

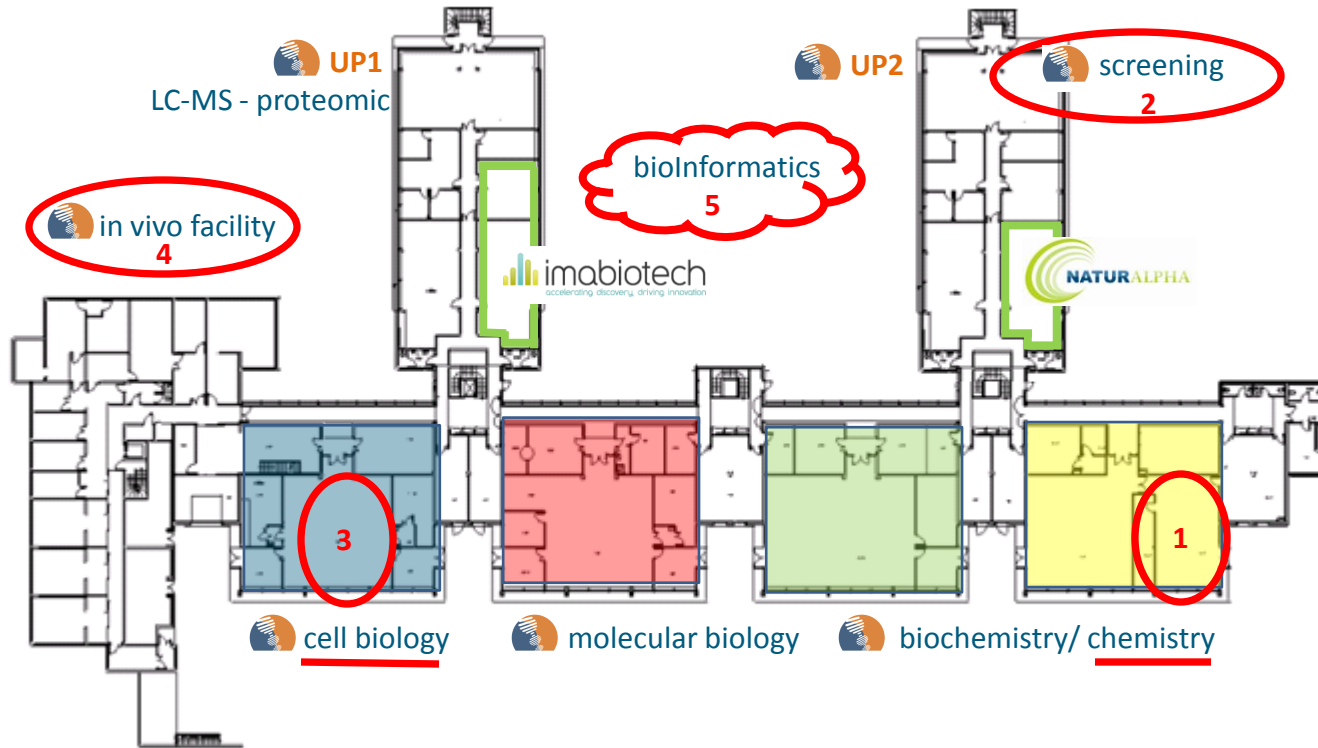


GENFIT, a Biopharmaceutical Company

New drugs for Cardiometabolic Diseases & Diabetes Complications



Welcome





GENFIT, Who Are We? <

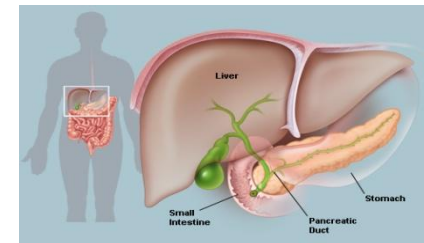
Jean-François MOUNEY (Chairman & CEO, GENFIT)



