



News Release

Communication in accordance with article 8, §1 of the Belgian Royal Decree of 27 April 2007 on public takeover bids.

Takeda announces intention to launch a potential voluntary and conditional public takeover bid for all shares, warrants, American Depositary Shares and convertible bonds of TiGenix

Osaka, Japan, January 5, 2018, 07:00 CET/15:00 JST – Takeda Pharmaceutical Company Limited (TSE: 4502) (“Takeda”) announces its intention to launch a potential voluntary and conditional public takeover bid in cash for all shares, warrants, American Depositary Shares and convertible bonds (which are not already owned by Takeda or its affiliates) of TiGenix NV (“TiGenix”).

The potential public takeover proposes an acquisition price of EUR 1.78 per share in cash and an equivalent price per American Depositary Share, warrant and convertible bond, representing a transaction value of approximately EUR 520 million on a fully diluted basis.

Subject to its fiduciary duties and review of the final bid prospectus, the bid is unanimously supported by TiGenix’s board of directors (including its CEO). Takeda and TiGenix entered into an offer and support agreement confirming TiGenix’s support and the terms and conditions of the bid set forth in this press release. Gri-Cel S.A., holding 32,238,178 TiGenix shares, and its affiliate Grifols Worldwide Operations Ltd., holding 7,189,800 TiGenix shares in the form of American Depositary Shares, have irrevocably confirmed that they will tender their shares and American Depositary Shares into the potential public takeover bid.

In July 2016, Takeda and TiGenix entered into an exclusive ex-U.S. license, development and commercialization agreement for Cx601, the leading investigational therapy in TiGenix’s pipeline. Cx601 is a suspension of allogeneic expanded adipose-derived stem cells (eASC) locally administered for the treatment of complex perianal fistulas in patients with non-active/mildly active luminal Crohn’s disease, who have had an inadequate response to at least one conventional or biologic therapy. In December 2017, the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) adopted a positive opinion recommending a marketing authorization for Cx601 in this indication, the first allogeneic stem cell therapy to achieve this. A decision from the EMA on the marketing authorization for Cx601 is expected in the first half of 2018.

A global, pivotal Phase III trial investigating Cx601 for the treatment of complex perianal fistulas in patients with non-active/mildly active luminal Crohn’s disease has been initiated for U.S. registration. In the U.S., Takeda intends to work with the U.S. Food and Drug Administration (FDA) to facilitate

the development and potential approval of Cx601. Takeda is also exploring the steps required for regulatory filing of Cx601 for patients in Japan, Canada and emerging markets.

The transaction is subject to the following conditions precedent: (i) the tender into the offer, in aggregate, of a number of securities that, together with all securities owned by Takeda and its affiliates, represents or gives access to 85% or more of the voting rights represented or given access to by all of the outstanding securities on a fully diluted basis as of the end of the first acceptance period, (ii) the absence of a material adverse effect occurring at any time after the date of this announcement, (iii) Cx601 obtaining marketing authorization in the E.U. from the EMA and (iv) the expiration, lapse or termination as appropriate of any applicable waiting periods (including any extensions thereof) under the Hart-Scott-Rodino Antitrust Improvements Act of 1976 in respect of the offer.

Following closing of the potential voluntary public takeover bid, Takeda intends to launch a squeeze-out if the applicable conditions for such squeeze-out are met to delist the shares of TiGenix from Euronext Brussels and NASDAQ. After the squeeze-out, TiGenix would become a wholly-owned subsidiary of Takeda.

This communication does not constitute a formal notification of a voluntary public takeover bid. In case Takeda would decide to formally launch the voluntary public takeover bid, full details of such public takeover bid will be covered by the prospectus to be filed with the Belgian Financial Services and Markets Authority and the offer documents which will be available at www.sec.gov. In the event that Takeda would decide not to proceed with the potential voluntary public takeover bid, then Takeda and TiGenix will issue a further public announcement to that effect.

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Takeda's Commitment to Gastroenterology

Gastrointestinal (GI) diseases can be complex, debilitating and life-changing. Recognizing this unmet need, Takeda and our collaboration partners have focused on improving the lives of patients through the delivery of innovative medicines and dedicated patient disease support programs for over 25 years. Takeda aspires to advance how patients manage their disease. Additionally, Takeda is leading in areas of gastroenterology associated with high unmet need, such as inflammatory bowel disease, acid-related diseases and motility disorders. Our GI research & development team is also exploring solutions in celiac disease, advanced liver disease and microbiome therapies.

