TiGenix

Living Medicines

Half Year 2017 Business and Financial Update

Webcast Presentation, 19th September 2017

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Forward-Looking Statements

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Compelling Investment Case

Lead product near approval in Europe, strong partner, significant upside potential

- ✓ Lead product Cx601 in development for complex perianal fistulas, an orphan indication with high unmet medical need
- ✓ Filed for approval in EU; expected in 2017
- ✓ Global pivotal phase III trial for BLA registration started in 1H2017

- ✓ Ex-US rights licensed to Takeda; key strategic partner for commercial launch
- ✓ Up to EUR 380M in potential milestones plus double-digit royalties

- ✓ Multiple assets in clinical-stage development
- ✓ Cx611 – sepsis; AlloCSC-01 - allogeneic cardiac stem cells

- ✓ Seasoned management team with deep experience in drug development
- ✓ Well capitalized
- ✓ Traded on Nasdaq and Euronext (TIG)

First Half 2017 and Post Period Business Highlights

Continued progress towards Cx601 CHMP opinion in 2017

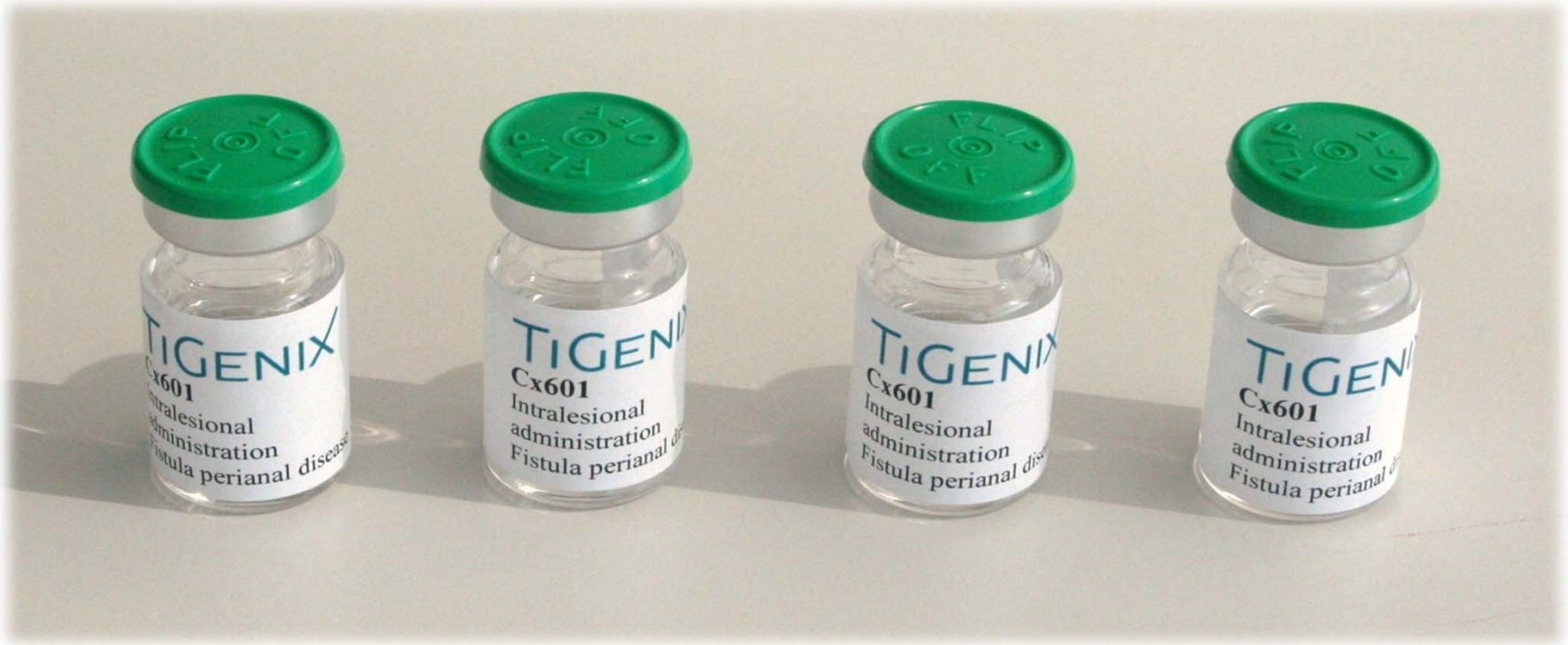
- **Cx601: On its way to European approval with best partner. Clear strategy to access US market**
  - **Clear progress towards marketing authorization.**

