TiGenix

Living Medicines

Dual-listed company
Lead asset on track for EU approval
Partnered with tier-one, big pharma company

May 2017

Forward-Looking Statements

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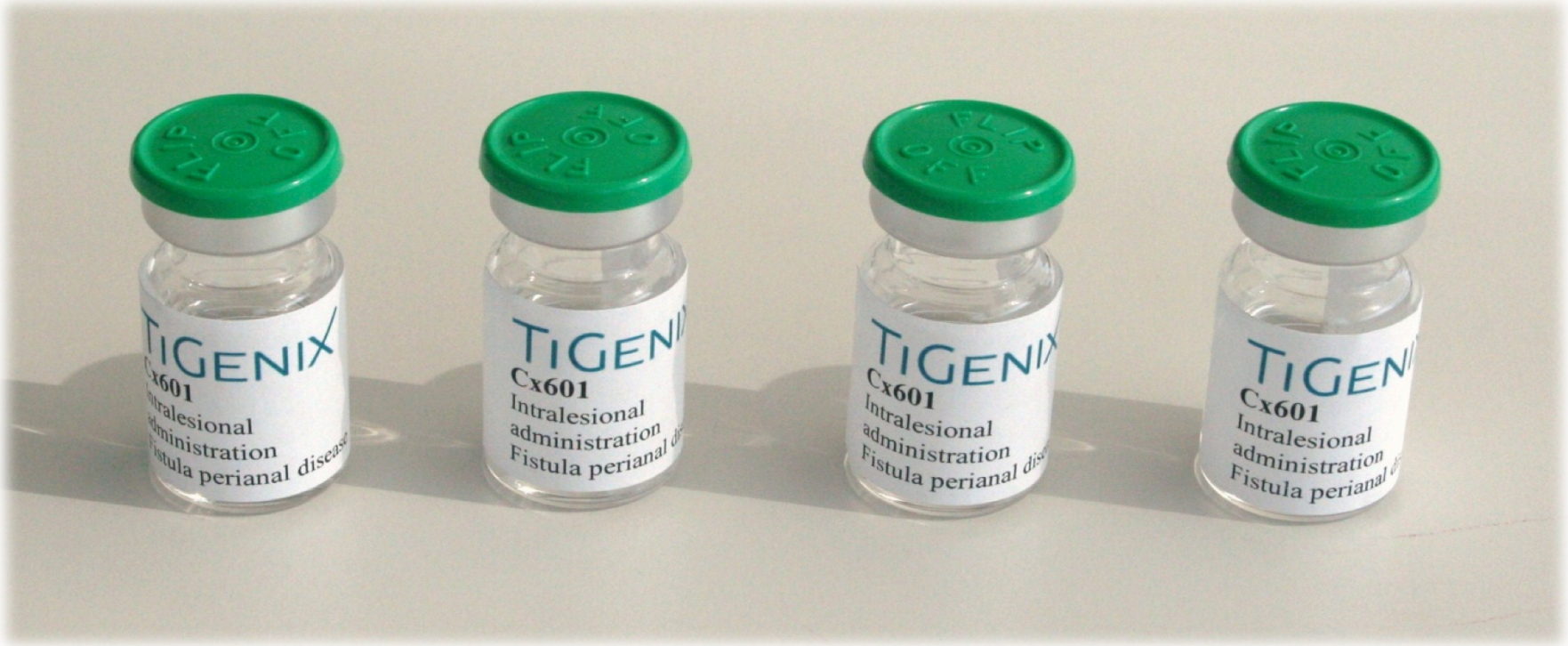
Compelling Investment Case

Robust platform with solid phase III data

- ✓ Positive pivotal phase III in complex perianal fistulas in Crohn's disease patients
- ✓ Results published in *The Lancet*[1] (July 2016)
- ✓ EU approval decision expected 2H2017
- ✓ Ex-US rights licensed to Takeda - best possible partner
- ✓ FDA's agreement on SPA obtained for pivotal phase III trial to start in 1H2017
- ✓ Pipeline with clinical-stage assets provides further upside
- ✓ Market cap ~EUR 200M (Euronext and Nasdaq: TIG) with strong, specialized, institutional shareholders. 18-24 months cash runway

1 Panés P, et al. Expanded allogeneic adipose-derived mesenchymal stem cells (Cx601) for complex perianal fistulas in Crohn's disease: a phase 3 randomised, double-blind controlled trial. The Lancet [online]. Published online July 28, 2016, available at http://dx.doi.org/10.1016/S0140-6736(16)31203-X.



Local administration of expanded Adipose-derived Stem Cells (eASCs) for the treatment of complex perianal fistulas in Crohn's disease patients

EU approval decision expected 2H2017

Adipose-Derived Stem Cells are Potent Anti-inflammatory Agents

Mechanism of Action (MoA) is IDO[1]-mediated

- eACSs broadly interact with many players in the immune system
- One of their key in vivo biological roles is the control of inflammation to prepare the return to homeostasis through:
  - Inhibition of T cell proliferation and pro-inflammatory cytokine secretion
  - Induction of anti-inflammatory cytokines
  - Induction of increased number of Tregs
  - Control of NK cell mediated killing
  - Control of monocyte and B cell maturation
- IDO enzyme is a key player in the MoA

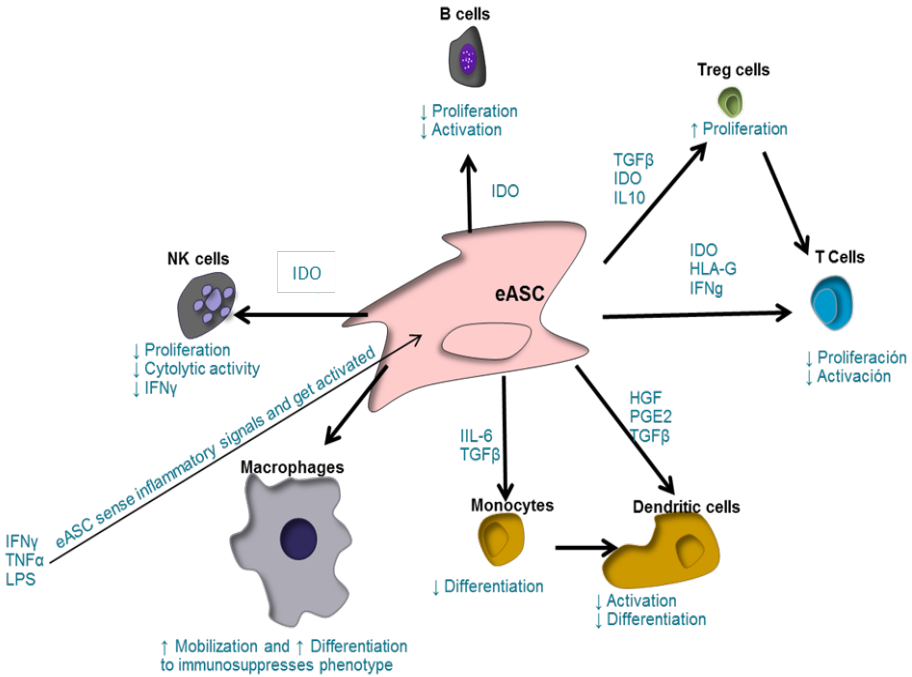


Image representation of the proprietary research that supports the key characteristics of eASC mechanism of action.

