Better Health, Brighter Future

Statement

Takeda Provides NATPARA U.S. Regulatory Update

OSAKA, Japan, March 22, 2022 and CAMBRIDGE, Massachusetts, March 22, 2022 – Takeda (**TSE:4502/NYSE:TAK**) and its wholly-owned subsidiary, Takeda Pharmaceuticals U.S.A., Inc. issued a statement today that Takeda has received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) in response to the Prior Approval Supplement (PAS) for NATPARA (parathyroid hormone) for Injection, stating that the PAS cannot be approved in its present form. The PAS was submitted in August 2021 to address the potential for rubber particulate formation that led to a local U.S. recall in September 2019. Takeda is evaluating the details of the CRL to determine next steps. In the meantime, NATPARA's commercial return in the U.S. is indefinitely delayed.

Takeda intends to provide patients who are enrolled in the NATPARA Special Use Program (SUP) with continued access to therapy free of charge, in accordance with regulatory oversight and under the discretion of the FDA, until a commercial product is available.

With the goal of limiting supply interruption for SUP patients, we continue to work on the separate supply challenges surrounding protein particle formation that we have described over the past year. Those challenges are unrelated to the PAS and the recall. It is important to underscore that all product released for patient use continues to meet Takeda's quality standards and the safety profile of NATPARA has not changed.

Takeda understands and has tremendous empathy for how much the community has been impacted without NATPARA. We will continue to support this community, and more information can be found in the Takeda U.S. Newsroom at https://www.takeda.com/en-us/newsroom/natpara-updates/.

Takeda does not expect a material impact on the full-year financial forecast for the year ending March 31, 2022, as a result of receiving the CRL and the supply challenges.

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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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. 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.

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