



## Takeda Information

### Financial FAQs regarding Q1 FY2020 earnings

Global Finance IR  
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The following are responses to some frequently asked questions (FAQs) regarding Q1 FY2020 earnings of Takeda Pharmaceutical Company Limited (Takeda), announced on July 31, 2020.

#### **Q1. What was the consensus estimate for Q1 FY2020 (April-June 2020) results?**

A1. To our knowledge, analysts from ten financial institutions<sup>1</sup> prepared estimates on Takeda's Q1 FY2020 (April-June 2020) results. Based on the estimates of these ten analysts, who provided an estimate for Q1 results after the Q4 FY2019 earnings announcement:

- Average estimated revenue was 822.5 bn yen
- Average estimated Core Operating Profit was 270.1 bn yen
- Average estimated Core Earnings Per Share (EPS) was 111 yen

Takeda's actual revenue was 801.9 bn yen, actual Core Operating Profit was 280.9 bn yen, and actual Core EPS was 122 yen for Q1 FY2020.

#### **Q2. What was the impact of the novel coronavirus infectious disease (COVID-19) on Takeda's Q1 FY2020 results?**

A2. To date, Takeda has not experienced a material effect on its financial results as a result of the global spread of COVID-19, despite the various effects on its operations as detailed on pages 14-16 of the [Summary of Financial Statements](#) submitted to the Tokyo Stock Exchange.

With regards to individual products, the underlying revenue growth of VYVANSE was +0.3%, which was a slowdown versus same period in the prior year, Q1 FY2019 underlying revenue growth (+12.8%). The lower growth was a result of COVID-19 related stay-at-home restrictions, which significantly reduced patient visits, subsequent diagnoses and created opportunities for children to temporarily discontinue medication - similar to what we would usually see in summer months when children are not in school. On the other hand, we experienced strong underlying revenue growth of NINLARO in Q1 FY2020 (+31.0%). NINLARO is the only all oral proteasome inhibitor regimen approved for the treatment of patients with relapsed/refractory multiple myeloma and it can be delivered to and taken at home, making it an option for appropriate patients to minimize clinic visits during this period. In addition, many guidelines around COVID-19 and cancer care, such as from

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<sup>1</sup> Bank of America, Citigroup, Cowen, Credit Suisse, Goldman Sachs, Jefferies, Mitsubishi UFJ Morgan Stanley, Mizuho Securities, Morgan Stanley and Nomura Securities.

the American Society of Hematology (ASH) and the American Society of Clinical Oncology (ASCO), have recommended delaying stem cell transplant for transplant-eligible patients until the pandemic subsides, though the specific guidelines may vary by region. These adjusted recommendations could lead to longer pre-transplant use of oncology products but only until transplant is advised for these patients. This situation had a positive impact on certain products in our oncology portfolio. COVID-19 has also impacted financial markets, including foreign exchange rates, and changes in foreign exchange rates negatively impacted reported revenue compared to the same period in the previous year (underlying revenue, which adjusts the effect of fluctuations in foreign exchange rates, was not affected).

Based on currently available information, Takeda believes that its financial results for FY2020 will not be materially affected by COVID-19 and, accordingly, our FY2020 forecast reflects this belief. However, the situation surrounding COVID-19 remains highly fluid, and future COVID-19-related developments in FY2020, including new or additional COVID-19 outbreaks and additional or extended lockdowns, shelter-in-place orders or other government action in major markets, could result in further or more serious disruptions to Takeda's business, such as slowdowns in demand for Takeda's products, supply chain related issues or significant delays in its clinical trial programs. These events, if they occur, could result in additional impacts on Takeda's business, results of operations or financial condition, as well result in significant deviations from our FY2020 forecast.

