

NON DESTINE A LA COMMUNICATION, PUBLICATION OU DISTRIBUTION, EN TOUT OU PARTIE, DANS OU AU SEIN OU DEPUIS UNE QUELCONQUE JURIDICTION OU CELA CONSTITUERAIT UNE VIOLATION DES LOIS APPLICABLES DANS CETTE JURIDICTION

## COMMUNIQUÉ DE PRESSE INFORMATION RÉGLEMENTÉE INFORMATION PRIVILEGIEE

Communication conformément à l'article 8, §1 de l'Arrêté Royal belge du 27 avril 2007 relatif aux offres publiques d'acquisition

## Takeda annonce son intention d'acquérir TiGenix

Louvain (BELGIQUE) – le 5 janvier 2018, 7:30h CET – TiGenix NV ("TiGenix") (Euronext Bruxelles et NASDAQ: TIG), une société biopharmaceutique de pointe axée sur l'exploitation des propriétés anti-inflammatoires des cellules souches allogéniques ou provenant de donneurs, pour le développement de nouveaux traitements destinés à des maladies graves, confirme aujourd'hui que Takeda Pharmaceutical Company Limited ("Takeda") a annoncé son intention de lancer une offre publique d'acquisition volontaire conditionnelle sur TiGenix.

Takeda a l'intention d'acquérir 100% des titres avec droit de vote ou donnant accès aux droits de vote de TiGenix, qui ne sont pas déjà détenus par Takeda ou ses sociétés liées, à un prix de 1,78 EUR par action en numéraire et un prix équivalent en numéraire par *American Depositary Share*, warrant ou obligation convertible.

Takeda a l'intention de lancer l'offre publique d'acquisition proposée peu après l'approbation du prospectus d'offre publique et du mémoire en réponse par l'Autorité des Services et Marchés Financiers ("FSMA"). L'offre sera soumise à ce que Takeda et ses sociétés liées détiennent au moins 85% des titres de TiGenix avec droit de vote ou donnant accès aux droits de vote sur une base entièrement diluée, ainsi qu'aux conditions suspensives suivantes: l'absence d'un effet défavorable important ayant lieu après la date de ce communiqué, l'obtention par le Cx601 de l'approbation de l'Agence Européenne des Médicaments et l'expiration du temps d'attente applicable conformément au *Hart-Scott Rodino Antitrust Improvements Act* de 1976 aux États-Unis. L'approbation de l'Agence Européenne des Médicaments pour le Cx601 est attendue pour la première moitié de 2018.

Conformément à ses obligations fiduciaires et sous réserve de la révision du prospectus final, l'offre est soutenue à l'unanimité par le conseil d'administration de TiGenix, qui va fournir sa réponse formelle à l'offre publique d'acquisition proposée dans un mémoire en réponse qu'il émettra en temps utile en conformité avec les dispositions légales applicables. Takeda et TiGenix ont conclu une convention d'offre et de soutien (*offer and support agreement*) confirmant le soutien de TiGenix et les termes et conditions de l'offre tel qu'établis dans le communiqué de presse de Takeda. Cowen and Company, LLC est intervenu en tant que conseiller financier de TiGenix.

Gri-Cel S.A., détenteur de 32.238.178 actions TiGenix, et la société liée Grifols Worldwide Operations Ltd., détenant 7.189.800 actions TiGenix détenues sous la forme d'*American Depositary Shares*, ont confirmé irrévocablement qu'ils apporteront leurs actions et leurs *American Depositary Shares* détenues dans TiGenix dans l'offre publique d'acquisition potentielle.

Pour plus d'informations sur les termes et conditions de l'offre publique d'acquisition par Takeda, il est fait référence au communiqué de presse de Takeda tel qu'attaché en [Annexe 1](#).

"Nous croyons que l'offre publique d'acquisition envisagée par Takeda est une étape positive pour les détenteurs de titre de TiGenix et reflète la véritable valeur de notre dévouement pour les patients ces dernières années. Nous croyons que l'expertise de TiGenix va aider à accélérer l'ambition qu'a Takeda

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de développer de nouveaux traitements à base de cellules souches," a déclaré Eduardo Bravo, CEO de TiGenix. "Takeda est une société centrée sur le patient, qui offre les meilleures capacités et ressources pour assurer l'accessibilité du Cx601 au patient du monde entier."

Ce communiqué de presse ne constitue pas une offre ou une invitation à l'achat ou à la vente des titres de TiGenix dans une quelconque juridiction. D'autres communiqués seront fait en temps voulu, si et quand les circonstances le requièrent.