    Responses to the Day 180 LoOI submitted in September 2017. The Day-181 falls within the first week of October, which may trigger a CHMP opinion in 2017. In parallel the Swiss Agency for Therapeutic Products ("Swissmedic") accepted for review the file on Cx601 for the treatment of complex perianal fistulas in patients with Crohn's disease
  - **Reached key milestone to secure potential launch after MA**.

    TiGenix obtained a commercial production license for its expanded manufacturing facility in Madrid to provide capacity for the potential initial European commercial roll out of Cx601. The expanded facility also secures manufacturing for other pipeline products
  - **Takeda is a strong partner for potential European launch.**

    Ex-U.S. rights for the primary indication licensed to Takeda Pharmaceuticals. European Commission decision will trigger a payment of EUR 15.0 million from Takeda Pharmaceuticals upon approval of a marketing authorization (MA)
  - **Launch of the global Phase III trial study for future U.S. BLA submission.**

    The global pivotal Phase III trial to support a future U.S. registration for Cx601 formally launched in Europe and Israel in June 2017. TiGenix opened its U.S. headquarters at the epicenter of the Boston area biotech hub, following the NASDAQ IPO in 2016. Strengthened U.S. operations with two senior appointments
- **Continued progress with pipeline**
- **Strong cash position (56,5M € end of June 2017) after successful U.S. IPO and enlargement of investor base with European and U.S. specialized investors**

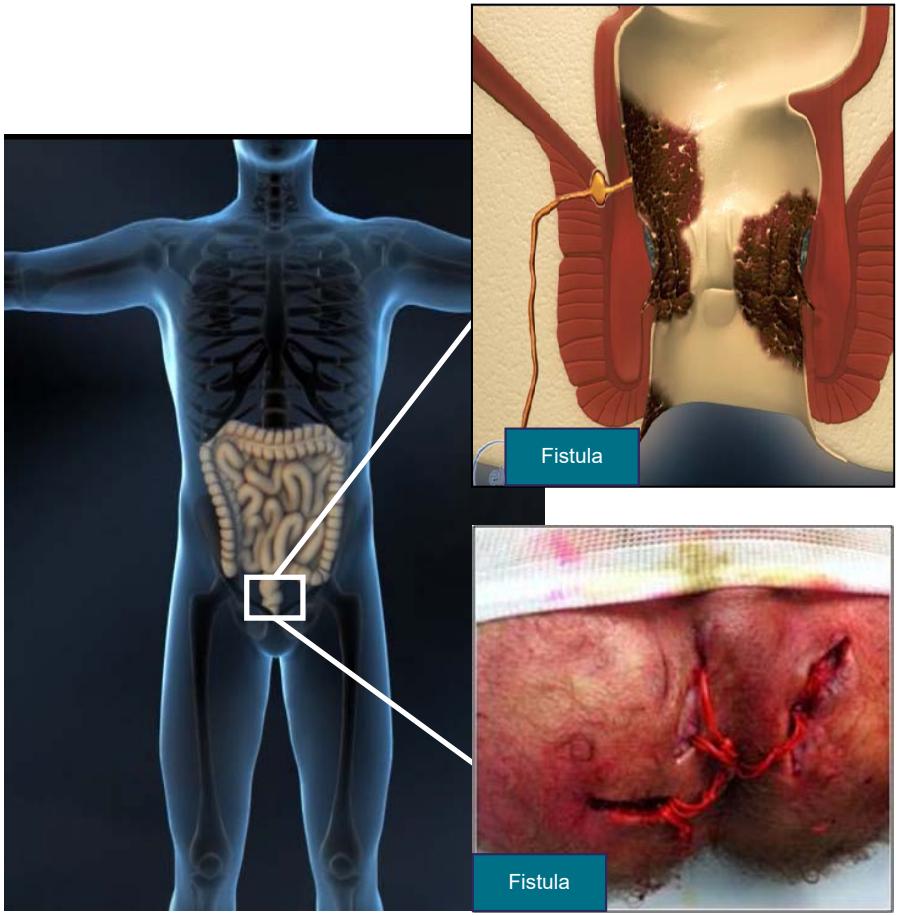


Novel, locally administered treatment for complex perianal fistulas in Crohn's disease