**Q3. What are the main factors driving the decline of -29.6% reported revenue in the 'Other' therapeutic area?**

A3. Four main factors can be identified to explain the 58.8 bn yen decline of "other" therapeutic area revenue in Q1 FY2020 compared to Q1 FY2019:

- (1) The negative impact of divestitures on revenue in the 'other' therapeutic area, including XIIDRA, was ~17 bn yen;
- (2) The decline in sales momentum of certain products, including ULORIC (-11.3 bn yen) due to loss of exclusivity;
- (3) The termination of Enbrel (etanercept) co-promotion with Pfizer in Japan (-8.7 bn yen); and
- (4) Foreign exchange impact

The FY2020 full-year reported forecast for "others" therapeutic area is a decline of -20% to -10%

**Q4. Why did Q1 SG&A expenses decline compared to FY2019? Did the impact derive from COVID-19?**

A4. The decline in SG&A was driven by a combination of factors including lower spend as a result of COVID-19, and the benefit from cost synergies, as described below.

- (1) For COVID-19, we saw broad lower spend in areas such as travel and events due to extended restriction on all non-essential international travels and continuation of our telework guidance. Takeda's underlying core operating profit margin in Q1 FY2020 was 34.7 %, an improvement of 320 basis points over prior year, of which approximately half can be estimated as attributable to lower spend due to COVID-19;
- (2) Synergy savings were led by Takeda's Procurement team, who held a Partner Value Summit in 2019 to re-negotiate contracts with our top suppliers. Takeda Business Solutions also contributed which created value through business insights and analytics, process optimization and automation, and enabling working capital improvements.

**Q5. Q1 FY2020 Reported EPS was 53 yen. Why was the achievement rate against full-year guidance (59 yen) so high at approximately 90%? What are the headwinds in Q2 FY2020 and onwards?**

A5. In Q1 FY2020, reported EPS benefitted from the one-time, non-cash gain from the revaluation of SHP647 liabilities. We expect lower reported EPS in Q2-Q4 for the following reasons:

- (1) Q1 reported tax rate was 36.7% but we expect the full-year reported tax rate to be 60% (please refer to Q9 for more details);
- (2) We have a 50 bn yen placeholder for impairment losses on intangible assets in the full-year forecast, but we only booked 1.9 bn yen in Q1; and
- (3) Takeda's Core Operating Profit is affected by seasonality, which historically has resulted in higher levels of OPEX after Q1.

**Q6. What is the progress of \$10bn divestiture target? How will Takeda use surplus cash that could be generated if Takeda's business divestitures exceed the target of \$10bn?**

A6. We are making solid progress on our commitment to simplify our portfolio and meet our deleveraging targets. We have not announced any time frame for divestitures, nor the specific assets, but we have a shortlist of non-core assets under consideration. We remain confident that, despite the unprecedented market conditions due to the COVID-19 public health crisis, we will execute on our goal to divest \$10bn in non-core assets. We have already made substantial progress on the divestiture program since April 2019, and as of July 31, 2020, we have announced six deals worth up to \$8 bn.

After achieving the \$10 bn divestiture target, we intend to deploy any excess generated cash pursuant to our capital allocation policy. Our first priority is to reduce debt toward our target of 2x net debt/adjusted EBITDA within fiscal years 2021 to 2023. Second, is to invest in growth drivers such as strategic investment in R&D, new product launches including in China, and expanding our presence in plasma-derived therapies. And third, is to use excess cash to further support our commitment to maintaining our well-established dividend policy of 180 yen per share annually.

**Q7. What are the main factors for upgrading Reported Operating Profit FY2020 full-year forecast?**

A7. We only upgraded the reported forecast, and have not changed underlying and core guidance. The reported forecast upgrade is driven by one-time non-cash items, such as the SHP 647 liability revaluation gain and XIIDRA contingent consideration asset revaluation loss. Takeda recognized 60.2 bn yen of revaluation gain (other operating income) as the impact on reported Operating Profit in Q1, reflecting the European Commission's decision to release Takeda from commitment to divest SHP647. In addition, Takeda remeasured the estimated fair value of the potential future milestone payments of XIIDRA reflecting the impact of Novartis' withdrawal of the MAA in Europe. Takeda recognized a loss (other operating expense) of 18.6 bn yen as the impact on reported Operating Profit in Q1. However, there is still the possibility for us to receive full \$1.9 billion in cash for XIIDRA milestones as none of them are attached to EU approval.