**Pour plus d'information, veuillez contacter:**

**TiGenix**

**Claudia Jiménez**

Senior Director Investor Relations and Communications

Tel: +34918049264

Claudia.jimenez@TiGenix.com

## **A propos de TiGenix**

*TiGenix NV (Euronext Brussels et NASDAQ: TIG) est une société biopharmaceutique qui développe de nouvelles thérapies pour le traitement de conditions médicales graves, centrées sur l'exploitation des propriétés anti-inflammatoires de cellules souches allogéniques expansées ou issues de donneurs.*

*Le produit phare de TiGenix, Cx601, a passé avec succès la phase européenne III essai clinique pour le traitement des fistules périanales complexes – une complication grave et invalidante de la maladie de Crohn. Cx601 a été déposé pour approbation réglementaire en Europe et un essai de phase globale III visant à soutenir une future demande de licence de produits biologiques (Biologic License Application - BLA) aux États-Unis a été lancé en 2017. TiGenix a conclu un accord de licence avec Takeda, une société pharmaceutique mondiale spécialisée en gastro-entérologie, selon lequel Takeda a acquis le droit exclusif de développer et commercialiser le Cx601 pour le traitement des fistules périanales complexes en dehors des États-Unis. Le deuxième produit de TiGenix dérivé du tissu adipeux, le Cx611, est en cours d'essai de phase Ib/IIa dans la septicémie sévère – une cause majeure de mortalité dans les pays développés. Enfin, l'AlloCSC-01, qui cible les cardiopathies ischémiques aiguës, a montré des résultats positifs dans un essai de phase I/II dans l'infarctus aigu du myocarde (IAM). Le siège social de TiGenix est basé à Louvain (Belgique) et la société a également des activités à Madrid (Espagne) et Cambridge (Massachusetts, États-Unis). Pour plus d'informations, veuillez consulter le site <http://www.TiGenix.com>.*

## **Information prospective**

*Ce communiqué de presse peut contenir des déclarations prospectives et des estimations à l'égard de futures performances anticipées de TiGenix et du marché sur lequel elle opère et des déclarations en relation avec la consommation anticipée de l'offre publique d'acquisition, qui implique un certain nombre de risques et d'incertitudes, en ce compris la satisfaction de certaines conditions suspensives à l'offre publique d'acquisition, la possibilité que la transaction ne soit pas achevée, l'impact de l'économie générale, l'industrie, le marché et les conditions politiques, et les autres risques et incertitudes discutées dans les dépôts publics de TiGenix auprès de la SEC, en ce compris la section "facteurs à risque" de la Forme 20-F de TiGenix publiée le 6 avril 2017, ainsi que les documents relatifs à l'offre publique d'acquisition à déposer par Takeda ("Offrant") et la déclaration de sollicitation/recommandation à déposer par TiGenix. Certaines de ces déclarations, prévisions, estimations peuvent être reconnues par l'utilisation de mots tels que "croit", "s'attend à", "projette", "planifie", "cherche", "estime", "peut", "veut" ou "continue" et d'autres expressions similaires. Elles comprennent toutes les questions qui ne sont pas des faits historiques. De telles déclarations, prévisions et estimations sont fondées sur diverses hypothèses et évaluations des risques, incertitudes et autres facteurs connus ou inconnus, qui ont été jugés raisonnables quand ils ont été formulés, mais qui pourrait s'avérer ou ne pas s'avérer corrects. Les événements réels sont difficiles à prédire et peuvent dépendre de facteurs indépendants de la volonté de TiGenix. Par conséquent, les résultats réels, conditions financières, performances ou réalisations de TiGenix, ou les résultats de l'industrie, peuvent s'avérer sensiblement différents des résultats, performances futurs, échéance ou réalisation tels qu'ils sont exprimés ou sous-entendus par ces déclarations, prévisions et estimations. Compte tenu de ces incertitudes, aucune déclaration n'est faite quant à l'exactitude ou l'équité de ces déclarations prospectives, prévisions et estimations. En outre, ces déclarations prospectives, prévisions et estimations ne sont valables qu'à la date de la publication du communiqué de presse. L'Offrant et TiGenix décline toute obligation d'actualiser ces*

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*déclarations prospectives, prévisions ou estimations afin de refléter tout changement dans les attentes de TiGenix à l'égard de celles-ci et tout changement dans les événements, conditions ou circonstances sur lesquels ces déclarations, prévisions ou estimations sont fondées, à l'exception de ce qui est requis par le législateur belge.*