[1] IDO: Indoleamine 2,3-dioxygenase

GMP Facility Approved for Commercial Manufacturing

Consistent and robust process

Allogeneic model translates into production scalability

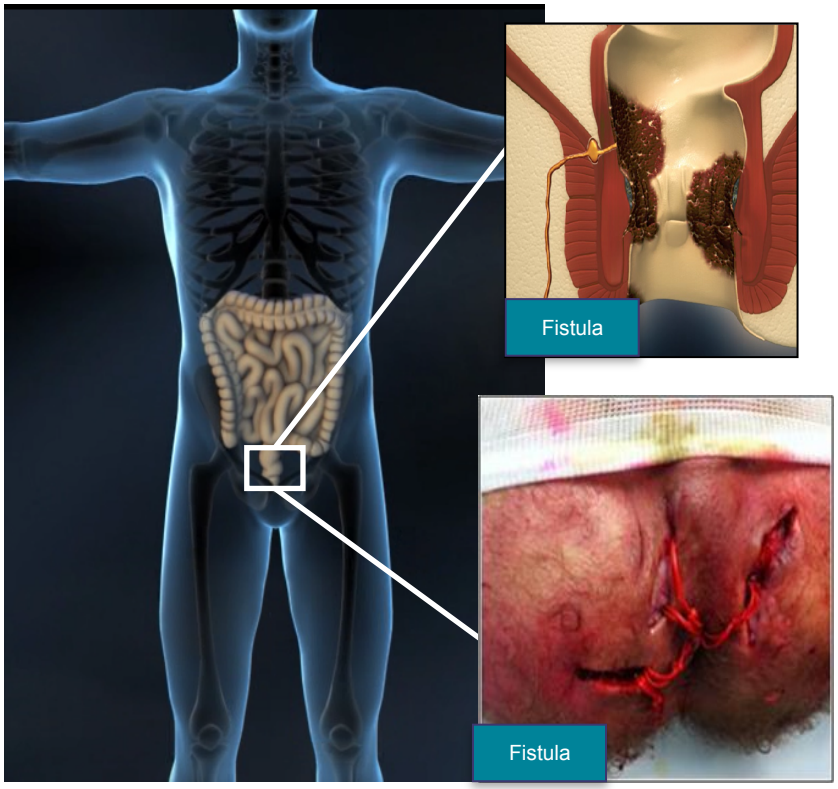
1 liposuction from healthy donor

2,400 finished products (Cx601)

A Common and Severe Complication of Crohn's Disease

Complex perianal fistulas affect 1 in 12 adult Crohn's disease patients

Current treatments lack long term efficacy and present safety issues



Current treatment options include:

- Antibiotics
- Immunosuppressants
- Anti-TNFs[1]
  - Low remission and high relapse
  - Safety concern with long term use and systemic immunosuppression
- Surgery
  - Conservative surgery risks recurrence
  - Risk of complications (incontinence, non healing wounds, abscesses)

[1] Infliximab- Remicade® and Adalimumab - Humira®

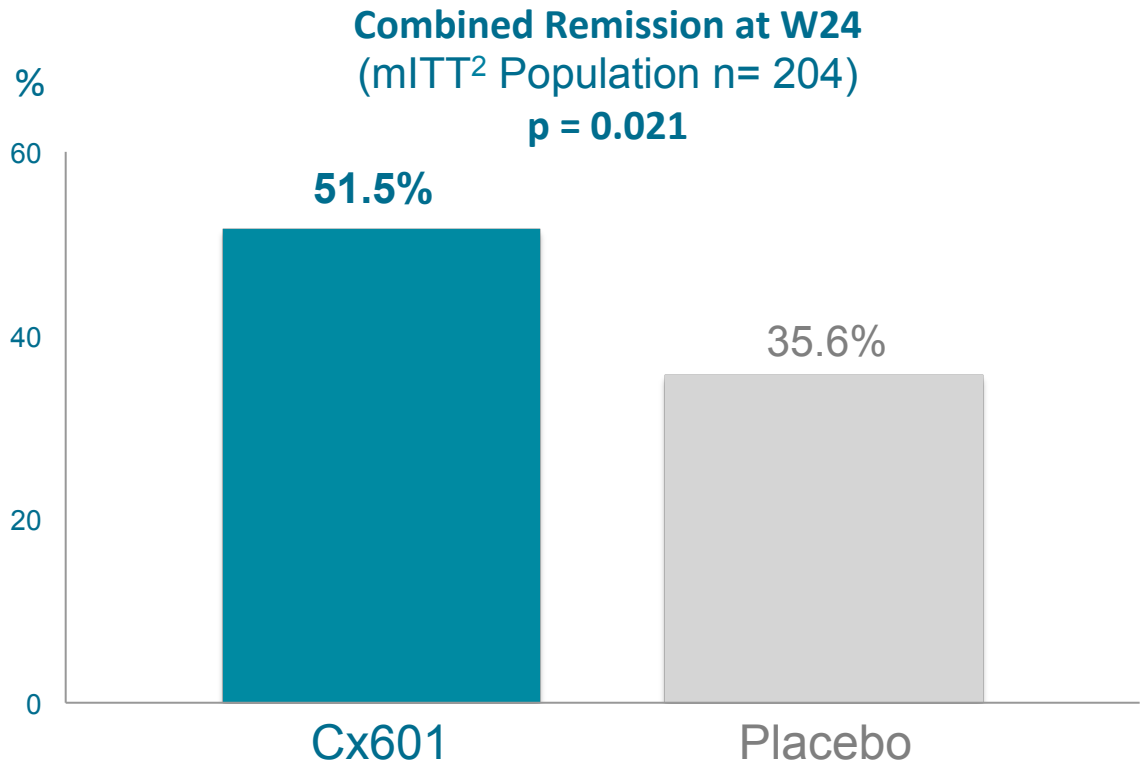
Pivotal Phase III Design Validated by EMA and FDA

Complex fistulas refractory to best available standard of care

- Randomized, double-blind, placebo controlled
- 212 patients randomized 1:1
- Patients with non-active or mildly-active Crohn's Disease
- 40% of patients with multiple tract fistulas
- Draining fistulas despite active treatment (majority anti-TNF)
- All patients stayed on their best standard of care treatment
- All draining tracts treated
- Efficacy defined as combined remission: clinical remission and lack of abscesses with magnetic resonance imaging
- Efficacy measured at 24 and 52 weeks. Safety follow up to 104 weeks