About Takeda Pharmaceutical Company

Takeda Pharmaceutical Company Limited ([TSE: 4502](#)) is a global, research and development-driven pharmaceutical company committed to bringing better health and a brighter future to patients by translating science into life-changing medicines. Takeda focuses its R&D efforts on oncology, gastroenterology and neuroscience therapeutic areas plus vaccines. Takeda conducts R&D both internally and with partners to stay at the leading edge of innovation. New innovative products, especially in oncology and gastroenterology, as well as Takeda's presence in emerging markets, are currently fuelling the growth of Takeda. Approximately 30,000 Takeda employees are committed to improving quality of life for patients, working with Takeda's partners in health care in more than 70 countries. For more information, visit <https://www.takeda.com/newsroom/>.

Forward-Looking Statements

This press release contains "forward-looking statements." Forward-looking statements include all statements other than statements of historical fact, including plans, strategies and expectations for the future, statements regarding the expected timing of filings and approvals relating to the transaction, the expected timing of the completion of the transaction, the ability to complete the transaction or to satisfy the various closing conditions, future revenues and profitability from or growth or any assumptions underlying any of the foregoing. Statements made in the future tense, and words such as "anticipate," "expect," "project," "continue," "believe," "plan," "estimate," "pro forma," "intend," "potential," "target," "forecast," "guidance," "outlook," "seek," "assume," "will," "may," "should," and similar expressions are intended to qualify as forward-looking statements. Forward-looking statements are based on estimates and assumptions made by management of Takeda and TiGenix that are believed to be reasonable, though they are inherently uncertain and difficult to predict. Investors and security holders are cautioned not to place undue reliance on these forward-looking statements.

Forward-looking statements involve risks and uncertainties that could cause actual results or experience to differ materially from that expressed or implied by the forward-looking statements. Some of these risks and uncertainties include, but are not limited to: required regulatory approvals for the transaction may not be obtained in a timely manner, if at all; the conditions to closing of the transaction may not be satisfied; competitive pressures and developments; applicable laws and regulations; the success or failure of product development programs; actions of regulatory authorities and the timing thereof; changes in exchange rates; and claims or concerns regarding the safety or efficacy of marketed products or product candidates in development.

The forward-looking statements contained in this press release speak only as of the date of this press release, and neither TiGenix nor Takeda undertakes any obligation to revise or update any forward-looking statements to reflect new information, future events or circumstances after the date of the forward-looking statement. If one or more of these statements is updated or corrected, investors and others should not conclude that additional updates or corrections will be made.

About TiGenix

TiGenix NV (Euronext Brussels and NASDAQ: TIG) is an advanced biopharmaceutical company developing novel therapies for serious medical conditions by exploiting the anti-inflammatory properties of allogeneic, or donor-derived, stem cells.

TiGenix's lead product, Cx601, has successfully completed a European Phase III clinical trial for the treatment of complex perianal fistulas - a severe, debilitating complication of Crohn's disease. Cx601 has been filed for regulatory approval in Europe and a global Phase III trial intended to support a future U.S. Biologic License Application (BLA) started in 2017. TiGenix has entered into a licensing agreement with Takeda, a global pharmaceutical company active in gastroenterology, under which Takeda acquired the exclusive right to develop and commercialize Cx601 for complex perianal fistulas outside the U.S. TiGenix's second adipose-derived product, Cx611, is undergoing a Phase I/II trial in severe sepsis – a major cause of mortality in the developed world. Finally, AlloCSC-01,

targeting acute ischemic heart disease, has demonstrated positive results in a Phase I/II trial in acute myocardial infarction (AMI). TiGenix is headquartered in Leuven (Belgium) and has operations in Madrid (Spain) and Cambridge, MA (USA). For more information, please visit <http://www.tigenix.com>.

About Cx601

Cx601 is an investigational administration of allogeneic (or donor derived) expanded adipose-derived stem cells (eASCs) for the treatment of complex perianal fistulas in adult patients with non-active/mildly active luminal Crohn's disease that have previously shown an inadequate response to at least one conventional therapy or biologic therapy. Crohn's disease is a chronic inflammatory disease of the intestine and complex perianal fistulas are a severe and debilitating complication.

Cx601 was granted orphan drug designation by the European Commission in 2009 and by the U.S. FDA in 2017. TiGenix completed a European Phase III clinical trial (ADMIRE-CD) in August 2015 in which the primary endpoint was met, with a significantly greater proportion of patients treated with Cx601 (50%, n=107) versus control (34%, n=105) achieving combined remission as defined by clinical assessment of closure of all treated external openings that were draining at baseline and absence of collections > 2 cm of the treated perianal fistulas confirmed by masked central MRI at week 24 (97.5% CI 0.2-30.3; p=0.024).¹ The most commonly reported treatment emergent adverse events were proctalgia, anal abscess and nasopharyngitis. A follow-up analysis was completed showing that the efficacy and safety profile of Cx601 were maintained at 52 weeks.² The 24-week results of the Phase III ADMIRE-CD trial were published in *The Lancet* in July 2016.¹ Based on the positive 24 weeks Phase III study results, TiGenix submitted a Marketing Authorization Application to the EMA, with the CHMP adopting a positive opinion recommending the granting of a marketing authorization.