CHMP decision expected 2017

Complex Perianal Fistulas

A chronic, common and severe complication of Crohn's disease



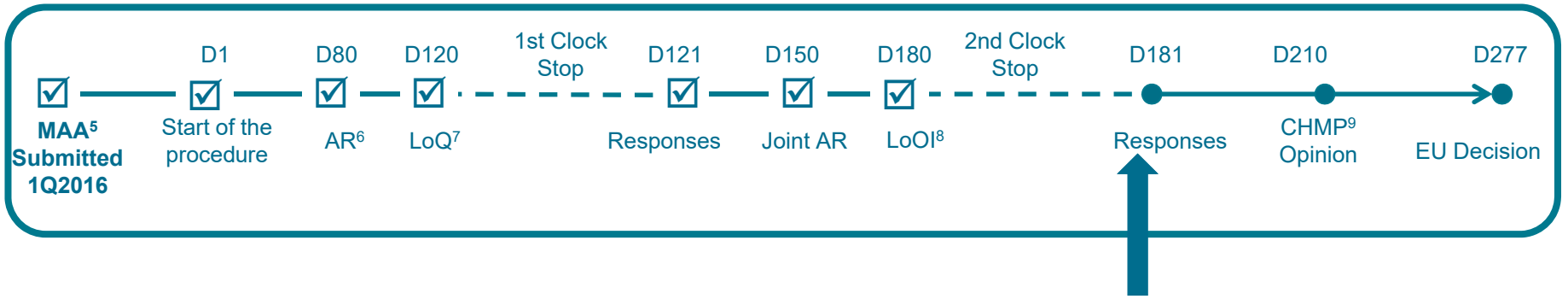
- ✓ Perianal fistulas are chronic, abnormal communication between the epithelialized surface of the anal canal and the perianal skin
- ✓ Perianal fistulas are a complication of Crohn's disease for 30−50% of patients[1]
- ✓ Perianal fistulas in Crohn's disease are difficult to treat with currently available therapies and often lead to pain, swelling, infection, incontinence and social, sexual and employment restrictions
- ✓ 70−80% of perianal fistulas are classified as complex[2,3]
  - Most challenging to treat
  - Often refractory to conventional treatment and anti-TNF agents[4-6]

1. Schwartz DA, et al. Gastroenterology. 2002;122:875-80; 2. Eglinton TW, et al. Dis Colon Rectum. 2012;55:773-7; 3. Bell SJ, et al Aliment Pharmacol Ther. 2003;17:1145-51; 4. Present DH, et al. N Engl J Med. 1999;340:1398-405; 5. Sands BE, et al. N Engl J Med. 2004;350:876-85; 6. Pearson DC, et al. Ann Intern Med. 1995;123:132-42;

Cx601: CHMP Opinion Expected 2017

Clear pathway to the market built on a solid regulatory strategy

- Team with previous experience in obtaining MA[1] of cell therapy product
- Orphan Designation received 2009
- 5 Scientific Advice Meetings held with EMA[2] (2 pre-clinical, 2 CMC[3], 1 clinical)
- Approved PIP[4] with 20 patients to be started not before 2020
- GMP license for commercial manufacturing granted
- CHMP opinion may be triggered in 2017



Current status: Responses to D180 LoOI submitted

TiGENIX Living Medicines

[1] MA: Marketing Authorization
[2] EMA: European Medicines Agency
[3] CMC: Chemistry Manufacturing and Controls
[4] PIP: Pediatric Investigational Plan
[5] MAA: Marketing Authorization Application
[6] AR: Assessment Report
[7] LoQ: List of Questions
[8] LoOI: List of Outstanding Issues
[9] CHMP: Committee of Human Medicinal Products (within EMA)