Cx601: Primary Endpoint Met at Week 24

Patients receiving Cx601 had a 44% greater probability of achieving **Combined Remission**[1] than placebo patients. Results published in ***The Lancet*** in July 2016



[1] Closure of all treated external openings draining at baseline despite gentle finger compression, and absence of collections > 2cm by MRI (Magnetic Resonance Imaging)

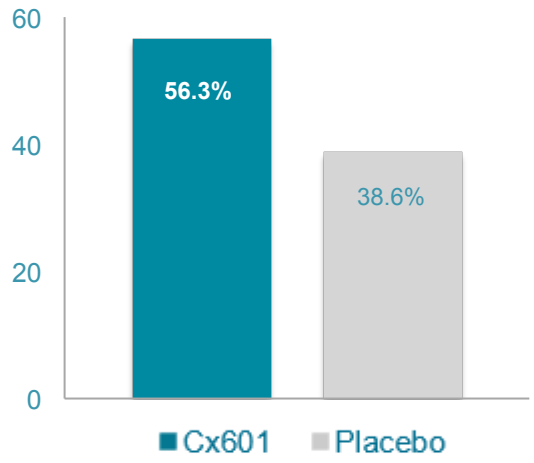
[2] mITT: modified Intention To Treat i.e. patients randomized, treated and with ≥1 post-baseline assessment. Efficacy results are consistent across all statistical populations

Cx601: Benefit Sustained, Lower Relapse Rate at Week 52

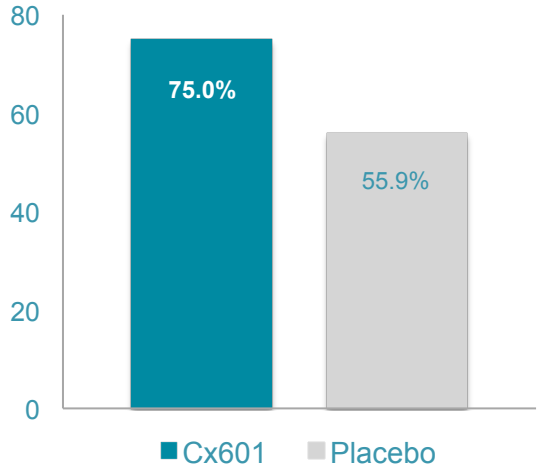
More than 50% of the patients receiving Cx601 had all treated fistulas in **Combined Remission**[1] one year after a single administration of the product

75.0% of the patients treated with Cx601 who were in combined remission at W24 did not relapse[2], compared to 55.9% for patients in the placebo arm

Combined Remission at W52
(mITT[3] Population n= 204)
p = 0.010



No Relapse Rate at W52



[1] Closure of all treated external openings draining at baseline despite gentle finger compression, and absence of collections > 2cm by MRI (Magnetic Resonance Imaging)

[2] Relapse: reopening of any of the treated external openings with active drainage as clinically assessed, or development of perianal collection ≥2cm of the treated perianal fistula confirmed by centrally blinded MRI assessment in patients with clinical remission at any previous visit

[3] mITT: modified Intention To Treat i.e. patients randomized, treated and with ≥1 post-baseline assessment. Efficacy results are consistent across all statistical populations

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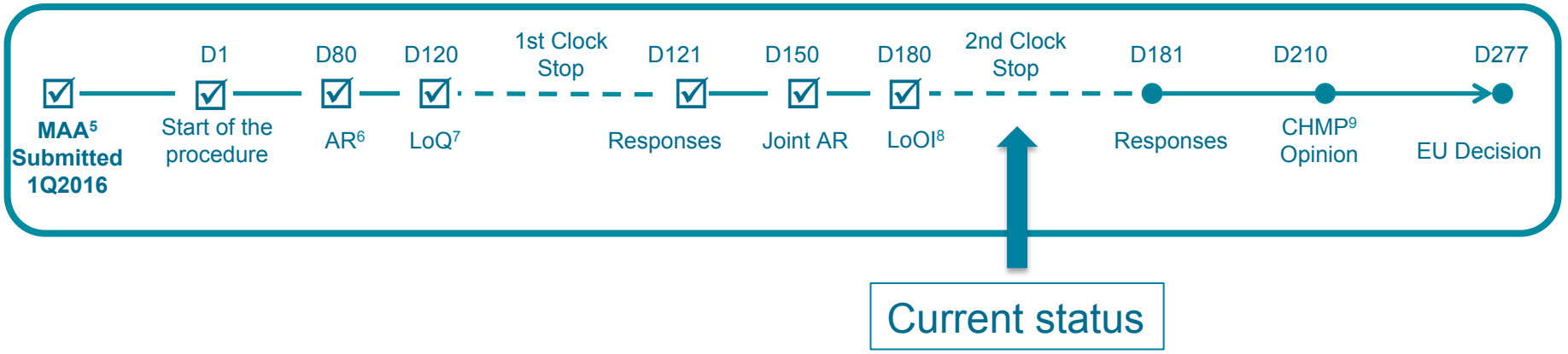
Cx601: EU Approval Decision Expected 2H2017

Clear and fast pathway to the market built on a solid regulatory strategy

- Team with previous experience in obtaining MA[1] of cell therapy product
- 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
- Assuming industry-average clock stops, final approval expected in 2H2017



[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)

