TiGenix

Living Medicines

Full Year 2014 Results
Webcast Presentation

17 March 2015

Eduardo Bravo

Chief Executive Officer

Welcome and Introduction

Forward Looking Statements

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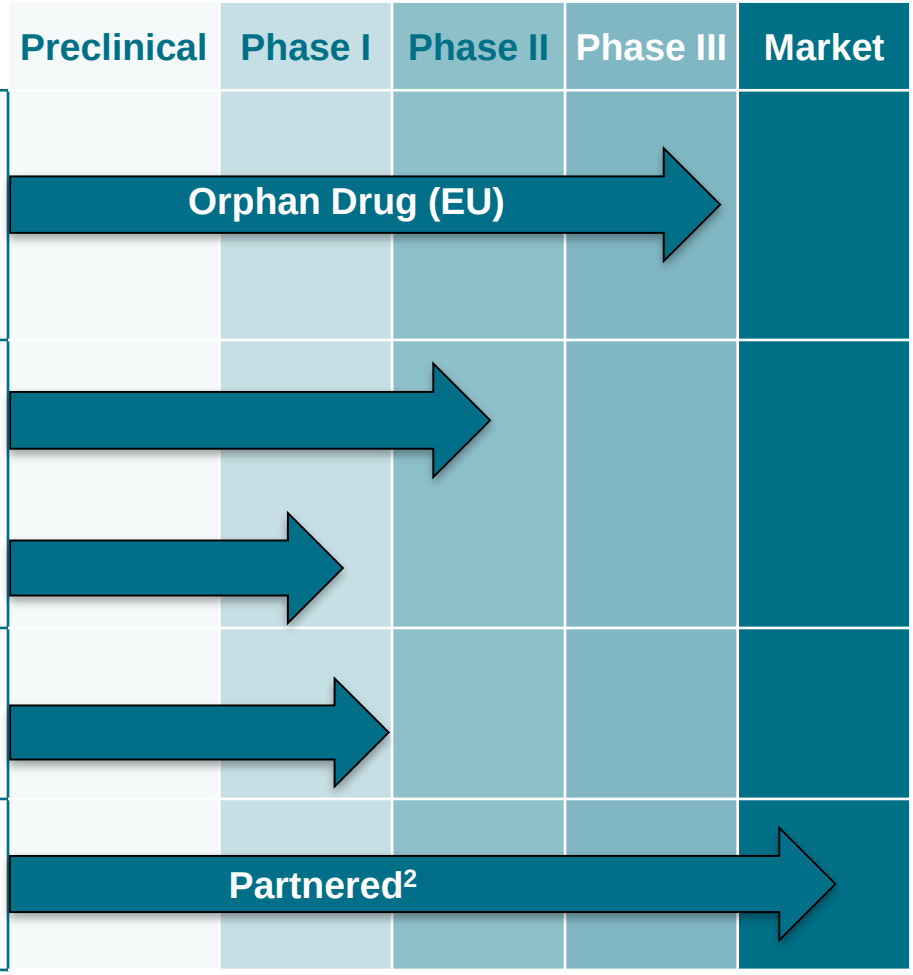
Agenda

- Welcome and introduction
- Business and Financial highlights of 2014
- Ongoing clinical trials
- Outlook
- Q&A

Multiple product candidates in clinical development

Product[1]	Cell Type	Indication
Cx601 (local)	allogeneic adipose-derived stem cells	complex perianal fistulas in Crohn's disease
Cx611 (intravenous)	allogeneic adipose-derived stem cells	rheumatoid arthritis severe sepsis
Cx621 (intralymphatic)	allogeneic adipose-derived stem cells	autoimmune disorders
ChondroCelect	characterised autologous chondrocytes	knee cartilage lesions



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[1] covered by 24 patent families
[2] distributed through Swedish Orphan Biovitrum ('Sobi') and the Finnish Red Cross Blood Service