**Q8. Why is the reported tax rate guidance for the full-year significantly higher than the Q1 FY2020 tax rate?**

A8. The increase of reported tax rate from ~37% in Q1 to ~60% in the full year forecast is primarily driven by forecasted tax charges to occur in future quarters for restructuring activities related to the Shire integration and certain one-time items such as divestitures.

**Q9. Could you explain the background regarding the FDA Warning Letter for the Hikari Plant? Is there any impact to product supply as a result of the Warning Letter?**

A9. On November 26, 2019, the FDA concluded a routine inspection of the Takeda Hikari Plant in Japan. The FDA regularly inspects manufacturing facilities in compliance with U.S. laws and regulations. This inspection was one of the routine FDA inspections of the Hikari manufacturing site. On March 11, 2020, the site received a designation as OAI (Official Action Indicated) status with an email that indicated the agency was still reviewing all submitted responses and updates. Subsequently, the FDA issued a Warning Letter to the Hikari site on June 9, 2020. The Warning Letter included several technical observations about procedures relating to production operations, aseptic controls, preventative maintenance of equipment, documentation maintenance, and quality oversight. As this situation is being resolved, we are monitoring product supply daily. We responded to the Warning Letter on June 30, within the 15 working day response deadline. Typically, it takes 12-18 months from the date of the original inspection to resolve a Warning Letter. We are confident that the comprehensive corrective action plan we've put in place will address the issues raised by the FDA. We are targeting end of calendar year 2020 to be ready for re-inspection.

ENTYVIO and leuprorelin are products manufactured at the Hikari Plant for the U.S. market. ENTYVIO is manufactured in a network of several internal and external production sites, including a new global manufacturing site for the ENTYVIO drug substance in Brooklyn Park, Minnesota, to sustainably support the growing demand for ENTYVIO. ENTYVIO continues to be manufactured at the Hikari Plant for the U.S. market and we do not anticipate any supply issues for ENTYVIO at this time. Leuprorelin supply volume has decreased due to a combination of reasons, including production stoppages initiated to enhance overall compliance in alignment with Takeda standards and current regulations. These stoppages were extended as a part of corrective actions following the recent inspections. We have been working to minimize disruption for patients treated with leuprorelin (e.g. with formulation switches), and manufacturing for the Japan and GEM market resumed on July 20, 2020. We expect to resupply leuprorelin in Japan in September, and therefore anticipate a temporary supply shortage of leuprorelin. At this stage, we do not anticipate a global supply shortage of leuprorelin, but there may be certain regions, including the U.S., that may experience periodic shortages.

**Q10. How did Takeda's plasma-derived therapies (PDT) business perform in Q1 FY2020?**

A10. PDT BU's strong Q1 2020 results delivered YoY growth of +14%, and both Revenue and Core Operating Profit exceeded expectations. The ramp up of our Covington facility production and continued investment in expanding our plasma collection network resulted in growing our Immunoglobulin (IG) supply through the full H2 FY2019 period and is expected to continue to contribute to FY2020 growth.

We reported strong IG revenue underlying growth of 30% in Q1 FY2020, mainly driven by higher demand in the U.S. for Gammagard-Liquid, and partially due to phasing and lower revenue in the U.S in Q1 FY2019. We expect IG to grow double digit in reported basis in FY2020 and market demand growth remains in line with expectations.

Albumin sales declined 14% in underlying basis versus Q1 FY2019, mainly due to a high supply spike in Q1 FY2019 sales following a blackout period in China.

