Better Health, Brighter Future

# News Release

## European Commission Releases Takeda from Commitment to Divest Shire's Pipeline Compound SHP647

**Osaka, JAPAN, May 29, 2020 –** Takeda Pharmaceutical Company Limited (TSE:4502/NYSE:TAK) ("Takeda") today announces that on May 28, the European Commission (the "EC") has released Takeda from the obligation to divest the pipeline compound SHP647 and certain associated rights ("SHP647"), a commitment that was provided by Takeda to secure regulatory clearance of its acquisition of Shire plc ("Shire"). Takeda will discontinue the current SHP647 clinical trial program, and it will be providing all eligible trial participants with the opportunity to have continued access to SHP647 in a post-trial access ("PTA") study. In addition, subject to obtaining trial participant consents and the satisfaction of regulatory and ethical considerations, Takeda will make SHP647 clinical trial data and biosamples available to the scientific community through the Crohn's & Colitis Foundation ("Foundation").

Takeda announced on November 20, 2018, that the EC approved its proposed acquisition of Shire (the "Acquisition"). The EC's approval was conditioned on Takeda fulfilling commitments provided to the EC in connection with the regulatory clearance. Specifically, in relation to the future potential overlap in the area of inflammatory bowel diseases between Takeda's marketed product Entyvio (vedolizumab) and Shire's pipeline compound SHP647, Takeda committed to divest SHP647. The divestment of SHP647 was not a condition to the completion of the Acquisition, which became effective on January 8, 2019.

Subsequent to the completion of the Shire acquisition, the SHP647 clinical trial program was affected by exceptional circumstances, which have caused the EC to conclude that the competition concerns previously identified by the EC no longer arise. Accordingly, the EC found that Takeda's obligation to divest SHP647 was no longer justified and the EC waived the commitment.

Takeda engaged in two formal and rigorous sale processes spanning 14-months to identify and engage with potential purchasers of SHP647. The first sales process was conducted by Takeda and the second by an independent Divestiture Trustee, which was appointed under the standard procedure provided for in Takeda's commitments to the EC. Takeda and the Divestiture Trustee each engaged with more than 60 potential purchasers, but the sale process was unsuccessful.

Takeda will no longer develop the SHP647 compound in any inflammatory bowel disease indication, including Ulcerative Colitis or Crohn's Disease. The SHP647 clinical trial program will be discontinued in an orderly

manner over the coming months. New patient enrolment into the study protocols was already stopped in late March due to the risks associated with the COVID-19 pandemic. The trials will be unblinded and not restarted. Takeda is committed to providing all eligible patients already in the SHP647 clinical trials and responding to treatment with the opportunity to have continued access to SHP647 in a PTA study. The parameters for this PTA study will be determined in collaboration with the SHP647 program's steering committee and relevant regulatory authorities, and subsequently launched, subject to applicable local regulations and ethical considerations. Patients should continue to adhere to the current study protocol until contacted by their study site after guidance has been provided by the Takeda study team members. Treatment will be made available to patients enrolled in this PTA study to meet their individual treatment needs.

In addition, Takeda will make SHP647 clinical trial data and biosamples available to the scientific community through the Foundation, via the IBD Plexus® platform, a first-of-its-kind research information exchange platform and biobank that centralizes data and biosamples from diverse research studies, subject to applicable local regulations and ethical considerations. The Foundation will serve as an independent body to review requests from investigators and physicians seeking access to anonymised SHP647 clinical trial data and biosamples, and to make final decisions on data sharing. Takeda is committed to sharing clinical trial data and biosamples that benefit patients and foster scientific discovery in a way that ensures patient consent to the use of the data, privacy and preserves the integrity of research.

Assets and liabilities related to SHP647, which were previously classified as held for sale on Takeda's consolidated statements of financial position, have ceased to be classified as held for sale as the result of the EC's decision. Takeda will reverse previously estimated liabilities and reassess the estimates of the future costs related to SHP647 such as program termination costs, which will have a net impact of gain on our Operating Profit in Q1 of the current fiscal year ending March 31, 2021 (i.e., FY2020). This impact will be disclosed in due course, after it becomes available.

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**About Takeda Pharmaceutical Company Limited**

Takeda Pharmaceutical Company Limited (TSE:4502/NYSE:TAK) 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.

**About the Crohn's & Colitis Foundation**

The Crohn's & Colitis Foundation is the leading non-profit organization focused on both research and patient support for inflammatory bowel disease (IBD). The Foundation's mission is to cure Crohn's disease and ulcerative colitis, and to improve the quality of life for the estimated 3 million Americans living with IBD. For over 50 years, we have been inspiring and engaging patients and caregivers in the country's largest IBD community and helping to dramatically accelerate the pace of research by breaking down traditional barriers to patients, data, funding, and collaborations. We also provide extensive educational resources for patients and their families, medical professionals, and the public.

For more information, visit www.crohnscolitisfoundation.org, call 888-694-8872, or email info@crohnscolitisfoundation.org.

**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.

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