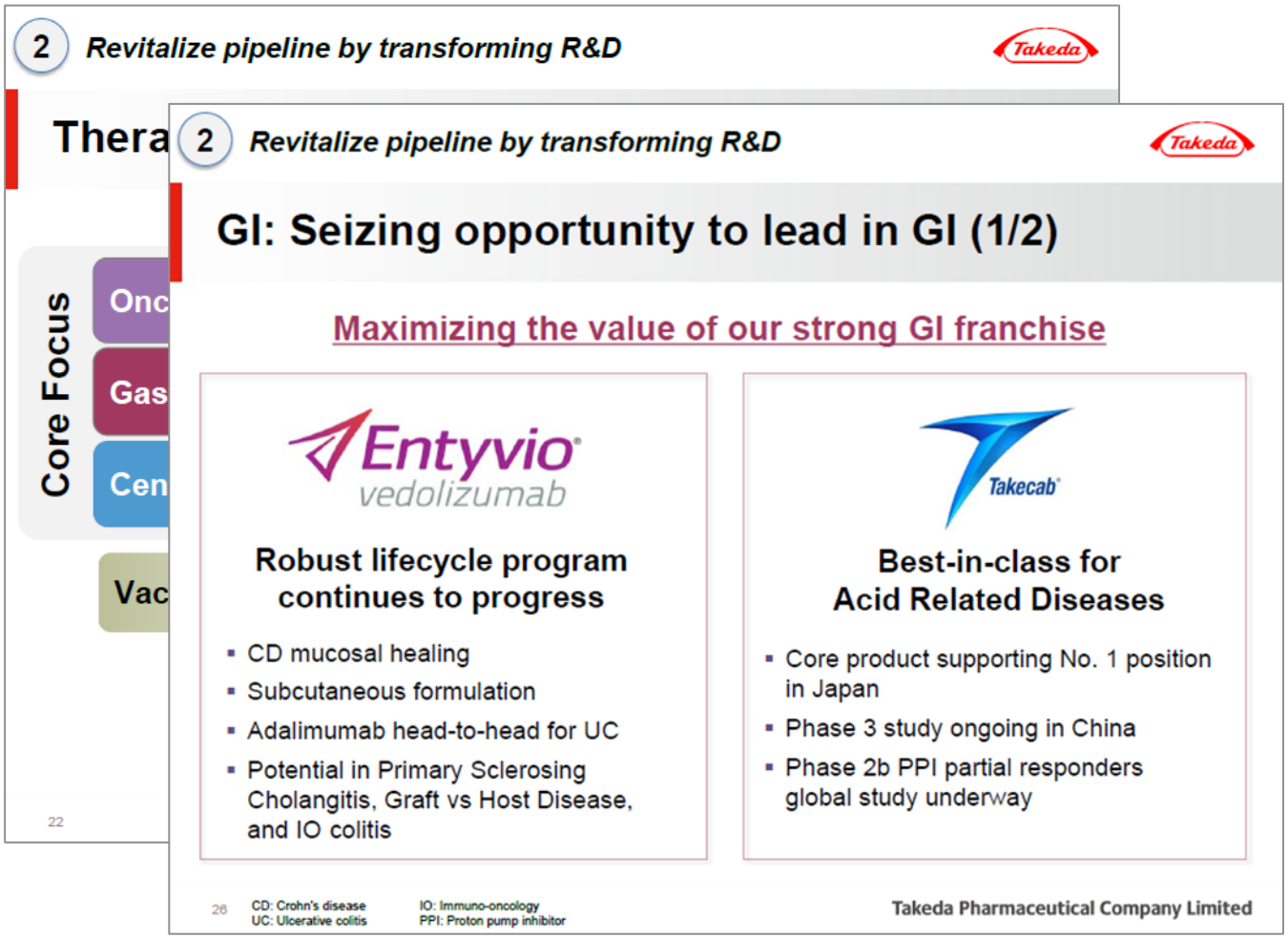
Ex-US Rights of Cx601 Licensed to Takeda

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 at cost for the EU

Takeda is The Best Potential Partner for Cx601

A global leader with strategic focus in GI



Source: Takeda presentation (JPM event 2017)

Cx601: A Key Pillar in Takeda's GI Strategy

Perfect fit with existing IBD portfolio

2 Revitalize pipeline by transforming R&D

Core Focus

22

2 Revitalize pipeline by transforming R&D

GI: Se

Robu
con

- CD muc
- Subcuta
- Adalimu
- Potentia
Cholang
and IO

26 CD: Crohn's d
UC: Ulcerative

2 Revitalize pipeline by transforming R&D

GI: Seizing opportunity to lead in GI (2/2)

Pipeline priorities

- Secure leadership with IBD portfolio
- Expand position in GI motility diseases
- Explore celiac, liver, and other GI diseases

Extensive external collaboration

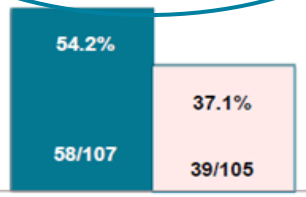
TiGENIX · enterome · ENGENE · PVP BIOLOGICS · COUR · Theravance Biopharma (Medicines That Make a Difference) · Altos THERAPEUTICS

Cx601 (filed in the EU) novel stem cell platform; breakthrough treatment of complex perianal fistulas in CD

- Licensed from TiGenix

Cx601 superior to placebo in achieving Combined Remission of Fistulas (52 Wk)

p = 0.012; 95%CI (3.9 - 30.3)



http://www.tigenix.com
Corporate Presentation 2016
Safety data show that Cx601 was reasonably tolerated in the study population

27 CD: Crohn's disease

Takeda Pharmaceutical Company Limited

Source: Takeda presentation (JPM event 2017)

Cx601: European Launch Expected 1H2018

Significant progress since signing licensing agreement

First wave of pre-launch activities completed or ongoing by Takeda

- ✓ Value proposition, positioning and branding
- ✓ Large-scale multi-stakeholder market research to understand unmet need, value perception and potential usage
- ✓ Price and market access research
- ✓ Preliminary structure of cost-effectiveness model
- ✓ Centers mapping
- ✓ Sizing of potential population eligible for Cx601 treatment
- ✓ Stakeholder facing function training
- ✓ Oral presentation on Cx601 and symposium at ECCO[1] 2017
- ✓ Oral presentation at the 2017 DDW[2] session dedicated to Controlled Clinical Trials in Inflammatory Bowel Diseases

[1] European Crohn's and Colitis Organization
[2] Digestive Disease Week, May 6-9 Chicago, IL, USA

Cx601: Preparing for US BLA[1] Filing

Leveraging EU data with approved phase III protocol

- Solid regulatory and clinical development strategy
  - Type B meeting with FDA[2] confirmed:
    - Adequacy of existing non-clinical package to support an IND[3] filing
    - Acceptability of using data from the ADMIRE-CD trial to support BLA
  - SPA[4] 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 scheduled to start in 1H2017
- Lonza selected as contract manufacturing organization for Cx601 in the US, technology transfer ongoing
- Exploring different expedited pathways with the FDA

[1] BLA: Biological License Application
[2] FDA: Food and Drug Administration
[3] IND: Investigational New Drug
[4] SPA: Special Protocol Assessment

The New RMAT Designation

A new potential avenue to accelerate Cx601 availability for US patients

Speakers:

Rachael Anatol, Ph.D., Deputy Director, Office of Tissues and Advanced Therapies, Center for Biologics Evaluation and Research (CBER), U.S. Food and Drug Administration (FDA)

Wilson Bryan, M.D., Director, Office of Tissues and Advanced Therapies, Center for Biologics Evaluation and Research (CBER), U.S. Food and Drug Administration (FDA)

"Under Regenerative Advanced Therapy Designation, flexibility on accelerated approvals would be built.."

