



Better Health, Brighter Future

## **Takeda to Discontinue Manufacturing of NATPAR<sup>®</sup> / NATPARA<sup>®</sup> for Patients with Hypoparathyroidism at the End of 2024**

**OSAKA, Japan, October 4, 2022** – Takeda ([TSE:4502/NYSE:TAK](https://www.takeda.com/stock)) today announced its decision, made on October 3, 2022, that it will discontinue manufacturing NATPAR<sup>®</sup>/NATPARA<sup>®</sup> (parathyroid hormone) for Injection<sup>1</sup> 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. Please see the attached statement for details.

Takeda does not expect a material impact on the consolidated financials for the fiscal year ending March 31, 2023 (FY2022), as a result of the decision. Takeda will update its FY2022 full-year consolidated financial forecasts at the appropriate timing by taking this decision as well as other factors into consideration.

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

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## Statement

### **Takeda to Discontinue Manufacturing of NATPAR<sup>®</sup> / NATPARA<sup>®</sup> 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<sup>®</sup>/NATPARA<sup>®</sup> (parathyroid hormone) for Injection<sup>1</sup> 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/NATPARA<sup>2</sup>. 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 2019<sup>2</sup>. 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.

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

<sup>2</sup> "Takeda Issues US Recall of NATPARA<sup>®</sup> (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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## **Forward-Looking Statements**

This press release and any materials distributed in connection with this press release may contain forward-looking statements, beliefs or opinions regarding Takeda's future business, future position and results of operations, including estimates, forecasts, targets and plans for Takeda. Without limitation, forward-looking statements often include words such as "targets", "plans", "believes", "hopes", "continues", "expects", "aims", "intends", "ensures", "will", "may", "should", "would", "could" "anticipates", "estimates", "projects" or similar expressions or the negative thereof. These forward-looking statements are based on assumptions about many important

factors, including the following, which could cause actual results to differ materially from those expressed or implied by the forward-looking statements: the economic circumstances surrounding Takeda's global business, including general economic conditions in Japan and the United States; competitive pressures and developments; changes to applicable laws and regulations, including global health care reforms; challenges inherent in new product development, including uncertainty of clinical success and decisions of regulatory authorities and the timing thereof; uncertainty of commercial success for new and existing products; manufacturing difficulties or delays; fluctuations in interest and currency exchange rates; claims or concerns regarding the safety or efficacy of marketed products or product candidates; the impact of health crises, like the novel coronavirus pandemic, on Takeda and its customers and suppliers, including foreign governments in countries in which Takeda operates, or on other facets of its business; the timing and impact of post-merger integration efforts with acquired companies; the ability to divest assets that are not core to Takeda's operations and the timing of any such divestment(s); and other factors identified in Takeda's most recent Annual Report on Form 20-F and Takeda's other reports filed with the U.S. Securities and Exchange Commission, available on Takeda's website at: <https://www.takeda.com/investors/sec-filings/> or at [www.sec.gov](http://www.sec.gov). Takeda does not undertake to update any of the forward-looking statements contained in this press release or any other forward-looking statements it may make, except as required by law or stock exchange rule. Past performance is not an indicator of future results and the results or statements of Takeda in this press release may not be indicative of, and are not an estimate, forecast, guarantee or projection of Takeda's future results.

#### **Medical information**

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