### **Décharge de responsabilité**

Ce communiqué de presse ne constitue ni une offre d'achat des titres de TiGenix, ni une sollicitation par quiconque dans une juridiction à l'égard de ces titres, tout vote ou approbation. Si l'Offrant décide de procéder à une offre d'achat des titres de TiGenix par le biais d'une offre publique d'acquisition, cette offre ne sera faite et ne pourra être faite que sur la base d'un document d'offre approuvé par la FSMA et des documents d'offre publique d'acquisition déposés auprès de la commission boursière américaine (U.S. Securities and Exchange Commission) ("SEC"), que les détenteurs de titres dans TiGenix devraient lire car ils contiendront des informations importantes. Ce communiqué de presse ne constitue pas un substitut pour ces documents d'offre. Ni ce communiqué de presse, ni toute information à cet égard contenue dans le présent document ne peut être produit dans une juridiction où une inscription, une qualification ou tout autre obligation en vigueur est en vigueur eu égard à son contenu. Toute défaillance dans la conformité avec ces restrictions peut constituer une violation des lois ou réglementations financières dans ces juridictions. L'Offrant, TiGenix et leurs sociétés liées respectives déclinent explicitement toute responsabilité pour la violation de ces restrictions par toute personne.

### **Information supplémentaire importante pour les Investisseurs Américains**

L'offre publique d'acquisition volontaire décrite dans le présent communiqué n'a pas encore commencé. Ce communiqué de presse est destiné à des fins d'information uniquement et ne constitue ni une recommandation, ni une offre d'acquisition ni une sollicitation à une offre pour vendre tout titre dans TiGenix.

Au moment où l'offre publique d'acquisition volontaire commencera, les actionnaires de TiGenix seront encouragés à lire les documents d'offre, qui seront disponibles sur [www.sec.gov](http://www.sec.gov). Au moment où l'offre publique d'acquisition volontaire aura commencé, celle-ci devra contenir deux offres séparées – (i) une offre pour tous les titres avec droit de vote ou donnant accès aux droits de vote émis par TiGenix (excepté pour les ADSs) (les "Titres") conformément à la loi belge applicable et (ii) une offre pour tous les détenteurs d'American Depositary Shares de TiGenix émis par Deutsche Bank Trust Company Americas agissant en tant que dépositaire ("ADSs") et les détenteurs de Titres résidant aux États-Unis conformément à la loi américaine applicable ("Offre Américaine").

L'Offre Américaine ne sera faite que suite à une offre d'acquisition et aux documents connexes. Au moment où l'Offre Américaine commencera, l'Offrant déposera, ou fera déposer, une déclaration d'offre publique d'acquisition dans l'annexe TO auprès de la SEC et, ensuite, TiGenix déposera une déclaration de sollicitation/recommandation dans l'annexe 14D-9, dans chacun des cas concernant l'Offre Américaine.

Les détenteurs d'ADSs ou de Titres dans TiGenix soumis à l'Offre Américaine' qui souhaitent participer à l'Offre Américaine, sont encouragés à revoir attentivement les documents en relation avec l'Offre Américaine qui seront déposés par l'Offrant auprès de la SEC étant donné que ces documents contiennent des informations importantes, en ce compris les termes et conditions de l'Offre Américaine. Les détenteurs d'ADSs et de Titres soumis à l'Offre Américaine qui souhaitent participer à l'Offre Américaine, sont également encouragés à lire la déclaration de sollicitation/recommandation connexe de l'annexe 14D-9 qui sera déposée auprès de la SEC, par TiGenix en relation avec l'Offre Américaine. Vous pouvez obtenir une copie gratuite de ces documents après qu'ils aient été déposés auprès de la SEC, et d'autres documents déposés par TiGenix et l'Offrant, sur le site web de la SEC sur [www.sec.gov](http://www.sec.gov). En plus de l'offre et des documents d'offre publique d'acquisition ainsi que de la déclaration de sollicitation/recommandation, TiGenix dépose des rapports et autre information auprès de la SEC. Vous pouvez lire et copier chacun de ces rapports et d'autres informations déposées par TiGenix auprès de la SEC Public Reference Room au 100F Street, N.E., Washington, D.C. 20549. Veuillez svp appeler la SEC au 1-800-SEC-0330 pour plus d'informations sur la Public Reference Room. Les documents déposés par TiGenix auprès de la SEC sont également disponibles au public à partir des services commerciaux de retrait de document et du site web entretenu par la SEC sur [www.sec.gov](http://www.sec.gov).

VOUS DEVRIEZ LIRE ATTENTIVEMENT LES DOCUMENTS DÉPOSÉS PAR L'OFFRANT ET TIGENIX AUPRÈS DE LA SEC AVANT DE PRENDRE UNE DÉCISION EN CE QUI CONCERNE L'OFFRE AMÉRICAINE.



