Statement

Takeda to Discontinue Manufacturing of NATPAR® / NATPARA® for Patients with Hypoparathyroidism at the End of 2024

OSAKA, Japan and CAMBRIDGE, Massachusetts, [October 4, 2022] -- Takeda (TSE:4502/NYSE:TAK) today announced its decision, made on October 3, 2022, that it will discontinue manufacturing NATPAR®/NATPARA® (parathyroid hormone) for Injection1 globally at the end of 2024 due to unresolved supply issues that are specific to the product. As a result, Takeda will not re-commercialize NATPARA in the U.S. and will discontinue manufacturing NATPAR globally.

Until the end of 2024, Takeda’s key priority is to maintain treatment continuity for patients who are currently receiving NATPAR/NATPARA, subject to available supply. This includes those enrolled in the U.S. Special Use Program and all patients receiving NATPAR in Europe and other regions around the world. Beyond 2024, Takeda intends to supply available doses until inventory is depleted or expired. Takeda will provide updates before the manufacturing end date and ahead of any potential supply interruptions.

Takeda has continued to communicate updates about persistent supply challenges surrounding protein particle formation that are unique and specific to NATPAR/NATPARA2. Over the past several years, Takeda has explored numerous ways to address the NATPAR/NATPARA protein particle issue to improve sustainable supply. Some of the specific steps have included focused root cause analysis, computational modeling, evaluation and implementation of manufacturing process changes and reformulation research and development. Separately, after evaluation of the U.S. Complete Response Letter received earlier this year, Takeda determined it cannot implement a solution to the rubber particle formation issue, which led to the U.S. recall of NATPARA in 20192. Despite these efforts, Takeda has unfortunately determined there is not a sustainable or viable path forward.

It is important to underscore that all product released for patient use continues to meet Takeda’s quality standards, and the safety profile of NATPAR/NATPARA has not changed.

Takeda has great empathy for hypoparathyroidism patients who rely on NATPAR/NATPARA and deeply regrets that we could not resolve these issues. Takeda is communicating this information now following consultation and alignment with regulatory authorities and to allow time for patients to consult with their healthcare teams to develop longer-term treatment plans.

1 NATPARA® for use in the U.S. / NATPAR® for use in Europe and all other markets, in which the medication is commercially available.

2 “Takeda Issues US Recall of NATPARA® (parathyroid hormone) for Injection Due to the Potential for Rubber Particulate” announced on September 6, 2019, and “Takeda Provides NATPARA U.S. Regulatory Update” announced on March 22, 2022.
About Takeda
Takeda is a global, values-based, R&D-driven biopharmaceutical leader headquartered in Japan, committed to
discover and deliver life-transforming treatments, guided by our commitment to patients, our people and the
planet. Takeda focuses its R&D efforts on four therapeutic areas: Oncology, Rare Genetics and Hematology,
Neuroscience, and Gastroenterology (GI). We also make targeted R&D investments in Plasma-Derived Therapies
and Vaccines. We are focusing on developing highly innovative medicines that contribute to making a difference
in people’s lives by advancing the frontier of new treatment options and leveraging our enhanced collaborative
R&D engine and capabilities to create a robust, modality-diverse pipeline. Our employees are committed to
improving quality of life for patients and to working with our partners in health care in approximately 80
countries and regions. For more information, visit https://www.takeda.com.

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