continued without interruption, and there is a large team dedicated to these efforts. As we continue this work, we also plan to schedule time to hear directly from the hypoparathyroidism community; please watch for information from the Hypoparathyroidism Association in the coming weeks.

Finally, I want to encourage you to check the CDC's guidance for those who are at higher risk for complications from COVID-19. Go to the COVID-19 page at https://www.cdc.gov/. The CDC's guidance includes – but is not limited to – information about COVID-19 symptoms, how to protect yourself and others from the virus, and people who maybe at higher risk for complications due to the virus. For information on risks and precautions in your community, please contact your healthcare team.

Sincerely,

Cheryl Schwartz
Head of US Hematology & Rare Disease Business Unit

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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)
  - fast heartbeat
  - itching
  - rash
  - hives
- **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.**