# 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](http://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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**Media Contacts:**

**Kazumi Kobayashi**

Media in Japan

T: +81 3 3278 2095

[kazumi.kobayashi@takeda.com](mailto:kazumi.kobayashi@takeda.com)

**Elissa Johnsen**

Media outside of Japan

T: +1 224 554 3185

[elissa.johnsen@takeda.com](mailto:elissa.johnsen@takeda.com)

**Luke Willats**

Media in Europe

T: +41 44 555 1145

[luke.willats@takeda.com](mailto:luke.willats@takeda.com)

**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](https://www.tse.com/stocks/stocks/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).<sup>1</sup> 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.<sup>2</sup> The 24-week results of the Phase III ADMIRE-CD trial were published in *The Lancet* in July 2016.<sup>1</sup> 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](http://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](http://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 depository (“**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](http://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](http://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**

<sup>1</sup> 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.

<sup>2</sup> 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 18<sup>th</sup> December 2017. <http://dx.doi.org/10.1053/j.gastro.2017.12.020>.



DEZE AANKONDIGING IS NIET BEDOELD VOOR VRIJGAVE, BEKENDMAKING OF VERSPREIDING, GEHEEL OF GEDEELTELIJK, IN, NAAR OF VAN ENIGE JURISDICTIE WAAR DIT ONWETTIG ZOU ZIJN.

## PERSBERICHT GEREGLEMENTEERDE INFORMATIE VOORWETENSCHAP

Kennisgeving in toepassing van artikel 8, §1 van het Koninklijk Besluit van 27 april 2007 op de openbare overnamebiedingen

### Takeda kondigt voornemen aan om TiGenix over te nemen

Leuven (BELGIË) – 5 januari 2018, 7:30 uur CET – TiGenix NV ("TiGenix") (Euronext Brussels en NASDAQ: "TIG"), een geavanceerd biofarmaceutisch bedrijf dat is gericht op het benutten van de ontstekingsremmende eigenschappen van allogene of van donors afkomstige stamcellen voor het ontwikkelen van nieuwe therapieën voor ernstige aandoeningen, bevestigt vandaag dat Takeda Pharmaceutical Company Limited ("Takeda") haar voornemen heeft aangekondigd om een vrijwillig voorwaardelijk openbaar overnamebod op TiGenix te lanceren.

Takeda is voornemens om 100% van de stemrechten of stemrechtverlenende effecten van TiGenix, die niet reeds gehouden worden door Takeda of met haar verbonden vennootschappen, te verwerven aan een prijs van EUR 1,78 per aandeel in cash en een gelijkwaardige prijs in cash per American Depositary Share, warrant en converteerbare obligatie.

Takeda is voornemens om het voorgestelde bod te lanceren kort na de goedkeuring van het biedprospectus en van de memorie van antwoord door de Belgische Autoriteit voor Financiële Diensten en Markten ("FSMA"). Het bod zal onderworpen zijn aan de voorwaarde dat Takeda en met haar verbonden vennootschappen minstens 85% van de stemrechten of stemrechtverlenende effecten van TiGenix op een volledig verwaterde basis zullen verwerven, alsook aan de volgende opschortende voorwaarden: de afwezigheid van een wezenlijk nadelig effect dat zich voordoet na de datum van deze aankondiging, goedkeuring van Cx601 door het Europees Geneesmiddelenbureau en het vervallen van de toepasselijke wachtperiode onder de Hart-Scott-Rodino Antitrust Improvements Act van 1976 in de V.S. De goedkeuring van Cx601 door het Europees Geneesmiddelenbureau wordt verwacht tijdens de eerste helft van 2018.

In overeenstemming met haar verplichtingen als raad van bestuur en onder voorbehoud van het nazicht van het finale biedprospectus, wordt het bod unaniem gesteund door de raad van bestuur van TiGenix, die haar formeel antwoord op het voorgestelde overnamebod in de memorie van antwoord zal geven, dat ten gepasten tijde zal bekendgemaakt worden in overeenstemming met de toepasselijke wetgeving. Takeda en TiGenix hebben een overeenkomst (*offer and support agreement*) afgesloten waarin de steun van TiGenix en de voorwaarden van het bod zoals uiteengezet in het persbericht van Takeda worden bevestigd. Cowen and Company, LLC trad op als financieel adviseur van TiGenix.

Gri-Cel S.A., die 32.238.178 aandelen van TiGenix aanhoudt, en de met haar verbonden vennootschap Grifols Worldwide Operations Ltd., die 7.189.800 aandelen van TiGenix in de vorm van American Depositary Shares aanhoudt, hebben onherroepelijk bevestigd dat ze hun aandelen en American Depositary Shares in TiGenix zullen inbrengen in het potentieel openbaar overnamebod.

