



Takeda Supply Update for the NATPARA® Special Use Program

Cambridge, MA, October 20, 2020 — Takeda Pharmaceutical Company Limited (“Takeda”) and its wholly-owned subsidiary, Takeda Pharmaceuticals U.S.A., Inc., are providing an update today regarding the potential for a near-term supply interruption of the 100-mcg dose of NATPARA® (parathyroid hormone) for Injection as early as November 21, 2020. This supply interruption is specific to the U.S. and may impact patients who are receiving NATPARA 100-mcg through the Special Use Program (SUP).

The anticipated supply interruption is related to unexpected manufacturing disruptions that are 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. Takeda deeply regrets that we are anticipating a supply interruption and is making it a priority to bring product back quickly. At the same time, we are working on possible options for alternate treatment approaches with U.S. Regulatory Authority (U.S. Food & Drug Administration or “FDA”) oversight and will keep all impacted patients and their prescribing physicians informed.

Takeda is communicating with healthcare professionals, patients and patient advocacy organizations in the U.S. regarding important actions related to this potential supply interruption. With patient safety as Takeda’s main priority, we are alerting impacted patients and their healthcare providers that 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. Specifically, we are emphasizing to impacted patients the importance of working closely with their prescribing physician for important medical recommendations, including frequent monitoring of blood calcium levels and close titration of active vitamin D and calcium supplements if the patient’s NATPARA is stopped or the dose is altered (e.g., as a result of supply interruption) to avoid hypocalcemia.

Takeda OnePath representatives will reach out to SUP-enrolled patients receiving NATPARA 100-mcg and their prescribing physicians in the coming days. Patients who have immediate questions or concerns may contact OnePath at 866-888-0660 Monday through Friday 8:30 AM – 8:00 PM ET. Healthcare providers may also contact our Medical Information department at 1-800-828-2088 with any questions.

Takeda developed the NATPARA Special Use Program with regulatory oversight following the U.S. recall that began on September 5, 2019. The Special Use Program was put in place to provide NATPARA to patients previously prescribed NATPARA who are at extreme risk of life-threatening complications that are a direct result of the acute effects of NATPARA’s discontinuation resulting from the U.S. recall. Through the Special Use Program, healthcare providers have applied for access to single-use NATPARA (one dose per cartridge) for these extraordinary cases free of charge.

Takeda recognizes the important medical need that NATPARA fills for patients who are living with chronic hypoparathyroidism. While we focus on restoring supply continuity for SUP-enrolled patients, we continue to prioritize the goal of safely bringing NATPARA back to the broader patient community with the oversight of the FDA.

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