➤ GENFIT as of Today

At a Glance

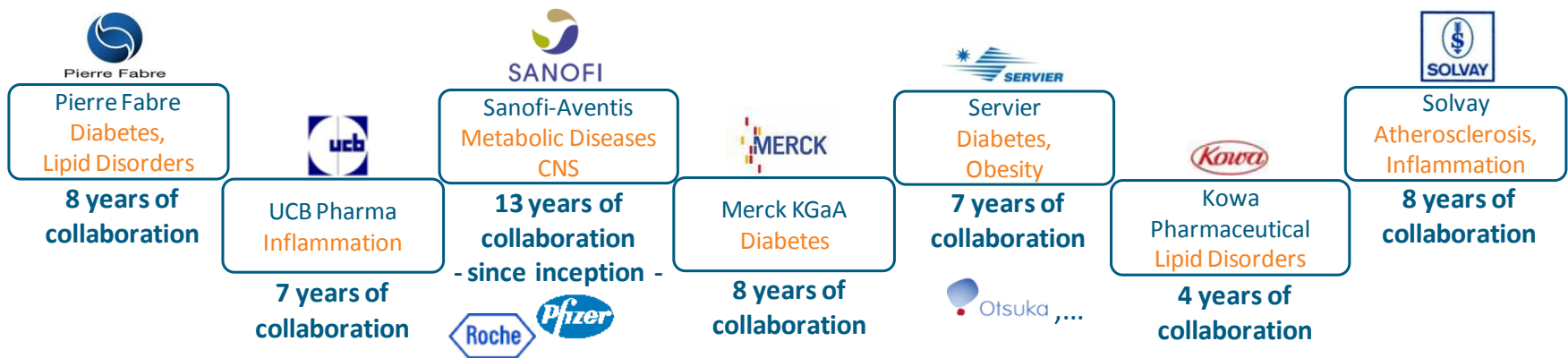
- ▶ A Biopharmaceutical Company
 - ▶ Founded in 1999 (Lille, France & Cambridge, US)
 - ▶ 80 employees (65 scientists)
- ▶ GENFIT's world-leading expertise
 - ▶ Gene regulation and Nuclear Receptor based drug discovery
 - ▶ Cardiometabolic diseases
 - ▶ obesity, dyslipidemia, prediabetes & diabetes
 - ▶ **Diabetes complications**
- ▶ GENFIT capabilities & organisation
 - ▶ Cover the whole Drug Discovery process
 - ▶ From therapeutic targets to the clinical development of drugs



➤ A Solid Track Record in Cardiometabolism

With Partners and Stand-Alone

- ▶ An history of successful partnerships
 - ▶ Exceeded 100M€ revenues for 13 years

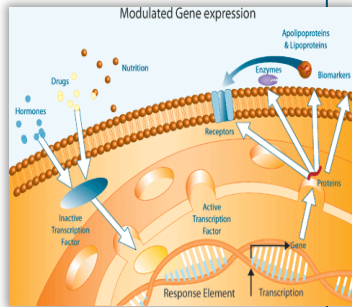


- ▶ Solid IP and patent portfolio: 232 patents or applications

➤ GENFIT, From 2000 To 2013

In the early 2000s: GENFIT's Genomics Expertise for Pharmas

Targets



- ▶ Inception of GENFIT in Lille Eurasanté Health Pole
- ▶ Research alliances with Sanofi, Aventis, Merck-Lipha, UCB Pharma, then Solvay/Abbott, Pierre Fabre, Kowa...
 - ▶ Strong scientific expertise
 - ▶ Nuclear Receptors
 - ▶ Functional genomics
- ▶ Business model: Research-fee based alliances providing access to Drug Discovery platforms
- ▶ Collaborative network / Pharma teams on site
- ▶ Creation of two subsidiaries
 - ▶ Cardialpha: Clinical trials
 - ▶ IT-Omics: Bioinformatics