The YoY quarter comparisons reflect different timing challenges from Q1 2019, which resulted in exceptionally

high growth for IG and a decline for albumin. For both IG and albumin, the underlying demand is stable and strong. We continue to execute on our previously communicated goals of increasing both plasma collection and manufacturing capacity by >65% by FY2024.

**Q11. What is the impact of the COVID-19 outbreak on Takeda's PDT business? Do you expect the pandemic to impact plasma volume targets/ plasma collection for FY2020 and beyond?**

A11. Takeda acknowledges current concerns about how the decline in plasma donation during the pandemic may impact our industry's ability to supply plasma-derived therapies short and mid-term to patients who rely on them. We are committed to doing everything we can to enable continuity of care for patients around the world. In view of the significant investments Takeda has been making to increase our plasma collection and production capacity, we expect to be able to maintain and support the planned growth in demand for Takeda's plasma-derived therapies through to the end of our fiscal year (March 2021). The continuing uncertainty regarding the progression of COVID-19 in the U.S. means that it is too early to gauge the extent of decline in plasma collections longer term, particularly given that this will be offset by how well we manage to mitigate for it over time through all the various actions we are taking. We are monitoring the situation closely, evaluating different scenarios and have implemented mitigation plans that cover a wide range of variables that influence plasma collections in order to meet our commitments to patients.

During the pandemic plasma collection centers have been designated as critical infrastructure and our centers are operational across all four countries (US, AT, HU, CZ). Moreover, we continue to open new centers as part of our sustained investment in increasing our plasma collection capacity (we have added five new centers already this year and expect this to total c.20 by end of our fiscal year).

Within our BioLife network, we have expanded our efforts to encourage donations through a variety of different actions and awareness initiatives, while continuing to prioritize the safety of our employees and donors with additional screening measures, distancing policies, and protective equipment for our staff. We are engaging broadly across the blood and plasma industries, with peers, professional associations, patient organizations, regulators and governments to emphasize the critical importance of plasma sourcing towards ensuring uninterrupted supply of these therapies for patients with chronic and complex conditions.

It is our belief that the positive awareness of plasma as a contributing solution to the pandemic will help foster recognition and support for the broader patient need for plasma around the world, including the need to permanently revise outdated regulation in order to improve availability of plasma.

**Q12. When does Takeda expect approval of CoVIg-19, an investigational treatment for COVID-19?**

A12. The Investigational New Drug (IND) application was submitted a couple of weeks ago by NIAID/ NIH and is expected to clear soon. Clinical supplies of CoVIg-19 are ready to ship from Takeda and CSL Behring facilities to the NIH's depots as soon as the IND is approved.

We are pleased with the remarkable progress we have made since initiating the CoVIg-19 Plasma Alliance in April. Thanks to the unprecedented collaboration from the Alliance members, commitment from those who have recovered from the virus and generously chosen to donate their plasma, as well as the strong support from the NIH, we are working toward being in a position to submit for regulatory authorizations before the end of the year. If the trial proves successful, this therapy could bring new hope to those at risk of serious complications from COVID-19.

## **About Takeda Pharmaceutical Company Limited**

Takeda Pharmaceutical Company Limited ([TSE:4502/NYSE:TAK](https://www.tse.or.jp/eng/stocks/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>.

## **Contacts**

### **Investor Relations**

Christopher O'Reilly, +81-(0)3-3278-2543  
[takeda.ir.contact@takeda.com](mailto:takeda.ir.contact@takeda.com)

### **Media Relations**

Kazumi Kobayashi, +81 (0)3-3278-2095  
[kazumi.kobayashi@takeda.com](mailto:kazumi.kobayashi@takeda.com)

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Further information on certain of Takeda's Non-IFRS measures is posted on Takeda's investor relations website at <https://www.takeda.com/investors/reports/quarterly-announcements/>

Reconciliation from reported revenue to underlying revenue growth presented in accordance with IFRS are included as an appendix to FY2020 Q1 presentation.

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