



flash
BIOSOLUTIONS

Biotherapies Days

13 & 14 novembre @ Montpellier

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CSO

#biotherapie
#bioproduction
#ADOCC



- Created in 2005
- Gene delivery experts (lentiviral vectors technologies)
- >10 000 custom batches produced
- World wide customers & collaborations



- ▶ 3300sqm , 650m² dedicated to GMP
- ▶ 50 EMPLOYEES
- ▶ GMP¹ CERTIFIED
- ▶ SERVING CELL & GENE THERAPIES
- ▶ INSPIRED BY INNOVATION

- ▶ STARTING MATERIAL GMP¹ CERTIFIED
- ▶ PHARMACEUTICAL ESTABLISHMENT CERTIFIED
- ▶ TRACK RECORDS IN EU & US
- ▶ IND² & REGULATORY SUPPORT
- ▶ GMO³ AUTHORIZED

(1) GMP : Good Manufacturing Practices

(2) IND : Investigational New Drug

(3) GMO : Genetically Modified Organism

Cutting-edge gene delivery Technologies



Proprietary Manufacturing process **from research grade to GMP grade batches**

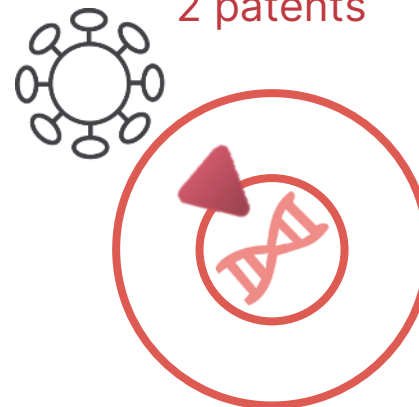


19-year running CDMO specialized purely in vector production, from molecular design to QCs

Integrative Lentiviral vectors

LentiCare®

Since 2005
2 patents



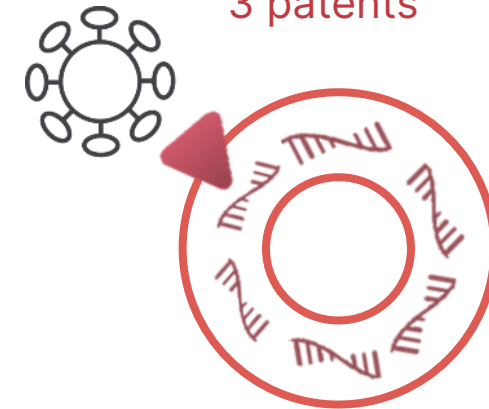
DNA delivery

Genome integration
Stable expression

RNA vectors (integrase free)

FlashRNA®

Since 2016
3 patents



RNA delivery

No GMO
Fast & transient expression

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Markets



TECHNOLOGIES	GENE THERAPY	CELL THERAPY GENE MODIFIED	CELL THERAPY GENE UNMODIFIED	VACCINATION PROPHYLACTIC	VACCINATION THERAPEUTIC
LentiCare®	GENE THERAPY	GOLD STANDARD CAR-T			
FlashRNA®	GENE THERAPY	GENE EDITION	CELL RE- PROGRAMING	mRNA VACCINES	ONCOLYTIC VACCINES

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Partnered clinical program (2024-2034)

Budget: 20M€ (150K€ allocated)

Innovative immunotherapies in autoimmune diseases

FlashRNA® for *in vivo* reprogramming of synovial macrophages and the impact on arthritis progression

Team "Molecular control of monocyte functions"

F. Apparailly, G. Courties

ILV for *ex vivo* engineering of CAR-Tregs

Team "Restore immune tolerance in rheumatoid arthritis"

P. Plence

ILV for *ex vivo* engineering of CAR-MSCs

Team "Mechanisms of Regeneration and Therapeutic Applications"

F. Djouad

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Partnered clinical program (2020-2025)

Budget: 8 M€ (1,1 M€ allocated)

FlashRNA® for *in vivo* dual RNA delivery to restore lymphatic flow in Lymphedema

- Aim: Restore the normal function of the lymphatic system in patients who developed lymphedema after breast cancer treatment (**Clinical study phase I/II**).
- Production of **GMP-grade FlashRNA®** batch as Drug Product, containing two different mRNAs.
- Scientists from 5 European countries and physicians from the Toulouse University Hospital. Leader: **B.Garmy-Susini** (INSERM I2MC Toulouse)
- Reglementary pre-clinical study in progress. **First in Human Q1 2025**