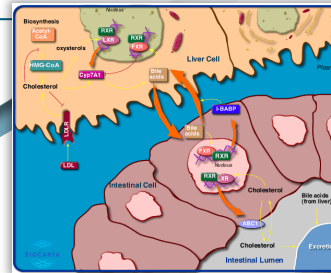
2000

➤ GENFIT, From 2000 To 2013

2005: Be Prepared to Fill Pharmas' Pipelines

- ▶ GENFIT finances its own programs of drug discovery
 - ▶ Be ready to offer late-stage products
- ▶ Renewal of the Alliances with Pharmas
 - ▶ Based on GENFIT's proposals / innovations
 - ▶ New targets, cellular pathways, mechanisms of action

2005



Cellular mechanisms

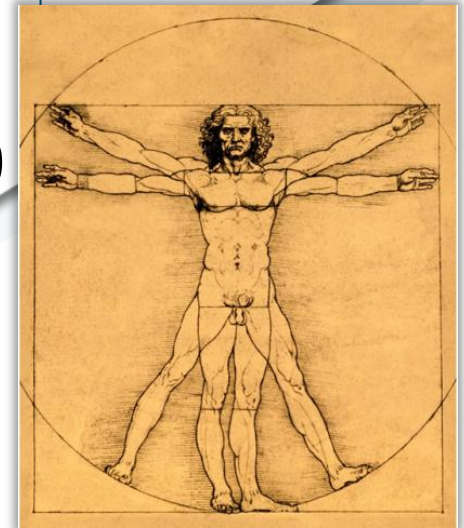
2000

- ▶ GENFIT's first participation in European framework programme
- ▶ GENFIT is a key player / founder of
 - ▶ The Nutrition, Healthcare, Longevity Cluster

➤ GENFIT, From 2000 To 2013

2009: Human Should Drive Research and Innovation

- ▶ GENFIT, leader of consortia for Diabetes and CVD
 - ▶ Large cohorts of patients (over 1000 patients)
 - ▶ Collaborations with Universities and Hospitals (France, Germany, UK,...) **2009**
 - ▶ Key biotech collaborators
 - ▶ Naturalpha (clinical trials / health & nutrition)
 - ▶ Genoway (humanized animals)
 - ▶ EGID (European Genomic Institute for Diabetes)



**Disease processes /
Human clinical
physiopathology**

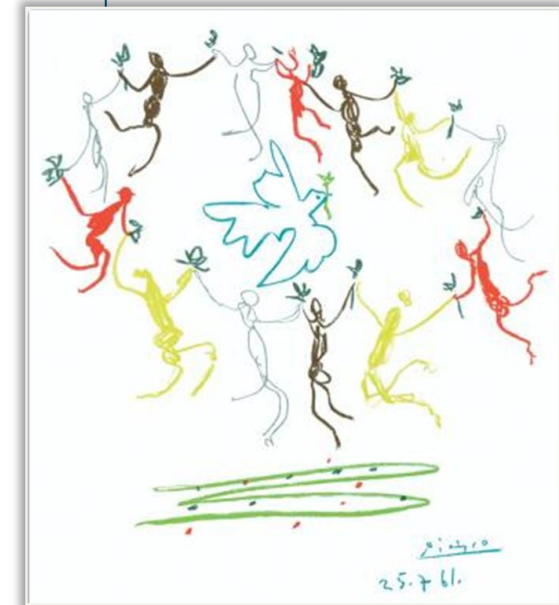
2000

➤ GENFIT, From 2000 To 2013

2012: Engineered to Find Drugs and Treat Patients

- ▶ Co-Research alliance with Sanofi on a risk-sharing basis
 - ▶ Strong mutual commitment / Task-shared activity
 - ▶ Leverage complementarities / collaborative exchanges
- ▶ GFT505, GENFIT's lead drug candidate in Phase IIb for NASH
 - ▶ Establishment of novel & dynamic clinical networks for cardiometabolic related liver diseases
- ▶ Nuclear Receptor based programs
 - ▶ Proprietary molecules with in-vivo PoC for Diabetes
 - ▶ Breakthrough for auto-immune diseases & fibrotic disorders

