Important Update Regarding the NATPARA Recall

Cambridge, MA, October 9, 2019 — On September 5, 2019, Takeda issued a US recall for all doses of NATPARA® (parathyroid hormone) for Injection (25 mcg, 50 mcg, 75 mcg, and 100 mcg). Please find the latest information about the NATPARA recall below.

On October 2, the FDA informed Takeda that they are classifying NATPARA as a Class I recall due to potential risk of rubber stopper particles clogging the needle and leading to under-dosing. The Class I recall requires that all patients with product received prior to the recall of September 5, 2019 ("Recalled Product") return their unused NATPARA to Takeda to prevent the use of Recalled Product. The safety profile of NATPARA remains consistent with the product label.

We are in the process of reaching out to all NATPARA patients, with different instructions based on their individual circumstances, and expect to complete our outreach during the week of October 14, 2019.

It is important to note that the Special Use Program is unaffected by the Class I recall and continues to support patients previously prescribed NATPARA who are at extreme risk of life-threatening complications as a result of discontinuation of NATPARA. This means that the single-use NATPARA cartridges provided under the Special Use Program are excluded from the Class I recall. Patients in the Special Use Program should continue to use their single-use cartridges as prescribed by their physicians.

Consistent with the product labeling, Takeda is alerting NATPARA patients and prescribers that discontinuing NATPARA abruptly can cause a sharp decrease in blood calcium levels (severe hypocalcemia) which can result in serious health consequences. It is critically important that patients contact their prescribing healthcare provider to discuss their individual treatment transition plan and ensure close supervision, including frequent monitoring of blood calcium levels and close titration of active vitamin D and calcium supplements upon stopping NATPARA to avoid low blood calcium (hypocalcemia).

Our commitment to patients remains our highest priority. We are dedicated to the hypoparathyroidism community and resuming supply of NATPARA for patients as soon as possible. We continue to work diligently with the FDA on this issue and will keep patients and healthcare providers informed as we move forward.