Significant business achievements in 2014

- ✓ **Strategic refocusing successfully completed**
  - Resources focused on advancing the allogeneic expanded adipose-derived stem cell (eASCs) product pipeline
  - ChondroCelect marketing and distribution rights licensed to Sobi and Dutch manufacturing facility sold to PharmaCell
  - Management team strengthened with the appointment of Chief Medical Officer and VP Medical Affairs & New Product Commercialisation
- ✓ **Patient recruitment of Cx601 European Phase III study completed**
  - Results at 24 weeks of the ADMIRE Phase III study expected in the third quarter of 2015
  - Key adipose-derived stem cell composition patent obtained in Europe
- ✓ **Cx601 development for the United States started**
  - Phase III trial design submitted to the Food and Drug Administration (FDA) for a Special Protocol Assessment (SPA)
  - Agreement signed with Lonza for the manufacture of Cx601 in the US
- ✓ **Development plan for Cx611 announced and implementation started**
  - Cx611 to be developed for early rheumatoid arthritis and severe sepsis
  - Recruitment of Phase I trial of Cx611 in sepsis model initiated

Claudia D'Augusta
Chief Financial Officer

Financial highlights

Income statement 2014

Thousands of euros	Years ended December 31 2014	2013*
CONSOLIDATED INCOME STATEMENT		
CONTINUING OPERATIONS		
Revenues		
Royalties	337	
Grants and other operating income	5.948	883
Total revenues	**6.285**	**883**
Research and development expenses	-11.443	-9.843
General and administrative expenses	-7.406	-5.829
Total operating charges	**-18.848**	**-15.671**
Operating Loss	**-12.563**	**-14.789**
Financial income	115	7
Financial expenses	-966	-45
Foreign exchange differences	1.101	-352
Profit/(Loss) before taxes	**-12.313**	**-15.179**
Income taxes	927	59
Profit/(Loss) for the period from continuing operations	**-11.386**	**-15.120**
DISCONTINUED OPERATIONS		
Profit/(Loss) for the period from discontinued operations	-1.605	-3.270
Profit/(Loss) for the period	**-12.990**	**-18.390**
Basic and diluted loss per share (EURO)	-0,08	-0,16
Basic and diluted loss per share from continuing operations (EURO)	-0,07	-0,13
Cash and cash equivalents	13.471	15.565

* 2013 figures have been restated to present ChondroCelect as discontinued operations

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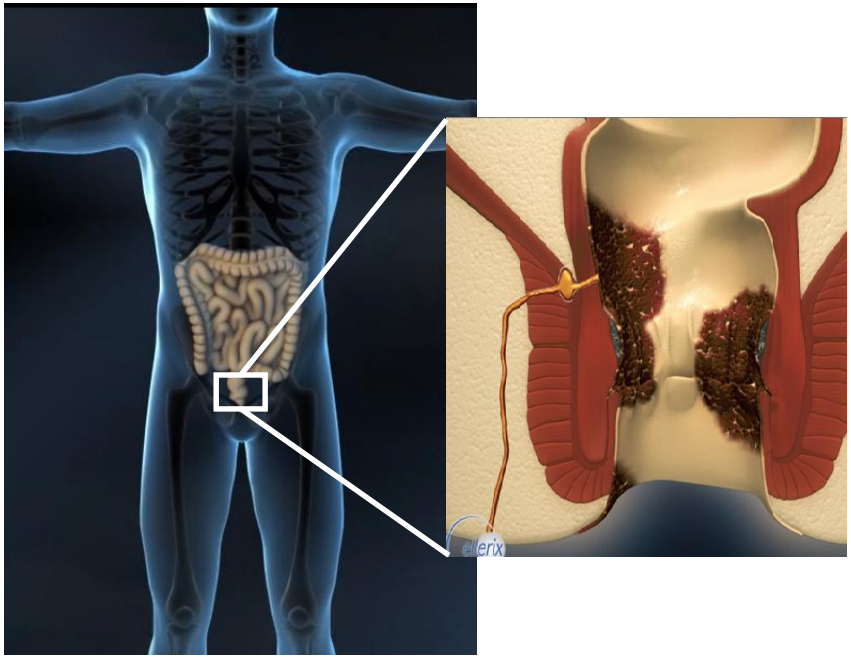
Cx601

Local injection of eASC's for the treatment of complex perianal fistulas in Crohn's disease patients

Perianal fistulas in Crohn's patients

A common and severe complication without effective treatment available

- Fistulas: sores or ulcers that tunnel through the affected area into surrounding tissues
- 12% of Crohn's disease patients are affected by perianal fistulas[1]
- 80% of these are complex
- Safety of current treatment options remains a concern (e.g. with long term use of biologics) or present low efficacy and high rate of relapse[2]