Voor meer informatie betreffende de voorwaarden van het voorgestelde overnamebod door Takeda wordt verwezen naar het persbericht van Takeda, hierbij aangehecht als [Bijlage 1](#).

"Wij zijn er van overtuigd dat het voorgenomen overnamebod van Takeda een positieve stap is voor de effectenhouders van TiGenix en dat het de werkelijke waarde reflecteert van onze toewijding aan

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patiënten gedurende de laatste jaren. We zijn er van overtuigd dat de expertise van TiGenix de ambitie van Takeda om nieuwe stamcelbehandelingen te ontwikkelen kan versnellen," zei Eduardo Bravo, CEO van TiGenix. "Takeda is een patiënt georiënteerde onderneming die de beste capaciteiten en middelen biedt om de toegang tot Cx601 voor patiënten wereldwijd te verzekeren."

Dit persbericht vormt geen aanbod of uitnodiging tot verkoop of aankoop van effecten van TiGenix in enige jurisdictie. Verdere aankondigingen zullen ten gepasten tijde gedaan worden, indien en wanneer de omstandigheden dit vereisen.

## Voor meer informatie:

### TiGenix

**Claudia Jiménez**

Senior Director Investor Relations and Communications

Tel: +34918049264

Claudia.jimenez@tigenix.com

## Over TiGenix

*TiGenix NV (Euronext Brussels en NASDAQ: TIG) is een geavanceerd biofarmaceutisch bedrijf dat nieuwe behandelingen ontwikkelt voor ernstige medische aandoeningen door de ontstekingsremmende eigenschappen van allogene, d.w.z. van een donor afkomstige, stamcellen te gebruiken.*

*Het hoofdproduct van TiGenix, Cx601, heeft met succes een klinisch fase III-onderzoek in Europa afgerond voor de behandeling van complexe perianale fistels - een ernstige en verzwakkende complicatie van de ziekte van Crohn. Cx601 is ingediend voor goedkeuring in Europa en in 2017 is er een wereldwijd fase III-onderzoek van start gegaan, bedoeld om een toekomstige aanvraag voor een licentie voor een biologisch middel (Biologics License Application, BLA) in de VS te ondersteunen. TiGenix heeft een licentieovereenkomst gesloten met Takeda, een internationaal farmaceutisch bedrijf dat actief is op het gebied van de gastro-enterologie, waardoor Takeda de exclusieve rechten heeft verworven om Cx601 buiten de VS te ontwikkelen en op de markt te brengen voor complexe perianale fistels. Het tweede uit vetweefsel afkomstig product van TiGenix, Cx611, doorloopt een fase Ib/Ila-onderzoek bij ernstige sepsis - een belangrijke oorzaak van sterfte in de ontwikkelde wereld. Ten slotte heeft AlloCSC-01, gericht op acute ischemische hartziekte, positieve resultaten laten zien in een fase I/II-onderzoek bij acuut myocardinfarct (AMI). TiGenix heeft haar hoofdzetel in Leuven en heeft vestigingen in Madrid (Spanje) en Cambridge, Massachusetts (VS). Voor meer informatie, zie <http://www.tigenix.com>.*

## Toekomstgerichte informatie

*Deze mededeling kan toekomstgerichte informatie en schattingen bevatten over verwachte toekomstige prestaties van TiGenix en de markt waarin het bedrijf actief is en informatie betreffende de verwachte voltooiing van het openbaar aanbod, dat een aantal risico's en onzekerheden omvat, waaronder de vervulling van de voorwaarden tot verwezenlijking van het overnamebod, de mogelijkheid dat de transactie niet zal plaatsvinden, de impact van algemene economische, industriële, markt of politieke omstandigheden, en andere risico's en onzekerheden vermeldt in openbare indiening bij de SEC, inclusief de "Risk Factors" afdeling van Form 20-F van TiGenix zoals ingediend op 6 april 2017, alsook de openbare overnamedocumenten in te dienen door Takeda (de "Bieder") en de verklaring tot uitnodiging/aanbeveling in te dienen door TiGenix. Bepaalde van deze beweringen, voorspellingen en schattingen kunnen herkend worden door het gebruik van woorden als bijvoorbeeld "denkt", "plant", "verwacht", "is van plan", "probeert", "schat", "kan", "zal" en "voortzetten" en gelijkaardige uitdrukkingen. Ze vertegenwoordigen zaken die geen historische feiten zijn. Dergelijke beweringen, voorspellingen en schattingen zijn gebaseerd op verschillende veronderstellingen en beoordelingen van bekende en niet-bekende risico's, onzekerheden en andere factoren, die werden beschouwd als redelijk toen ze werden gedaan/gemaakt, maar die al dan niet juist kunnen zijn. Werkelijke gebeurtenissen zijn moeilijk te voorspellen en kunnen afhankelijk zijn van factoren die buiten de controle van het bedrijf liggen. Daarom kunnen de werkelijke resultaten, de financiële situatie, de prestatie of successen van TiGenix, of de resultaten van de sector, aanzienlijk afwijken van toekomstige resultaten, prestaties of successen die tot uitdrukking worden gebracht door of die kunnen worden afgeleid van dergelijke beweringen, voorspellingen en schattingen. Gezien deze onzekerheden, kan men geen verhaal halen over de juistheid of redelijkheid van dergelijke toekomstgerichte beweringen, voorspellingen en schattingen. Bovendien spreken*

