



News Release

Takeda Announces Anticipated Financial Impact from Novartis' withdrawal of the Marketing Authorisation Application for Xiidra®

Osaka, JAPAN, June 29, 2020 – Takeda Pharmaceutical Company Limited ([TSE:4502/NYSE:TAK](https://www.takeda.com/stock)) (“Takeda”) today announced the anticipated financial impact from Novartis Europharm Limited’s (“Novartis”) withdrawal of the Marketing Authorisation Application (“MAA”) for Xiidra® (lifitegrast ophthalmic solution) 5% product (“Xiidra®”) in Europe, as posted on the European Medicines Agency’s website on June 26, 2020.

Xiidra® is the first and only prescription treatment approved by the U.S. Food and Drug Administration for both signs and symptoms of dry eye disease, with a mechanism of action that targets inflammation. It was one of the products obtained through the acquisition of Shire plc by Takeda in January 2019. In July 2019, Takeda completed the sale of Xiidra® to Novartis for a sales price of \$3.4 billion upfront in cash and up to an additional \$1.9 billion in potential milestone receipts, including certain sales-based milestones. As of March 31, 2020, Takeda had recognized a financial asset of approximately \$850 million on its Consolidated Statements of Financial Position based on the estimated fair value of the contingent consideration related to these potential milestone receipts.

Takeda will remeasure the financial asset to its estimated fair value as at June 30, 2020. As a result of Novartis’ withdrawal of the MAA for Xiidra®, Takeda expects that the probability of receiving certain sales-based milestones may be reduced, although the total potential milestone receipts of up to \$1.9 billion remain unchanged. As a result of the remeasurement, Takeda anticipates that it will recognize a loss of approximately \$200 million in Reported Operating Profits resulting in a loss of approximately \$150 million in Reported Net Profit attributable to owners of the Company for the three-month period ending June 30, 2020. The amounts will be finalized as part of Takeda’s quarter-end procedures in connection with its results for the three-month period ending June 30, 2020, and the actual loss may be higher or lower as a result. The final impact for the three-month period ending June 30, 2020 will be disclosed in due course, after it becomes available.

Since the impact to Takeda of Novartis’ withdrawal of the MAA represents a loss related to the divestment of a non-core business, it will impact reported profit, but will not impact Core Operating Profit or Core Net Profit. In addition, there will be no material negative impact on cash flows or Adjusted EBITDA. Takeda will continue to assess the impact of the MAA withdrawal and other factors and will update its forecast for the fiscal year ending March 31, 2021 at the appropriate timing. Finally, Takeda remains committed to \$10 billion of divestitures of its non-core assets, and this announcement does not impact this commitment.

Media Contacts:

Japanese Media

Kazumi Kobayashi

kazumi.kobayashi@takeda.com

+81 (0) 3-3278-2095

Media outside Japan

Tsuyoshi Tada

tsuyoshi.tada@takeda.com

+1 (617) 551-2933

About Takeda Pharmaceutical Company Limited

Takeda Pharmaceutical Company Limited ([TSE:4502/NYSE:TAK](https://www.tse-europe.com/quote/TSE:4502)) is a global, values-based, R&D-driven biopharmaceutical leader headquartered in Japan, committed to bringing Better Health and a Brighter Future to patients by translating science into highly-innovative medicines. Takeda focuses its R&D efforts on four therapeutic areas: Oncology, Rare Diseases, 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.

For more information, visit <https://www.takeda.com>.

Important Notice

For the purposes of this notice, “press release” means this document, any oral presentation, any question and answer session and any written or oral material discussed or distributed by Takeda Pharmaceutical Company Limited (“Takeda”) regarding this release. This press release (including any oral briefing and any question-and-answer in connection with it) is not intended to, and does not constitute, represent or form part of any offer, invitation or solicitation of any offer to purchase, otherwise acquire, subscribe for, exchange, sell or otherwise dispose of, any securities or the solicitation of any vote or approval in any jurisdiction. No shares or other securities are being offered to the public by means of this press release. No offering of securities shall be made in the United States except pursuant to registration under the U.S. Securities Act of 1933, as amended, or an exemption therefrom. This press release is being given (together with any further information which may be provided to the recipient) on the condition that it is for use by the recipient for information purposes only (and not for the evaluation of any investment, acquisition, disposal or any other transaction). Any failure to comply with these restrictions may constitute a violation of applicable securities laws.

The companies in which Takeda directly and indirectly owns investments are separate entities. In this press release, “Takeda” is sometimes used for convenience where references are made to Takeda and its subsidiaries in general. Likewise, the words “we”, “us” and “our” are also used to refer to subsidiaries in general or to those who work for them. These expressions are also used where no useful purpose is served by identifying the particular company or companies.

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; the success of or failure of product development programs; decisions of regulatory authorities and the timing thereof; 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/reports/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. 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.

###