"... forget about the old two randomized controlled trials—single arm, compelling studies are okay in this setting" Peter Marks, director of the US Food and Drug Administration's (FDA) Center for Biologics Evaluation and Research (CBER)

- **"Humacyte** Receives FDA Regenerative Medicine Advanced Therapy (RMAT) Expedited Review Designation for HUMACYL® in Vascular Access for Hemodialysis", 20 March 2017
- "**Enzyvant** Receives FDA Breakthrough Therapy Designation and Regenerative Medicine Advanced Therapy Designation for Investigational Therapy RVT-802", 17 April 2017
- "**Vericel** Receives FDA Regenerative Medicine Advanced Therapy (RMAT) Designation for Ixmyelocel-T for the Treatment of Advanced Heart Failure Due to Ischemic Dilated Cardiomyopathy", 10 May 2017

- Global phase III trial scheduled to start in 1H2017. In parallel TiGenix is exploring applying for Regenerative Medicine Advanced Therapy designation (21st Century Cures Act) at the time of submitting its Cx601 IND[1]

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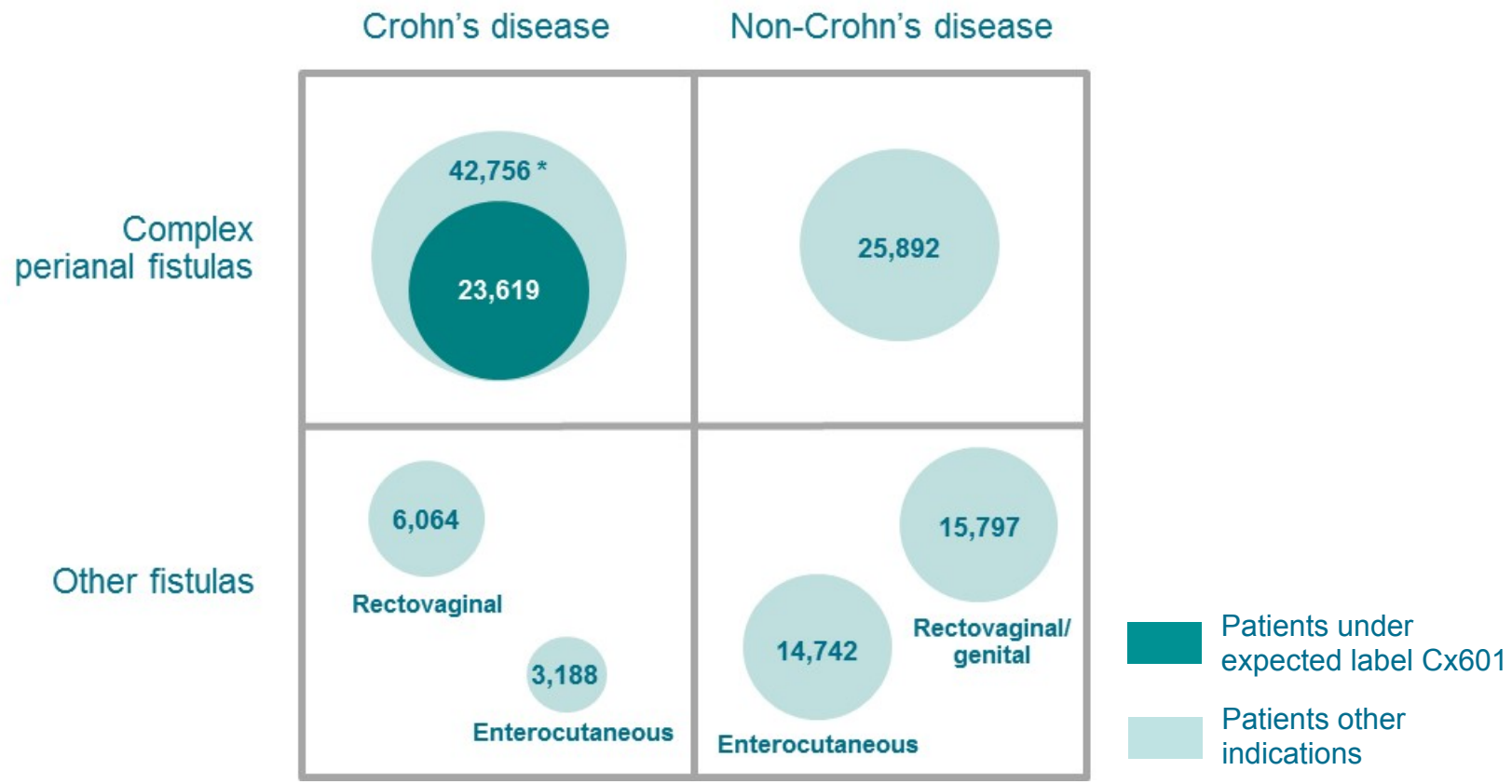
1 IND: Investigational New Drug. The request for RMAT designation must be made either concurrently with submission of an IND or as an amendment to an existing IND

2 See more at: http://www.raps.org/Regulatory-Focus/News/2017/05/08/27503/CBER-Director-Focuses-on-Flexibility-to-Advance-Regenerative-Medicines/#sthash.C1Fjf1IX.dpuf"

Cx601: Estimated Patient Populations in US (2014)

Significant potential in future related indications



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

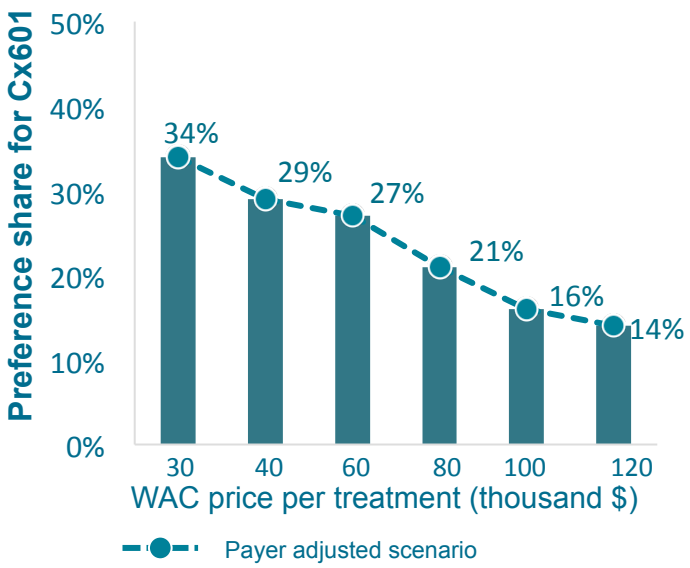
[1] Study Commissioned to Vencore Health Analytics Inc, 2016

Cx601: US Price Range Allows Significant Margin

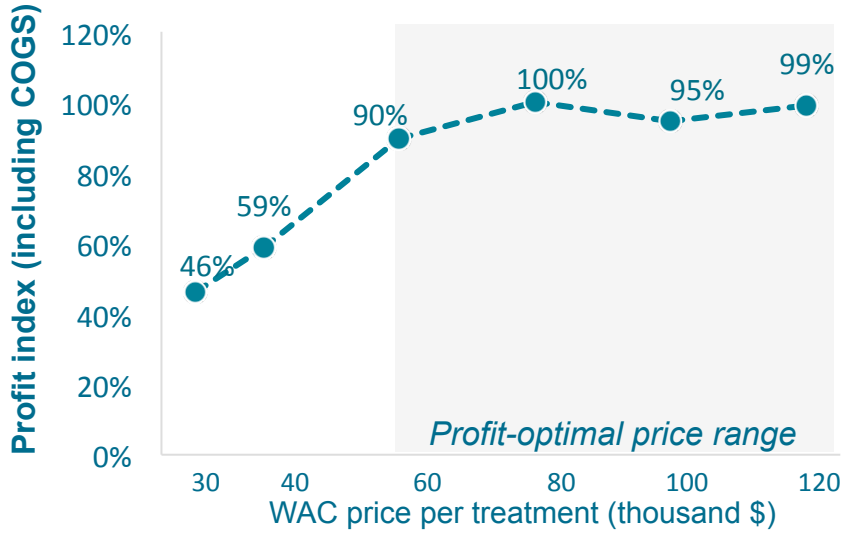
Research indicates profit-optimal prices between $60 and $120k