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*toekomstgerichte beweringen, voorspellingen en schattingen slechts vanaf de datum van publicatie van dit persbericht. De Bieder en TiGenix verwerpen elke verplichting om dergelijke toekomstgerichte beweringen, voorspellingen of schattingen aan te passen aan eventuele veranderingen in de verwachtingen van het bedrijf hieromtrent, of aan eventuele wijzigingen in de gebeurtenissen, voorwaarden of omstandigheden waarop dergelijke beweringen, voorspellingen of schattingen zijn gebaseerd, behalve voor zover bij Belgische wetgeving verplicht.*

## **Disclaimer**

Deze mededeling vormt geen aanbod tot aankoop van effecten van TiGenix, noch een uitnodiging door iemand in enige jurisdictie betreffende zulke effecten, stemming of goedkeuring. Indien de Bieder besluit om door te gaan met een aanbod tot verwerving van de effecten van TiGenix via een openbaar overnamebod, dan zal en kan dergelijk bod enkel en alleen gedaan worden op basis van een overnamedocument goedgekeurd door de FSMA en overnamedocumenten ingediend bij de U.S. Securities and Exchange Commission ("SEC"), die houders van effecten van TiGenix dienen te lezen aangezien deze belangrijke informatie bevatten. Deze mededeling is geen vervanging van dergelijke overnamedocumenten. Noch deze mededeling, noch enige andere informatie met betrekking tot de onderwerpen hierin vermeld mag verspreid worden in enige jurisdictie waar een registratie, kwalificatie of enige andere verplichting van kracht is of zou zijn in verband met de inhoud hiervan en daarvan. Elke niet-naleving van deze beperkingen zou een schending van de financiële wetgeving en regelgeving van dergelijke jurisdicties kunnen uitmaken. De Bieder, TiGenix en de met hun respectievelijke verbonden vennootschappen wijzen uitdrukkelijk elke aansprakelijkheid af voor een inbreuk op deze beperkingen door enige persoon.

## **Belangrijke Bijkomende Informatie voor V.S. Investeerders**

Het vrijwillig overnamebod hierin beschreven is nog niet van start gegaan. Deze mededeling is enkel en alleen voor informatieve doeleinden en is geen aanbeveling, aanbod tot aankoop of uitnodiging tot een aanbod tot verkoop van enige effecten van TiGenix.

Op het ogenblik dat het vrijwillig overnamebod van start gaat, worden de aandeelhouders van TiGenix aangeraden om de overnamedocumenten te lezen, welke beschikbaar zullen zijn op [www.sec.gov](http://www.sec.gov). Op het moment dat het vrijwillig overnamebod van start gaat, zal het bestaan uit twee aparte biedingen – (i) een bod op alle stemrechten of stemrechtverlenende effecten, uitgegeven door TiGenix (met uitzondering van ADSs) (de "Effecten"), in overeenstemming met de toepasselijke Belgische wetgeving, en (ii) een bod aan de houders van American Depositary Shares van TiGenix, uitgegeven door Deutsche Bank Trust Company Americas in haar hoedanigheid van bewaarnemer ("ADSs"), en aan de houders van TiGenix Effecten die inwoner zijn van de V.S. in overeenstemming met de toepasselijke Amerikaanse wetgeving (het "V.S. Bod").

Het V.S. Bod zal enkel gedaan worden ingevolge een aanbod tot aankoop en gerelateerde documenten. Op het ogenblik waarop het V.S. Bod begint te lopen, zal de Bieder een verklaring tot overnamebod in de vorm van een Schedule TO bij de SEC indienen of laten indienen en daarna zal TiGenix een verklaring tot uitnodiging/aanbeveling in de vorm van een Schedule 14D-9 indienen, in beide gevallen met betrekking tot het V.S. Bod.