Ex-US Rights of Cx601 Licensed to Takeda

TiGenix keeps significant upside potential

- Takeda acquired the exclusive ex-US development and commercialization rights to Cx601 for the treatment of complex perianal fistulas in Crohn's disease patients
- TiGenix retains the right to develop Cx601 in new indications
- Takeda paid EUR 25M up front and a EUR 10M equity investment
- TiGenix eligible to receive potentially up to EUR 355M in regulatory and sales milestones, including a EUR 15M EU marketing approval milestone
- Double-digit royalties on net sales, tiered to reimbursement price
- Takeda will assume manufacturing responsibilities for Cx601 after an initial period of product supply by TiGenix for the EU

Cx601: Approach to US Market

Leveraging EU data with approved phase III protocol

- Solid regulatory and clinical development strategy
  - Type B meeting with FDA[1] confirmed:
    - Adequacy of existing non-clinical package to support an IND[2] filing
    - Acceptability of using data from the ADMIRE-CD trial to support BLA
  - SPA[3] for US Phase III protocol agreed with FDA:
    - Primary end-point identical to ADMIRE-CD trial
    - p-value < 0.05 (vs. p-value <0.025 in ADMIRE-CD trial)
- Global phase III trial for BLA registration at FDA started in 1H2017
- Lonza selected as contract manufacturing organization for Cx601 in the US, technology transfer ongoing
- Exploring different expedited pathways with the FDA

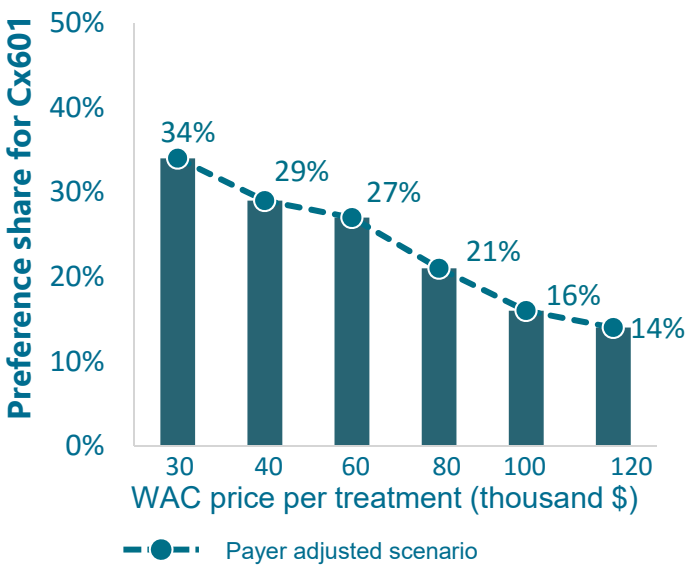
[1] FDA: Food and Drug Administration
[2] IND: Investigational New Drug
[3] SPA: Special Protocol Assessment

Cx601: US Price Range Allows Significant Margin

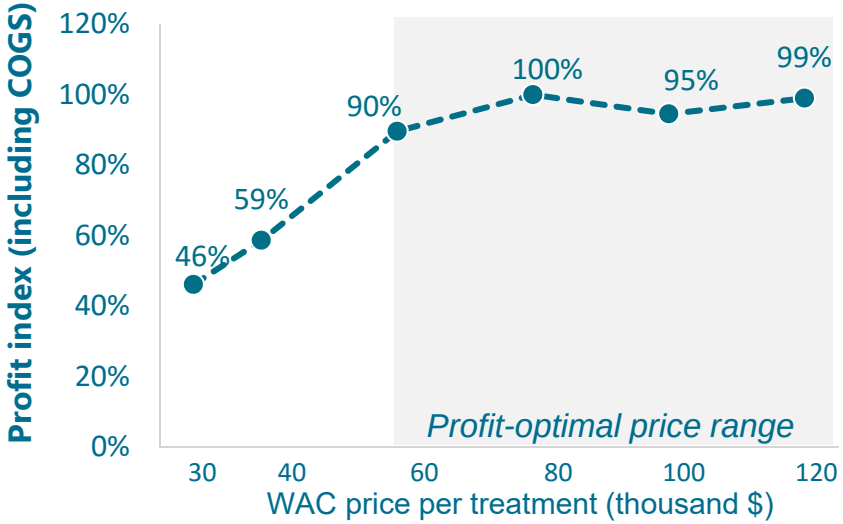
Research indicates profit-optimal prices between $60 and $120k