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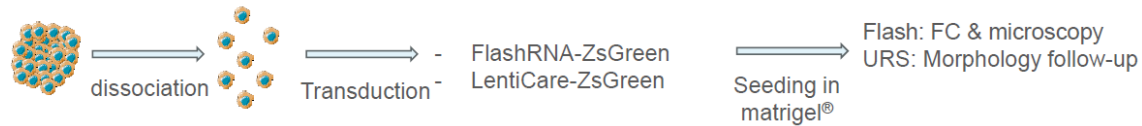


Organoids gene engineering

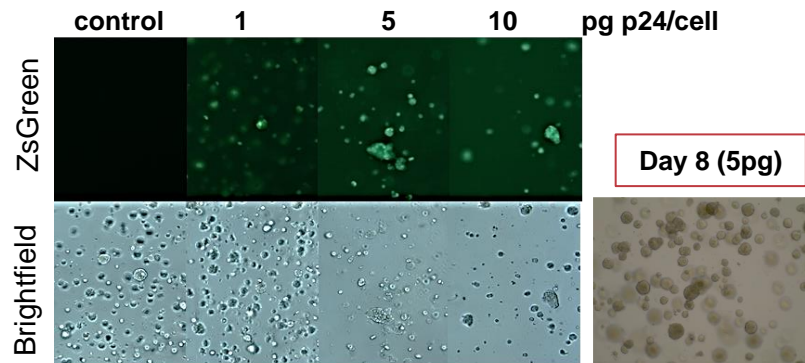
Proof of concept for gene delivery in bladder organoids

RNA delivery for **transient** gene expression using **FlashRNA®**

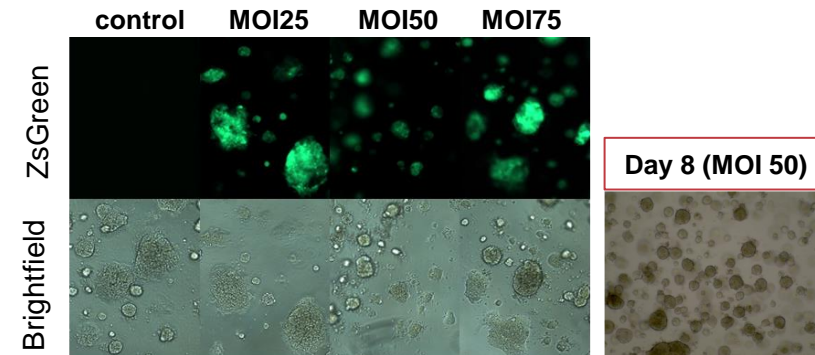
DNA insertion for **stable** gene expression using **LentiCare®** (integrative lentiviral vector)



FlashRNA®
(Day 2)



ILV
(Day 7)



Efficient expression with both technologies
No mortality, no impact on proliferation
Normal organoid formation



Strategic Industrial program (2024-2028)

Budget: 16,5 M€ (3,3 M€ allocated)

Comprehensive development initiative aimed at significantly boosting our production capacity

Expected outcome is a **20-fold increase in productivity.**



TECHNOLOGY ASSESSMENT

Rigorous comparison of vector productivity and potency derived from both suspension and adherent cell cultures (2024-2025).



SELECTION & FURTHER DEVELOPMENT

Strategic selection and development of a stable cell line technology (2025-2026).



UP-STREAM SCALE-UP

Implementation of cutting-edge technologies (2026-2028).



DOWN-STREAM SCALE-UP

Optimization of downstream processes and fill & finish scale adjustments (2026-2028).

Next : « Regenetix »



Partnered clinical program (20xx-...)

Forecast Budget: 5,5 M€

Ex vivo gene therapy to repair bronchial epithelium using induced pluripotent stem cells (iPSCs)

FlashRNA® successfully tested for genome editing in human iPSCs, including the repair of genetic defects. Collaborative project 2019-2021 with John De Vos' team (IRMB) : Mianné J, et al. BMC Biol. 2022 Jan 7;20(1):8.

Next step: Funding a phase I clinical trial for a rare, serious disease with no curative treatment to date: primary ciliary dyskinesia (PCD)

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Remerciements

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bpi**france**



MONTPELLIER UNIVERSITÉ D'EXCELLENCE

