



## **Emerging Medicinal Products**

London, 12 December 2015



# Forward Looking Statements

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# Multiple Product Candidates in Different Stages of Development

Product <sup>1</sup>	Indication	Preclinical	Phase I	Phase II	Phase III	Market
Allogeneic Adipose-Derived Stem Cells						
Cx601 (local)	Complex Perianal Fistulas in Crohn's disease	EMA-granted Orphan Drug				
		FDA-endorsed SPA				
Cx611 (intravenous)	Severe Sepsis					
Allogeneic Cardiac Stem Cells						
AlloCSC-01 (intracoronary)	Acute Myocardial Infarction					
AlloCSC-02 (intramyocardial)	Cardiology					
Characterized Autologous Chondrocytes						
ChondroCelect	Knee Cartilage Lesions	Partnered <sup>2</sup>				

# ChondroCelect® – 1st ATMP approved

Underlying research  
(ECFA-Assay and  
ChondroCelect  
molecular markers)

Pre clinical testing & validation

Phase III Clinical trial

Compassionate use in 370 patients

Marketing  
authorization  
application at  
EMA\*

Approval



1994...

2001

2002

2003

2004

2005

2006

2007

2008

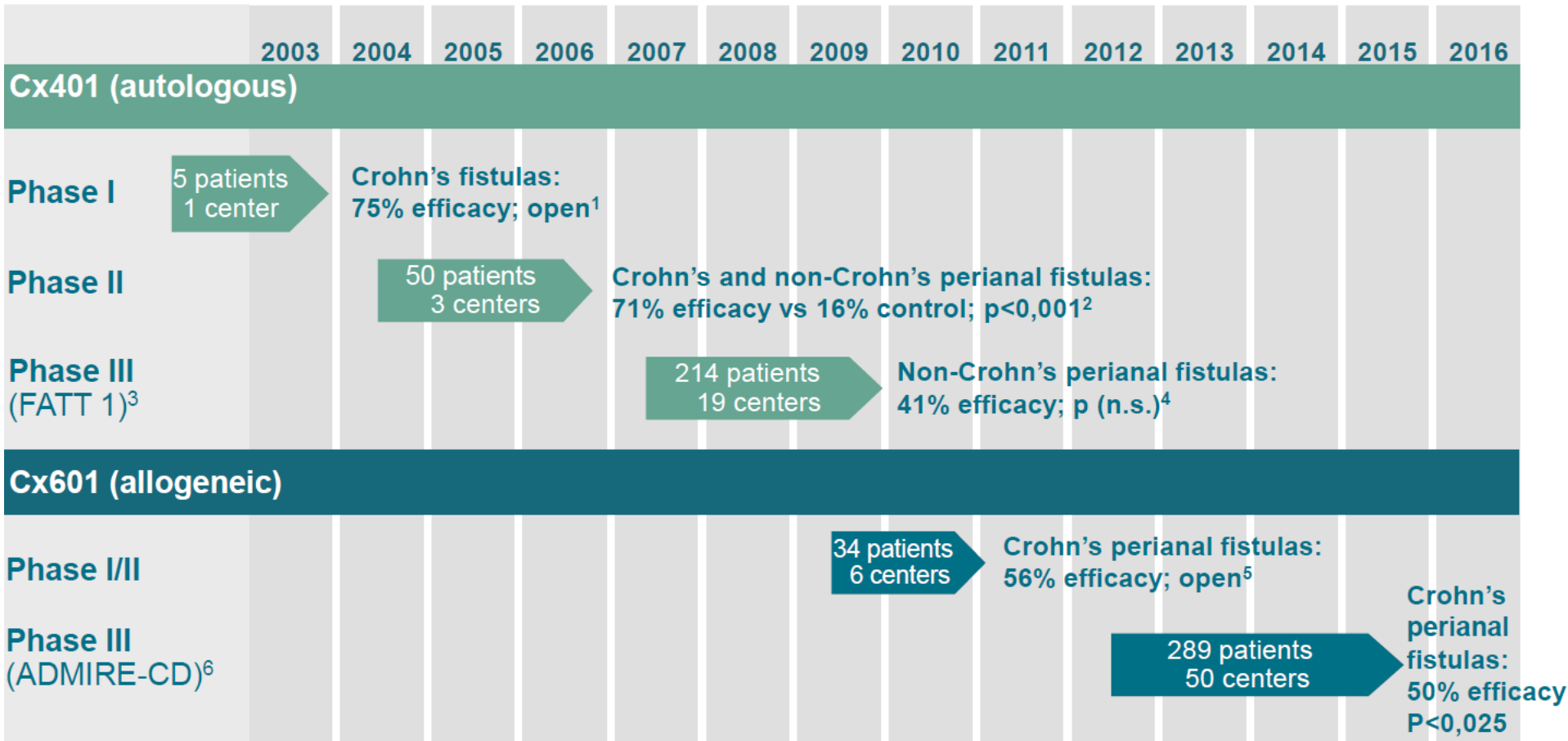
2009

2010

Year

# Cx601: First positive RCT phase III study

*>10 years of experience, consistent efficacy and safety*



<sup>1</sup> García –Olmo, et al., 2005. Diseases of the Colon & Rectum

<sup>3</sup> Fistula Advanced Therapy Trial

<sup>5</sup> de la Portilla, F. et al., 2012. Int. Journal of Colorectal Disease

<sup>6</sup> Adipose Derived Mesenchymal Stem Cells for Induction of Remission in Perianal Fistulizing Crohn's Disease

<sup>2</sup> García –Olmo, et al., 2009. Diseases of the Colon & Rectum

<sup>4</sup> Herreros, et al., 2012. Diseases of the Colon & Rectum

# Development Challenges

- Financial resources
- Intellectual property
- Manufacturing
- Compelling clinical data
- Reimbursement
- Commercial success



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