At increasing prices, physicians would prescribe Cx601 to less patients given likely restrictions of payers. However, profits would be optimized between $60 and $120k

Aggregated price-response curve
(physicians' coverage and payers' Rx)



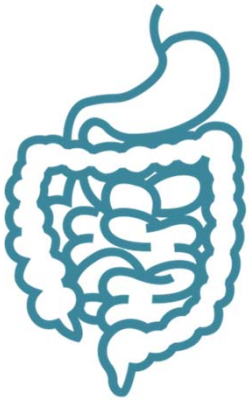
Profit index function for Cx601
(physicians' coverage and payers' Rx)



Sources: Simon-Kucher & Partners; expert discussions June 2016 with 5 medical directors, 2 ex-Medicare carriers, 2 hospital pharmacy directors, 5 KOLs and 16 HVPs. Assumptions on costs provided by TiGenix

Cx601: Pipeline Expansion Under Evaluation

Potential for Cx601 growth beyond complex perianal fistulas



Other gastrointestinal fistulas

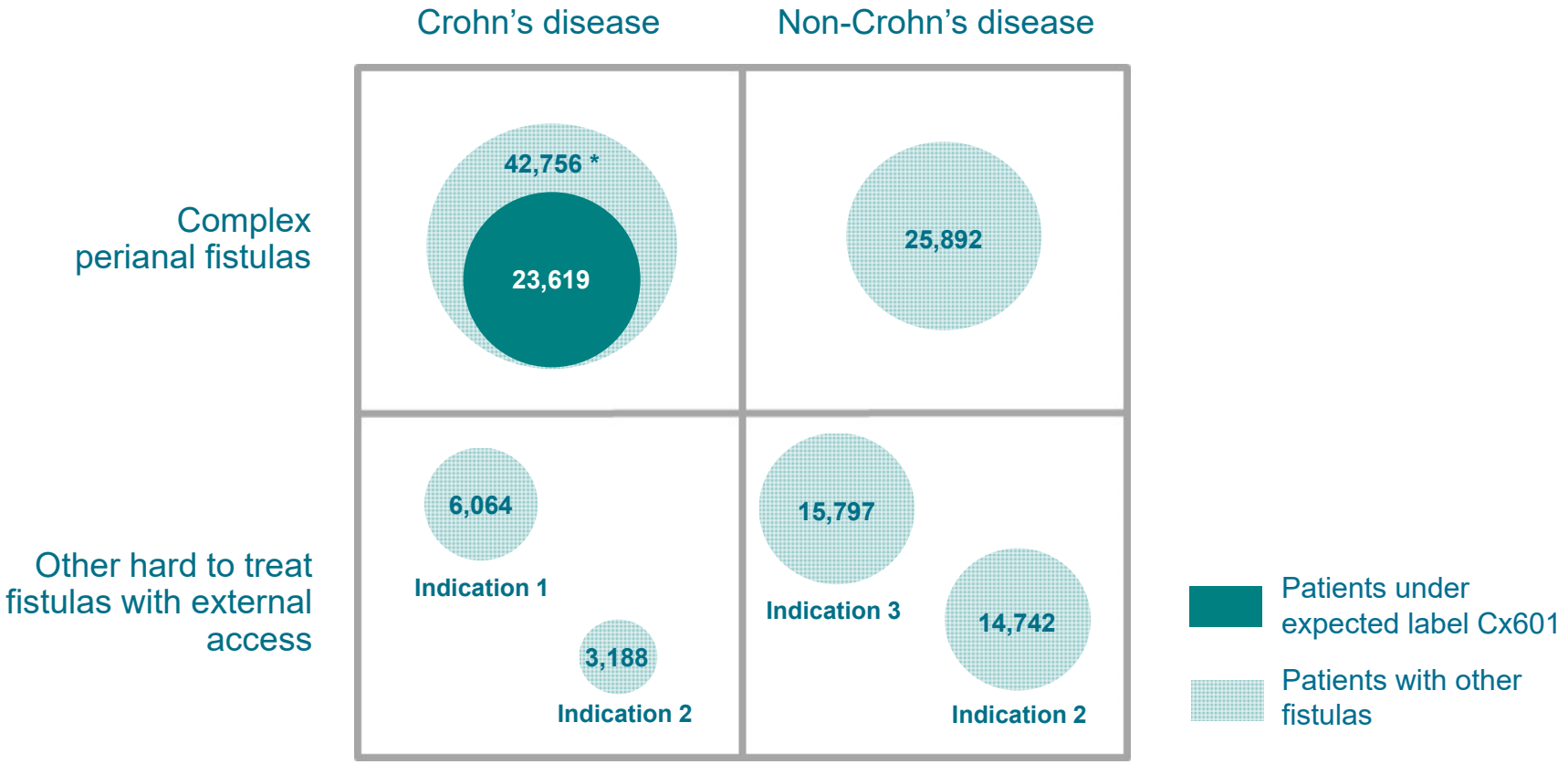
Gastrointestinal indications other than fistulas