Houders van ADSs en Effecten van TiGenix onderworpen aan het V.S. Bod die wensen deel te nemen aan het V.S. Bod, worden aangeraden om de documenten met betrekking tot het V.S. Bod die ingediend zullen worden door de Bieder bij de SEC nauwkeuring na te lezen aangezien deze documenten belangrijke informatie zullen bevatten, inclusief de voorwaarden van het V.S. Bod. Houders van ADSs en Effecten van TiGenix onderworpen aan het V.S. Bod die wensen deel te nemen aan het V.S. Bod, worden aangeraden om ook de gerelateerde verklaring tot uitnodiging/aanbeveling betreffende de V.S. aanbidding in de vorm van een Schedule 14D-9 te lezen dat zal worden ingediend bij de SEC door TiGenix. U kunt een gratis kopie van deze documenten ontvangen nadat deze ingediend zijn bij de SEC door TiGenix, en van andere documenten ingediend door TiGenix en de Bieder bij de SEC, op de website van de SEC: [www.sec.gov](http://www.sec.gov). Naast het bod en zekere andere overnamedocumenten, alsook de verklaring tot uitnodiging/aanbeveling, dient TiGenix rapporten en andere informatie in bij de SEC. U kan alle rapporten en andere documenten ingediend door TiGenix inkijken en kopiëren in de SEC Public Reference Room te 100 F Street, N.E., Washington, D.C. 20549. Gelieve de SEC te contacteren op het nummer 1-800-SEC-0330 voor meer informatie over de Public Reference Room. De publicaties van TiGenix bij de SEC zijn ook beschikbaar voor het publiek via commerciële documentenbeheer diensten en op de website beheerd door de SEC: [www.sec.gov](http://www.sec.gov).

U WORDT AANGERADEN OM DE FILINGS DIE DOOR DE BIEDER EN TIGENIX WORDEN GEDAAN BIJ DE SEC NAUWKEURING NA TE LEZEN VOORDAT U EEN BESLISSING MAAKT BETREFFENDE HET V.S. BOD.

# 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](http://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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**Media Contacts:**

**Kazumi Kobayashi**

Media in Japan

T: +81 3 3278 2095

[kazumi.kobayashi@takeda.com](mailto:kazumi.kobayashi@takeda.com)

**Elissa Johnsen**

Media outside of Japan

T: +1 224 554 3185

[elissa.johnsen@takeda.com](mailto:elissa.johnsen@takeda.com)

**Luke Willats**

Media in Europe

T: +41 44 555 1145

[luke.willats@takeda.com](mailto:luke.willats@takeda.com)

**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](https://www.tse.co.jp/eng/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).<sup>1</sup> 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.<sup>2</sup> The 24-week results of the Phase III ADMIRE-CD trial were published in *The Lancet* in July 2016.<sup>1</sup> 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](http://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](http://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 depository (“**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](http://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](http://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**

<sup>1</sup> 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.

<sup>2</sup> 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 18<sup>th</sup> December 2017. <http://dx.doi.org/10.1053/j.gastro.2017.12.020>.



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**PRESS RELEASE  
REGULATED INFORMATION  
INSIDE INFORMATION**

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

## **Takeda announces its intention to acquire TiGenix**

**Leuven (BELGIUM) – January 5, 2018, 7:30h CET – TiGenix NV ("TiGenix") (Euronext Brussels and NASDAQ: "TIG"), an advanced biopharmaceutical company focused on exploiting the anti-inflammatory properties of allogeneic, or donor-derived, stem cells to develop novel therapies for serious medical conditions, today confirms that Takeda Pharmaceutical Company Limited ("Takeda") has announced its intention to launch a voluntary conditional takeover bid on TiGenix.**

Takeda intends to acquire 100% of the securities with voting rights or giving access to voting rights of TiGenix not already owned by Takeda or affiliates at a price of EUR 1.78 per share in cash and an equivalent price in cash per American Depositary Share, warrant and convertible bond.

Takeda intends to launch the proposed takeover bid shortly after the approval of the bid prospectus and the response memorandum by the Belgian Financial Services and Markets Authority ("**FSMA**"). The bid will be subject to Takeda and its affiliates owning at least 85% of the securities of TiGenix with voting rights or giving access to voting rights on a fully diluted basis, as well as the following conditions precedent: the absence of a material adverse effect occurring after the date of this announcement, Cx601 obtaining European Medicines Agency approval and expiration of the applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976 in the U.S. The European Medicines Agency approval for Cx601 is expected during the first half of 2018.

Consistent with its fiduciary duties and subject to review of the final bid prospectus, the bid is unanimously supported by TiGenix' board of directors, who will provide its formal response to the proposed takeover bid in a response memorandum which it will issue in due course in accordance with the applicable legal provisions. Takeda and TiGenix entered into an offer and support agreement confirming TiGenix' support and the terms and conditions of the bid set forth in the press release of Takeda. Cowen and Company, LLC served as financial advisor to TiGenix.