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

Cx611

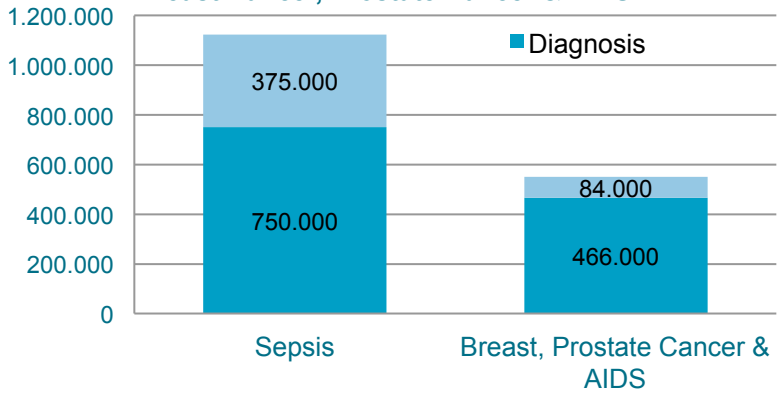
Intravenous administration of eASCs for the treatment of severe sepsis
Recruitment ongoing. Data expected 2019

Severe Sepsis

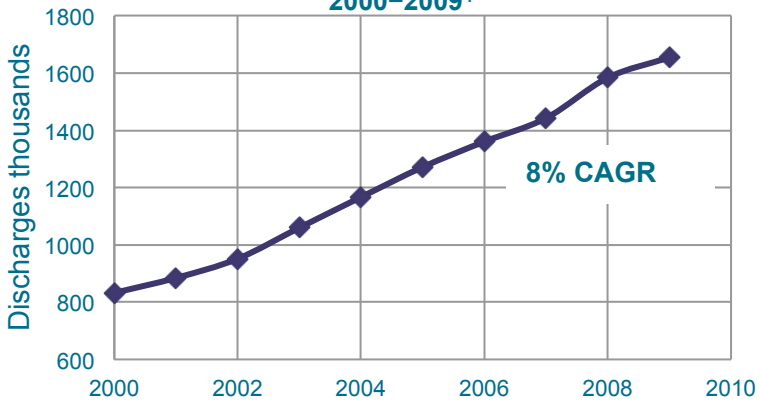
Leading cause of mortality in the developed world

- 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

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



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



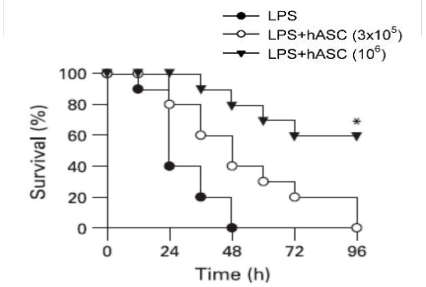
[1] The Lancet Infectious Diseases; Volume 12; issue 2; page 89; February 2012
[2] Martin GS Expert Rev Anti Infect Ther. 2012 June ; 10(6): 701–706.
[3] Adapted from Lagu, T., et al. Critical Care Medicine, 40(3):754-761; 2012
[4] Adapted from: Elixhauser et al. Septicemia in U.S. Hospitals 2009, AHRQ,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

Cx611: Strong Efficacy and Favorable Safety

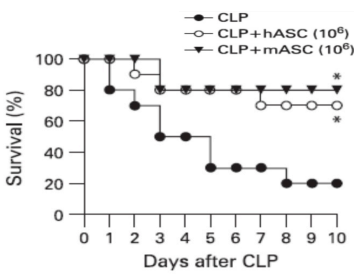
"In Vivo" models show therapeutic effect and phase I study confirms safety

- Demonstrated increased survival in both LPS (dose dependent) and CLP *in vivo* models
- This effect is due to a combination of reducing pro-inflammatory and increasing anti-inflammatory mediators, production of anti-microbial effectors
- CELLULA phase I trial results: favorable safety and tolerability profile of Cx611, consistent with phase I/IIa in refractory RA patients