> 100,000 Crohn's disease patients suffer from complex perianal fistula in Europe and the US alone => **compromised QoL, pain, depression, risk of anal epithelial carcinoma**

[1] Source: >60 publications (including Schwartz 2002, Lapidus 2006), the European Federation of Crohn's and Colitis Associations, US Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Health Statistics

[2] Remission of 23% and relapse rate of 54% for infliximab after 1 year (Sands BE et al. (2004). N Engl J Med 350: 876–885)

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Cx601: Phase III ADMIRE-CD[1] trial

Robust Phase III designed to qualify as a single pivotal study

	TRIAL SUMMARY
Start	July 2012
Completion	Ongoing
Condition	Complex perianal fistula in Crohn's disease patients
Study design	• Randomized, double blind, placebo controlled trial • All tracts treated. Fixed single dose[2]
Enrolment	289 patients recruited
# of centers	51 sites in 8 countries
Primary endpoint	Combined Remission[3] at week 24
Secondary endpoints at weeks 24 and 52	• ClinicalRemission[4] • Response[5] • Time to remission / to response • PDAI[6] score and Quality of Life assessment (IBDQ[7])

PATIENT SELECTION

- Older than 18 years: both genders
- Non active luminal Crohn's disease (CDAI[8] ≤ 220) diagnosed for ≥ 6 months
- Patients with perianal fistulizing Crohn's disease refractory to antibiotics, immunosuppressants and/or anti-TNF
- ≤ 2 internal openings (fistulas) and ≤ 3 external openings (tracts)
- Fistula draining < 6 weeks prior to inclusion
- Exclusion of naïve patients
- Concomitant treatments allowed without modification of treatment dose or regimen
- Limit of patients refractory to antibiotics to < 25% of total recruited patients

[1] Adipose Derived Mesenchymal Stem Cells for Induction of Remission in Perianal Fistulizing Crohn's Disease
[2] 120 million cells
[3] Closure of all treated external openings draining at baseline despite gentle finger compression confirmed by MRI (no collections > 2cm)
[4] Closure of all treated external openings draining at baseline despite gentle finger compression
[5] Closure of 50% of all treated external openings draining at baseline despite gentle finger compression
[6] Perianal Disease Activity Index
[7] Inflammatory Bowel Disease Questionnaire
[8] Crohn's Disease Activity Index

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Cx601: Phase III ADMIRE-CD[1] trial

Six month read-out expected in Q3 2015

- **Patient enrolment: completed in November 2014**
- **Statistical plan:**
  - Evaluations at Weeks 6, 12, 18, 24, 36 and 52 (after dosing)
  - Primary efficacy analysis at Week 24
  - Efficacy and safety evaluations at Week 52
  - Blind clinical and MRI assessment
- **Power:** designed for finding at least 25% difference between study groups

Cx601 could be approved and launched by H1 2017

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[1] Adipose Derived Mesenchymal Stem Cells for Induction of Remission in Perianal Fistulizing Crohn's Disease

Clear US strategy defined for Cx601

Capturing the value of the biggest market

- **Positive Type B meeting** held with FDA in December 2013
  - Adequacy of the existing non-clinical package to support an IND[1] filing for a US-based pivotal Phase III trial
  - Acceptability of using data from the ongoing ADMIRE-CD[2] Phase III study in Europe to support a biologic license application (BLA)
  - Agreement on key parameters of future US pivotal Phase III trial
- **Development plan for the US being implemented**
  - Lonza selected as contract manufacturing organisation for Cx601 in the US
  - Special protocol assessment application (SPA) submitted to FDA Q4 2014
  - IND[1] to be filed as soon as technology transfer finalised

US Phase III protocol confirmation expected by the time of the European Phase III results read-out

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[1] Investigational New Drug
[2] Adipose Derived Mesenchymal Stem Cells for Induction of Remission in Perianal Fistulizing Crohn's Disease