Other indications

Cx601: Significant Potential in Other Gastrointestinal Fistulas

Addressable population could be four times larger

Estimated Patient Populations in US (2014)



Source: Truven MarketScan® database[1]

* Complex perianal fistulas out of the expected label include those in patients with non-controlled luminal symptoms, those that are not refractory to currently available therapies, and those affecting children

[1] Study Commissioned to Vencore Health Analytics Inc, 2016

Pipeline

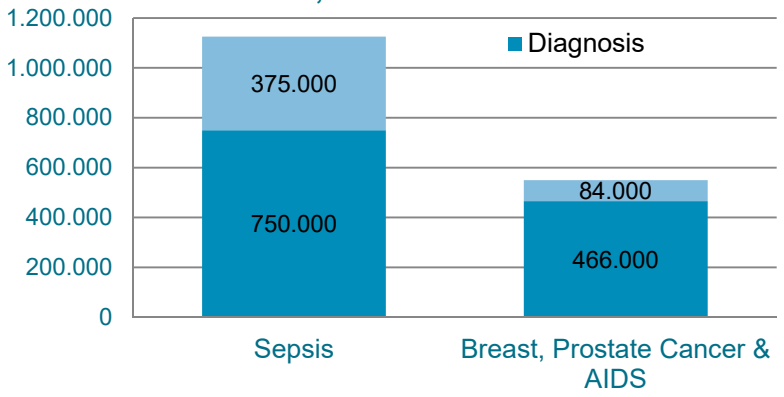
Cx611 – novel treatment for severe sepsis
AlloCSC-01 – allogeneic cardiac stem cells to treat heart disease

Cx611 – A Novel Treatment Approach to Severe Sepsis

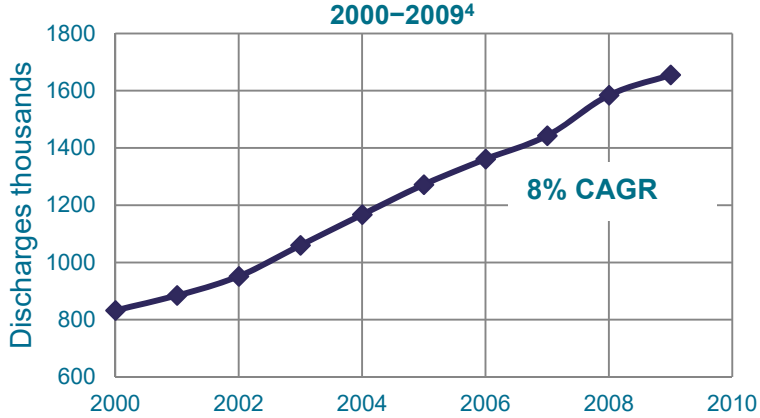
Leading cause of mortality in the developed world