A global Phase III clinical trial (ADMIRE-CD II) intended to support a future U.S. Biologic License Application (BLA) started in 2017, based on a trial protocol that has been agreed with the U.S. FDA through a special protocol assessment procedure (SPA) (clinicaltrials.gov; NCT03279081). ADMIRE-CD II is a randomized, double-blind, placebo-controlled study designed to confirm the efficacy and safety of a single administration of Cx601 for the treatment of complex perianal fistulas in Crohn's disease patients. In July 2016, TiGenix entered into a licensing agreement with Takeda, a global pharmaceutical company active in gastroenterology, under which Takeda acquired exclusive rights to develop and commercialize Cx601 for complex perianal fistulas in Crohn's patients outside of the U.S.

Disclaimer

This communication does not constitute an offer to purchase securities of TiGenix nor a solicitation by anyone in any jurisdiction in respect of such securities, any vote or approval. If Takeda decides to proceed with an offer to purchase TiGenix's securities through a public tender offer, such offer will and can only be made on the basis of an approved offer document by the FSMA and tender offer documents filed with the U.S. Securities and Exchange Commission ("SEC"), which holders of TiGenix's securities should read as they will contain important information. This communication is not a substitute for such offer documents. Neither this communication nor any other information in respect of the matters contained herein may be supplied in any jurisdiction where a registration, qualification or any other obligation is in force or would be with regard to the content hereof or thereof. Any failure to comply with these restrictions may constitute a violation of the financial laws and regulations in such jurisdictions. Takeda, TiGenix and their respective affiliates explicitly decline any liability for breach of these restrictions by any person.

Important Additional Information for U.S. investors

The voluntary takeover bid described herein has not yet commenced. This communication is for informational purposes only and is neither a recommendation, an offer to purchase nor a solicitation of an offer to sell any securities of TiGenix.

At the time the voluntary public takeover bid is commenced, shareholders of TiGenix are urged to read the offer documents which will be available at www.sec.gov. At the time the voluntary public takeover bid is commenced, it shall be comprised of two separate offers – (i) an offer for all securities with voting rights or giving access to voting rights, issued by TiGenix (except for ADSs) (the “**Securities**”), in accordance with the applicable law in Belgium, and (ii) an offer to holders of TiGenix’s American Depositary Shares issued by Deutsche Bank Trust Company Americas acting as depositary (“**ADSs**”), and to holders of Securities who are resident in the U.S. in accordance with applicable U.S. law (the “**U.S. Offer**”).

The U.S. Offer will only be made pursuant to an offer to purchase and related materials. At the time the U.S. Offer is commenced, Takeda will file, or cause to be filed, a tender offer statement on Schedule TO with the SEC and thereafter, TiGenix will file a solicitation/recommendation statement on Schedule 14D-9, in each case with respect to the U.S. Offer.

Holders of TiGenix ADSs and Securities subject to the U.S. Offer who wish to participate in the U.S. Offer, are urged to carefully review the documents relating to the U.S. Offer that will be filed by Takeda with the SEC since these documents will contain important information, including the terms and conditions of the U.S. Offer. Holders of TiGenix ADSs and Securities subject to the U.S. Offer who wish to participate in the U.S. Offer, are also urged to read the related solicitation/recommendation statement on Schedule 14D-9 that will be filed with the SEC by TiGenix relating to the U.S. Offer. You may obtain a free copy of these documents after they have been filed with the SEC, and other documents filed by TiGenix and Takeda with the SEC, at the SEC’s website at www.sec.gov. In addition to the offer and certain other tender offer documents, as well as the solicitation/recommendation statement, TiGenix files reports and other information with the SEC. You may read and copy any reports or other information filed by TiGenix at the SEC Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the Public Reference Room. TiGenix’s filings at the SEC are also available to the public from commercial document-retrieval services and at the website maintained by the SEC at www.sec.gov.

YOU SHOULD READ THE FILINGS MADE BY TAKEDA AND TIGENIX WITH THE SEC CAREFULLY BEFORE MAKING A DECISION CONCERNING THE U.S. OFFER.

References

¹ Panés J, García-Olmo D, Van Assche G, *et al.*, Expanded allogeneic adipose-derived mesenchymal stem cells (Cx601) for complex perianal fistulas in Crohn’s disease: a phase 3 randomized, double-blind controlled trial. *The Lancet*. 2016; 388(10051): 1281-1290.

² Panés J, *et al.*, Long-term efficacy and safety of stem cell therapy (Cx601) for complex perianal fistulas in patients with Crohn’s disease. *Gastroenterology*. Published online 18th December 2017. <http://dx.doi.org/10.1053/j.gastro.2017.12.020>.