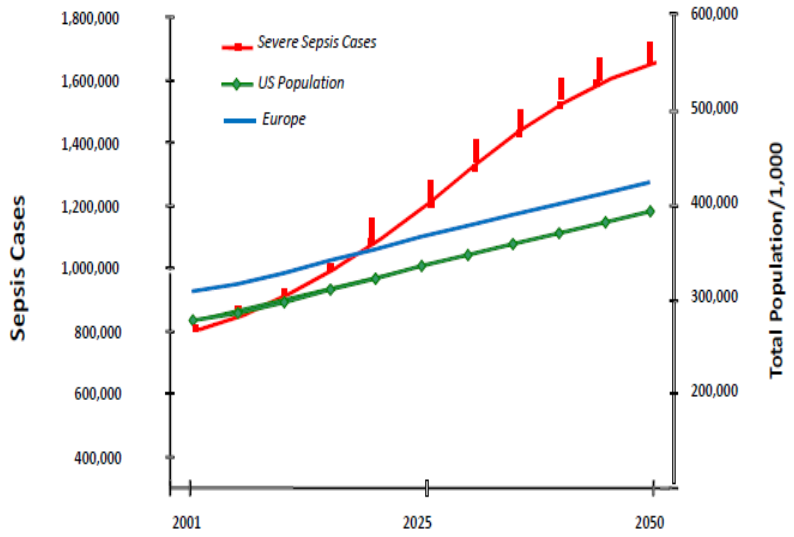
Cx611

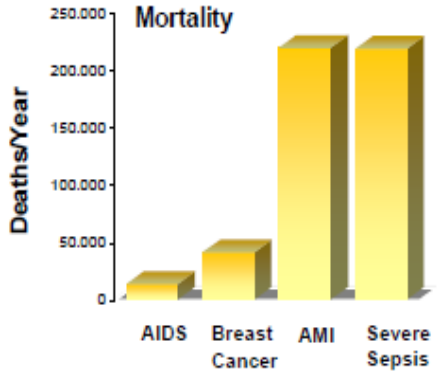
Intravenous administration of eASC's
for early rheumatoid arthritis and severe sepsis

Severe Sepsis: a high unmet medical need

- Systemic illness due to an attack of host pro-inflammatory cytokines and other humoral substances commonly induced by a bacterial infection
- An estimated 15—19M sepsis cases occur worldwide each year[1]
- Incidence is estimated at approx. 300 cases per 100,000 population p.a.[2]
- Incidence has dramatically increased over the last decade (CAGR of 8-13%)[3]
- Sepsis mortality was estimated at 36% in a recent major European study[3]
- In the case of septic shock, mortality can reach up to 80% (28 –50% of patients die within the first month of diagnosis) [4]

Incidence forecasted to grow at 1.5% p.a.[4]





[1] The Lancet Infectious Diseases; Volume 12; issue 2; page 89; February 2012
[2] Hall MJ et al. Inpatient care for septicemia or sepsis: NCHS data brief, no 62. Hyattsville, MD: National Center for Health Statistics. 2011
[3] Vincent JL et al Sepsis in European intensive care units. Critical Care Medicine 2006; 34: 344-353
[4] University Hospital of Valme & Biomedical Research Institute of Seville: Presentation at Farmaindustria meeting July 2014

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The challenge which Cx611 addresses

Targeting the underlying immune dysfunction

- Current molecular approaches to the treatment of sepsis have inadequately addressed the complex immuno-modulatory pathways involved in sepsis pathogenesis
- Cellular therapies offer a novel multifaceted mechanism of action that is potentially able to address the underlying immune dysregulation through multiple pathways

Science Translational Medicine

AAAS

Editor's summary

"a Swiss army knife for treating sepsis"

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Phase I trial synopsis and rationale: CELLULA[1] study

Evaluation of the therapeutic effect of eASCs on the inflammatory response to LPS[2] in healthy volunteers

	TRIAL SUMMARY
Start	Q4 2014
Expected completion	Q2 2015
Objective	Effect of eASCs on inflammatory response to LPS
Study design	• Parallel groups: 0,250, 1M and 4M eASCs/kg and placebo • Randomisation scheme: 3:1
Enrolment	32 healthy volunteers
# of centres	1 (Academic Medical Center, University of Amsterdam)
Primary endpoint	• Vital signs and symptoms • Laboratory measures and functional assays of innate immunity

Rationale

- Model mimics clinical signs of sepsis
  - Fever, chills
  - Headache, myalgia
  - Nausea
  - Mild tachycardia
  - Insignificant change in blood pressure
- Genomic response similar as in sepsis (not the case for animal studies)
- Provides proof-of-principle - essential information on the mechanism of action of eASCs to counteract the consequences of an LPS exposure
- Results will guide for a proposed phase II study in severe sepsis