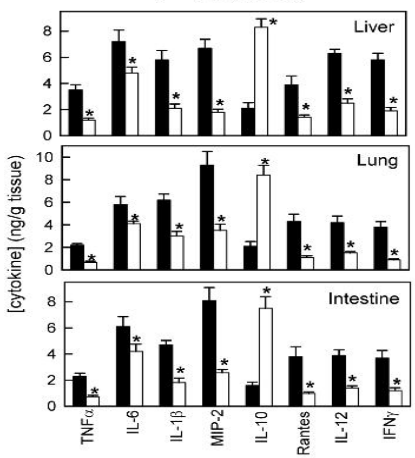
LPS[1] Model

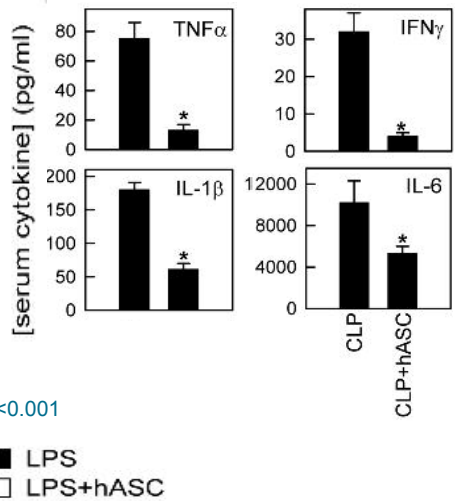


CLP[2] Model



* p < 0.001





* p<0.001

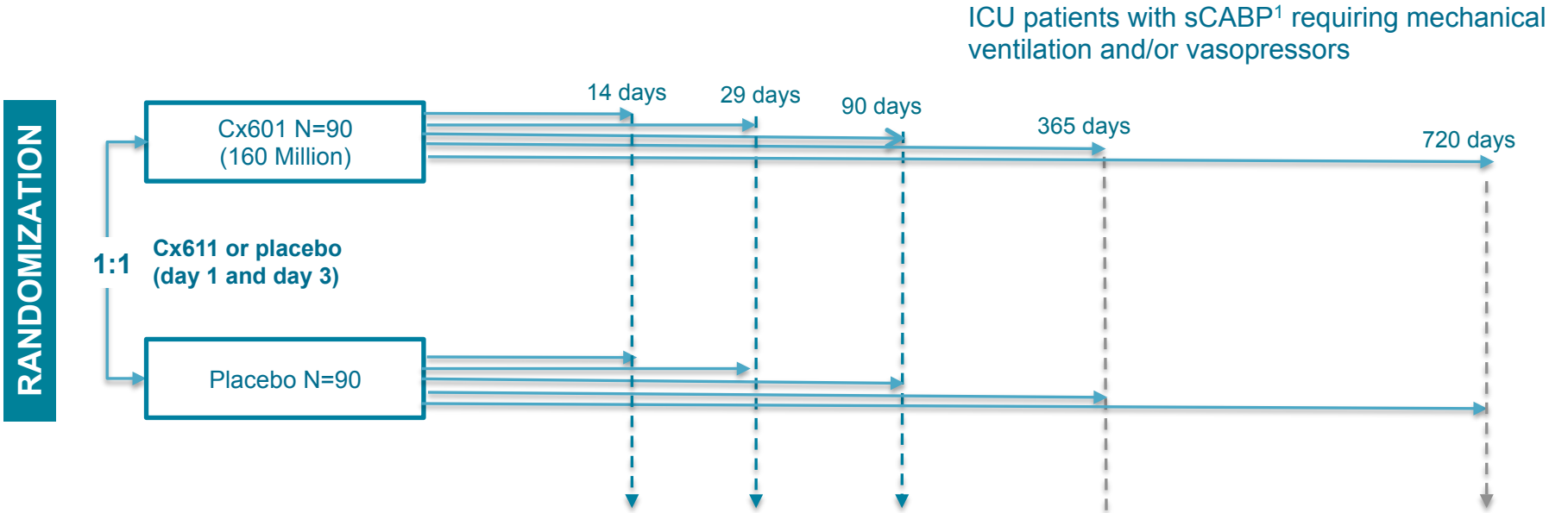
LPS
LPS+hASC

Source: Gonzalez-Rey et al. Gut. 2009 Jul;58(7):929-39

[1] LPS: lipopolysaccharide. LPS model is based on endotoxemia induced by high-dose of endotoxin
[2] CLP: cecal ligation and puncture. This model mimics the clinical situation of patients with colonic leakage following surgical procedures or diffused peritonitis

Cx611: Phase I/II SEPCELL Trial

Recruitment ongoing: data available in 2019



Secondary efficacy clinical endpoints: Survival; mechanical ventilator and/or vasopressor treatment/free days; sCABP clinical response; other efficacy endpoints, such as time to discharge from ICU

Exploratory Safety Endpoint: Long-term safety follow-up (through phone calls)

Primary safety endpoints: Safety measured throughout 90 days by the incidence of treatment emergent adverse events (TEAEs) judged related or not to study treatment

Secondary safety endpoints: potential host immune response to administered cells. Side effects: frequency, duration, severity, relatedness to study treatment

[1] Severe Community-Acquired Bacterial Pneumonia

AlloCSC-01

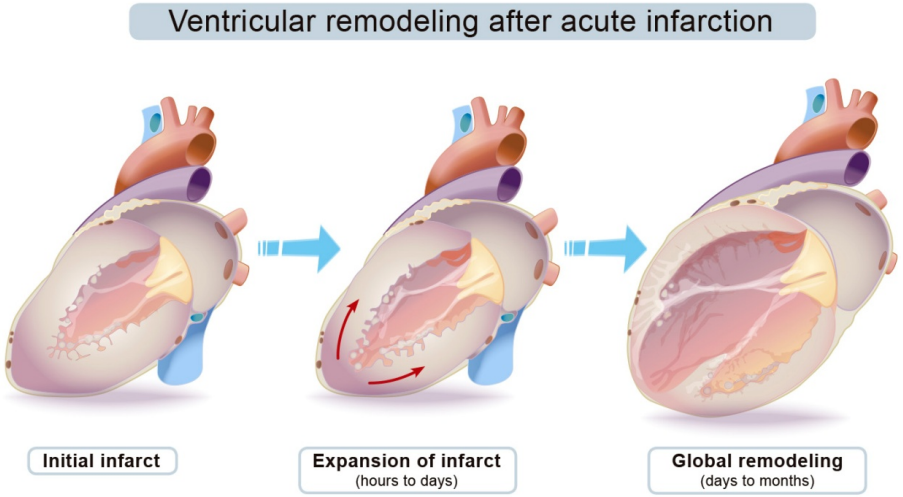
Intracoronary administration of allogeneic cardiac stem cells for the treatment of acute ischaemic heart disease

Top-line results announced on March 13, 2017

AlloCSC-01: Preventing Chronic Heart Failure

Myocardial repair may be the only feasible alternative

- 1.9M Acute Myocardial Infarctions (US+EU and Japan)[1] occur annually, mostly treated by PCI[2] and stent implantation
- Successful treatment of Acute Myocardial Infarctions ("AMI") has increased short term survival but contributed to a Chronic Heart Failure (CHF) epidemic (26M patients worldwide[3])
- **CHF post-AMI is a terminal disease** with an annual mortality rate of ~5% after the first episode, for which no curative treatment exists with the exception of heart transplantation



Myocardial repair is the only feasible treatment to address the post-acute phase of the disease and prevent the onset of CHF

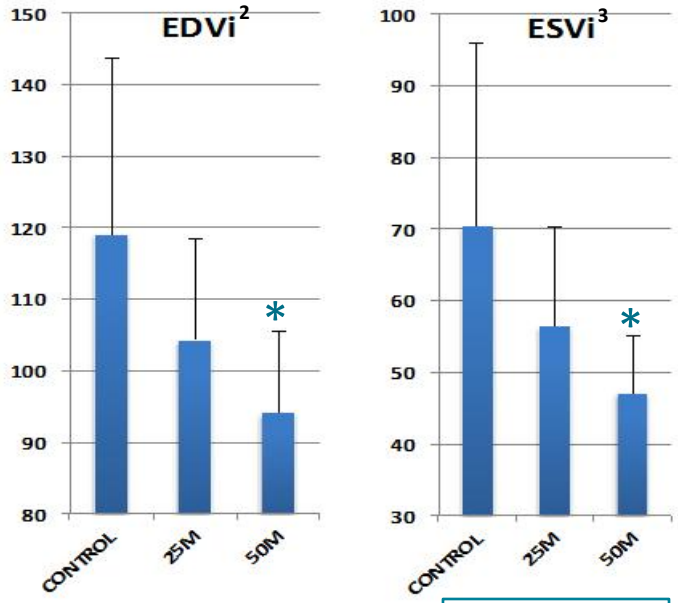
[1] Datamonitor: Stakeholder Insight: Acute coronary syndromes, DMHC2347, 2007
[2] PCI: Percutaneous Coronary Intervention
[3] Ambrosy PA et al., J Am Coll Cardiol. 2014;63:1123-1133.