- Sepsis is a life-threatening complication of infection leading to systemic inflammation and organ failure
- Between 15M to 19M sepsis cases occur worldwide each year[1]. Mortality reaches 50% for severe sepsis raising to 80% in septic shock[2]
- Cx611's novel mechanism of action may offer an innovative alternative to the treatment of severe sepsis: efficacy in *in vivo* models and good Phase I results
- TiGenix' Phase II trial (SEPCELL) has received the support of the Horizon 2020 European Commission Program and the endorsement of Key Opinion Leaders
- SEPCELL launched in H2 2016 and first patient dosed in January 2017; recruitment ongoing: data available in 2019

Diagnosed cases and mortality of Sepsis vs. Breast Cancer, Prostate Cancer & AIDS[3]



Trend in U.S. hospital stays with septicemia 2000–2009[4]



[1] The Lancet Infectious Diseases; Volume 12; issue 2; page 89; February 2012
[2] Martin CS Expert Rev Anti Infect Ther. 2012 June ; 10(6): 701–706.
[3] Adapted from Lagu, T., et al. Critical Care Medicine, 40(3):754-761; 2012
[4] Adapted from: Elixhauser et al. Septicemia in U.S. Hospitals 2009, AHRQ, Healthcare Cost Brief No. 122 October 2011

AlloCSC-01: Allogeneic Cardiac Stem Cells

Top-line results met all safety objectives. Study revealed valuable insight

"First-in-human" phase I/II trial focused on a **safety primary objective** and the evaluation of the feasibility of an intracoronary infusion of 35 million of AlloCSC-01 in patients following a high-risk AMI

The main findings were:

- **Safety primary objective was met**: no death or major cardiac adverse events at 30 days. Same results at 6 or 12 months; no immune-related adverse events throughout the trial
- A larger **reduction in infarct size** was found in the AlloCSC-01 arm in a **pre-specified subgroup of patients with poor long-term prognosis** associated with a characteristic MRI signature, offering an exciting prospect for further targeted trials in this population
- Top-line results announced on March 13, 2017. Full results to be presented at upcoming medical congress

Financial Highlights & Outlook

EUR 56,5 million at June 30, 2017

Short-term catalysts and long-term value creation opportunities

Financial Highlights

Half year results 2017

Strong cash position at June 30, 2017 of EUR 56.5 million

Thousands of euros (€), except for share data (in euros)	SIX-MONTH PERIOD ENDED JUNE 30, 2017	2016
CONSOLIDATED INCOME STATEMENTS		
Revenues		
Royalties	-	293
Grants and other operating income	588	650
Total revenues and other operating income	588	943
Research and development expenses	(16,637)	(9,702)
General and administrative expenses	(4,408)	(4,322)
Total operating charges	**(21,045)**	**(14,024)**
Operating Loss	(20,457)	(13,081)
Financial income	88	57
Interest on borrowings and other financial costs	(3,509)	(3,766)
Fair value gains	-	8,606
Fair value losses	(2,284)	(856)
Foreign exchange differences	(33)	(292)
Loss before taxes	(26,195)	(9,332)
Income taxes	4	(48)
Loss for the period	(26,191)	(9,380)
Attributable to equity holders of TiGenix	(26,191)	(9,380)
Basic income (loss) per share	**(0.10)**	**(0.05)**
Diluted income (loss) per share	**(0.10)**	**(0.05)**

TiGenix Outlook

Short term catalysts and long-term value-creation opportunities

- **2H 2017 - Cx601 CHMP opinion**
- **2H 2017 - Plan on new indications for Cx601**
- **1H 2018 - EUR 15M milestone potential payment by Takeda on EU approval decision**
- **1H 2018 - Takeda to launch Cx601 in EU markets**
- **1H 2018 - Cx601 IND and start of recruitment in US centers**


Hope
Solutions
Innovation
Future
Stem cells are **full of possibilities.** We make them a **reality.**
Efficacy
Well-being
Working hard to turn hope into reality
TiGenix is a leading company in **biotechnology** specialized in **stem cells research**, providing breakthrough therapies in order to improve patients' lifes.
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