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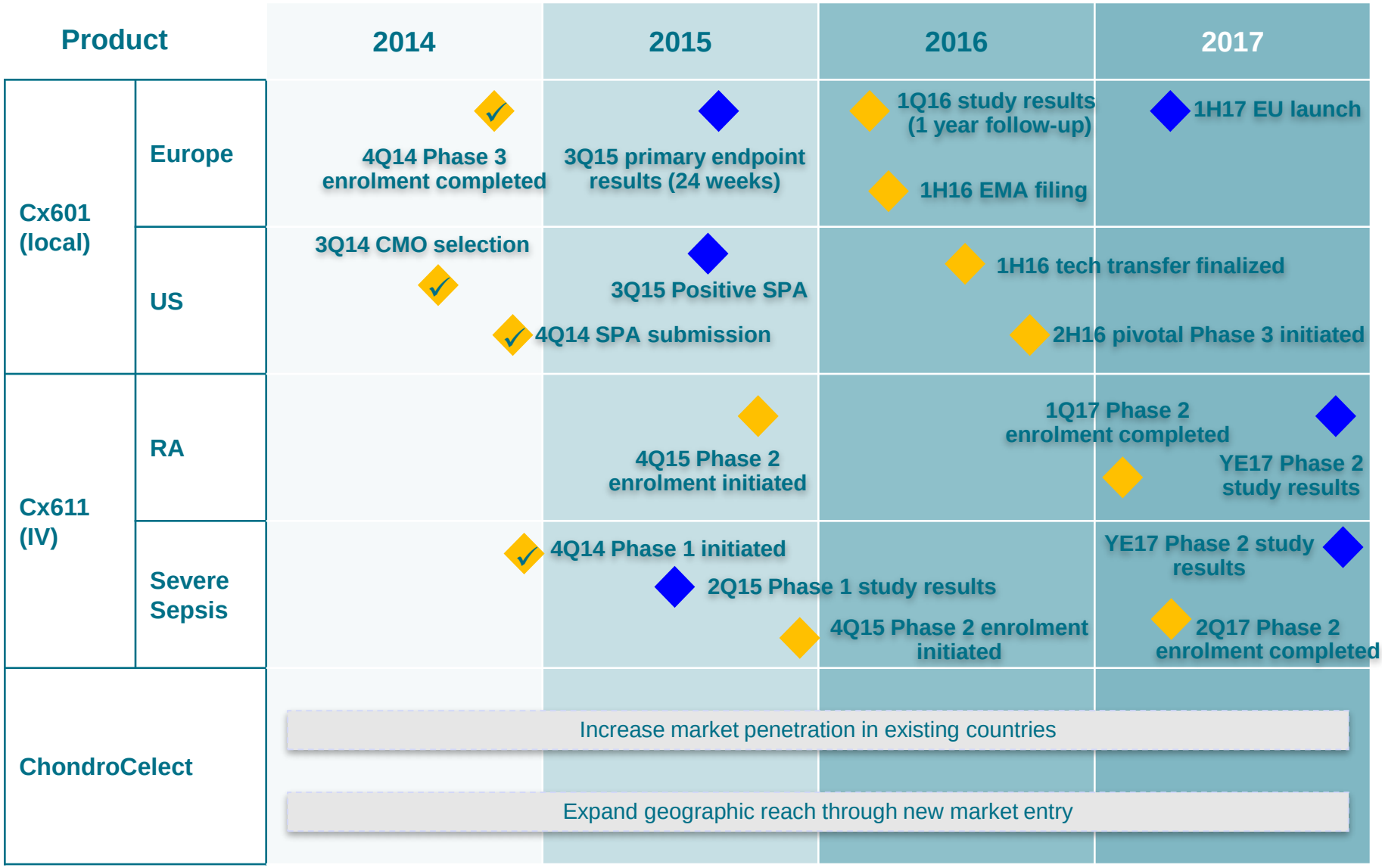
[1] The effect of expanded human allogeneic adipose-derived mesenchymal adult stem CELLs on the hUman response to Lipopolysaccharide in human volunteers
[2] Lipoplysaccharide

Key Milestones



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Q&A

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