AlloCSC-01: Efficacy Demonstrated in Pig Model

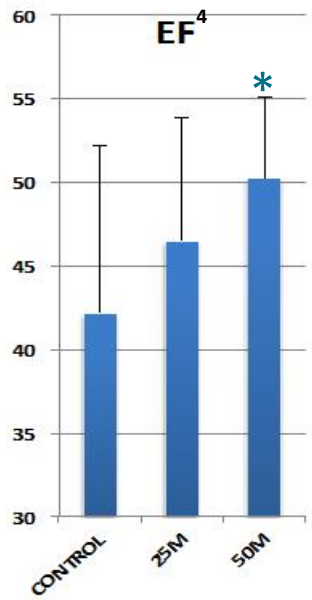
- AlloCSC-01 prevents cardiac remodelling after infarction preserving heart function
- AlloCSC-01 reduces scar size promoting formation of new contractile tissue
- Significant dose effect observed

Efficacy Data from MRI[1]

CARDIAC REMODELING

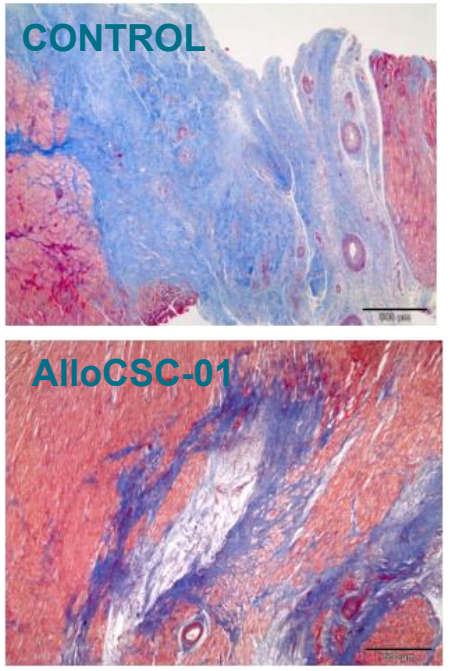


CARDIAC FUNCTION



* p-value < 0.05

Histological Analysis



[1] MRI: Magnetic Resonance Imaging
[2] EDVi: End-Diastolic Volume Index
[3] ESVi: End-Systolic Volume Index
[4] EF: Ejection Fraction

CAREMI Trial – Phase I/II in Acute Myocardial Infarction

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

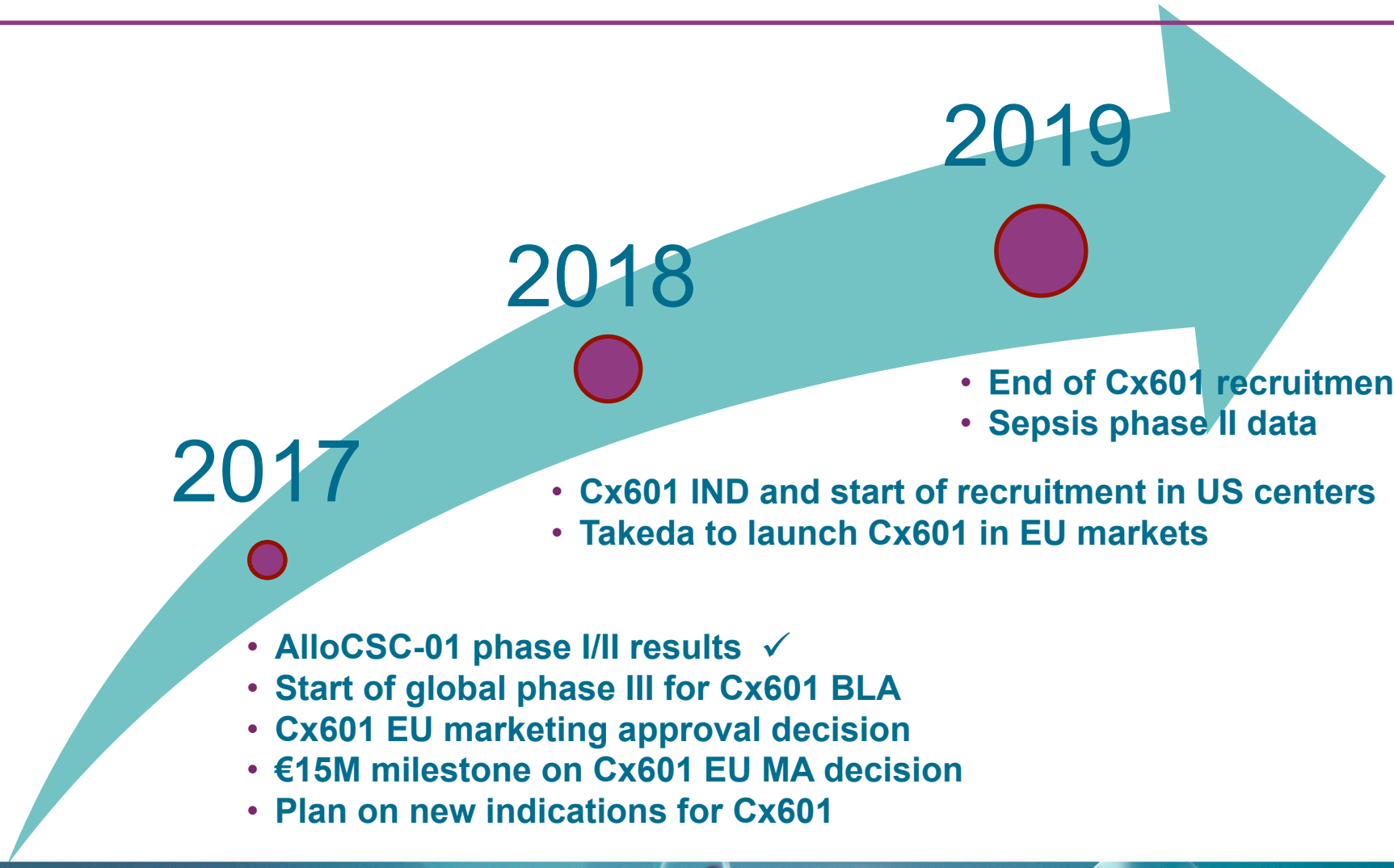
"First-in-human" phase I/II trial focused on a **safety primary objective** and the evaluation of the feasibility of an intracoronary infusion of 35 million of AlloCSC-01 in patients following a high-risk AMI

The study included 49 patients in its randomized phase with a 12-month follow-up. AlloCSC-01 were infused in the affected coronary between the 5th and 7th day post-infarction. 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

Outlook

Short Term Catalysts and Long-term Value-creation Opportunities



Stem cells are **full of possibilities.** We make them a **reality.**

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.

TiGenix
Living Medicines