Gri-Cel S.A., holding 32,238,178 TiGenix shares, and its affiliate Grifols Worldwide Operations Ltd., holding 7,189,800 TiGenix shares held in the form of American Depositary Shares, have irrevocably confirmed that they will tender their shares and American Depositary Shares held in TiGenix into the potential public takeover bid.

For further information on the terms and conditions of the proposed takeover bid by Takeda, reference is made to the Takeda press release attached as [Annex 1](#).

"We believe the intended takeover bid of Takeda is a positive step for TiGenix' security holders and reflects the true value of our dedication to patients over the last few years. We believe that TiGenix's expertise would help accelerate Takeda's ambition to develop novel stem cell therapies," said Eduardo Bravo, CEO of TiGenix. "Takeda is a patient centric company that offers the best capabilities and resources to ensure access to Cx601 to patients worldwide."



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This press release does not constitute an offer or invitation for the sale or purchase of securities of TiGenix in any jurisdiction. Further announcements will be made in due course, if and when circumstances so require.

**For more information please contact:**

**TiGenix**

**Claudia Jiménez**

Senior Director Investor Relations and Communications

Tel: +34918049264

Claudia.jimenez@tigenix.com

**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, expanded stem cells.*

*TiGenix' 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' second adipose-derived product, Cx611, is undergoing a Phase Ib/IIa 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>.*

**Forward-looking information**

*This communication may contain forward-looking statements and estimates with respect to the anticipated future performance of TiGenix and the market in which it operates and statements regarding the expected consummation of the tender offer, which involves a number of risks and uncertainties, including the satisfaction of closing conditions for the tender offer, the possibility that the transaction will not be completed, the impact of general economic, industry, market or political conditions, and the other risks and uncertainties discussed in TiGenix' public filings with the SEC, including the "Risk Factors" section of TiGenix' Form 20-F filed on April 6, 2017, as well as the tender offer documents to be filed by Takeda (the "Offeror") and the solicitation/recommendation statement to be filed by TiGenix. Certain of these statements, forecasts and estimates can be recognised by the use of words such as, without limitation, "believes", "anticipates", "expects", "intends", "plans", "seeks", "estimates", "may", "will" and "continue" and similar expressions. They include all matters that are not historical facts. Such statements, forecasts and estimates are based on various assumptions and assessments of known and unknown risks, uncertainties and other factors, which were deemed reasonable when made but may or may not prove to be correct. Actual events are difficult to predict and may depend upon factors that are beyond TiGenix' control. Therefore, actual results, the financial condition, performance, timing or achievements of TiGenix, or industry results, may turn out to be materially different from any future results, performance or achievements expressed or implied by such statements, forecasts and estimates. Given these uncertainties, no representations are made as to the accuracy or fairness of such forward-looking statements, forecasts and estimates. Furthermore, forward-looking statements, forecasts and estimates only speak as of the date of this communication. The Offeror and TiGenix disclaim any obligation to update any such forward-looking statement, forecast or estimates to reflect any change in TiGenix' expectations with regard thereto, or any change in events, conditions or circumstances on which any such statement, forecast or estimate is based, except to the extent required by Belgian law.*

**Disclaimer**

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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. The Offeror, 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](http://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’ American Depositary Shares issued by Deutsche Bank Trust Company Americas acting as depository (“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, the Offeror 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 the Offeror 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 the Offeror with the SEC, at the SEC’s website at [www.sec.gov](http://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’ 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](http://www.sec.gov).

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

# 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](http://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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**Media Contacts:**

**Kazumi Kobayashi**

Media in Japan

T: +81 3 3278 2095

[kazumi.kobayashi@takeda.com](mailto:kazumi.kobayashi@takeda.com)

**Elissa Johnsen**

Media outside of Japan

T: +1 224 554 3185

[elissa.johnsen@takeda.com](mailto:elissa.johnsen@takeda.com)

**Luke Willats**

Media in Europe

T: +41 44 555 1145

[luke.willats@takeda.com](mailto:luke.willats@takeda.com)

**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](https://www.tse.or.jp/eng/stock/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).<sup>1</sup> 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.<sup>2</sup> The 24-week results of the Phase III ADMIRE-CD trial were published in *The Lancet* in July 2016.<sup>1</sup> 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](http://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.

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### **Important Additional Information for U.S. investors**

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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.

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

#### **References**

<sup>1</sup> 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.

<sup>2</sup> 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 18<sup>th</sup> December 2017. <http://dx.doi.org/10.1053/j.gastro.2017.12.020>.