2012



➤ GENFIT, From 2000 To 2013

2013: A robust Pipeline

2013

GFT505	dual PPAR α / δ -non PPAR γ	Phase IIB ongoing in NASH
<ul style="list-style-type: none">▶ NASH▶ CV Prevention		
TGFTX1	ROR γ t	Hit to Lead
<ul style="list-style-type: none">▶ Autoimmune diseases (including, among others, IBD)		
TGFTX3	Reverb α	Lead Optimization
<ul style="list-style-type: none">• Diabetes, NASH, AHF		
DGFTX1		New Molecules Development
<ul style="list-style-type: none">▶ Other fibrotic disorders		
BMGFT02		Biomarker Candidate
<ul style="list-style-type: none">▶ Prediabetes / Diabetes		
BMGFT03		Biomarker Candidate
<ul style="list-style-type: none">▶ NASH		

2000



GENFIT's approach for diabetes associated complications

- ▶ GFT505, a phase IIb drug candidate for NASH

➤ Disease Complications, the Challenges in Diabetes

GFT505, A Therapeutic Solution for Liver and CV Complications

Glucose reduction is not sufficient to avoid Type 2 diabetes complications

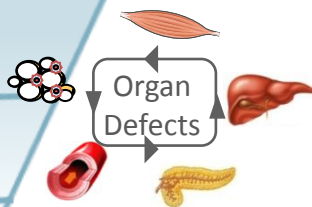
OADs
METFORMIN
SULFONYLUREAS
GLITAZONES
DPP-IV
...

RISK FACTORS

- ▶ Altered glucose metabolism
- ▶ Lipid Disorders
- ▶ Overweight, obesity
- ▶ Pro-inflammatory & oxidative stress
- ▶ Hypertension
- ▶ Liver Dysfunction

PREDIABETES

Insulin Resistance
Hyperglycemia



DIABETES

COMPLICATIONS

- Retinopathy / Blindness
- Nephropathy
- Diabetic Foot
- CV Events
- NASH

High need for products to treat complications and comorbid diseases associated with diabetes

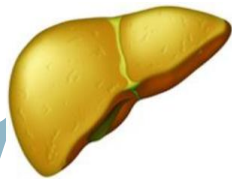
GFT505

➤ NASH, Non-Alcoholic Steato-Hepatitis

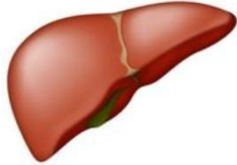
A severe form of Non-Alcoholic Fatty Liver Disease

25% of the general population
70% in diabetic and obese patients

STEATOSIS

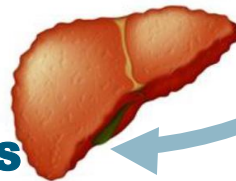


HEALTHY LIVER



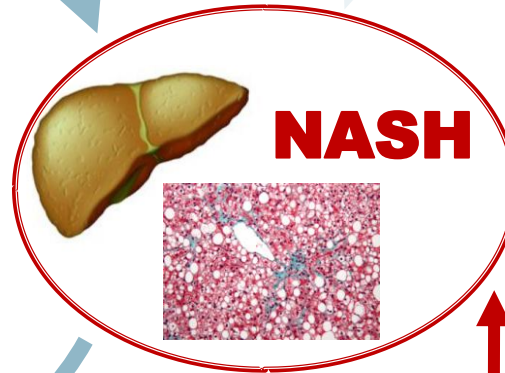
**Hepatocellular Carcinoma
Transplant
Death**

CIRRHOSIS



5-7 % of the general population in western countries
45M people in North America & Europe
25-30% in diabetic and obese patients

NAFLD



NASH

↓ Survival vs. the general population

↑↑ Liver-related mortality

↑ Cardiovascular mortality

Cirrhosis : an independent risk factor of death

➤ Scientific Rationale for Developing GFT505 in NASH

A Pluripotent Product Is Needed, GFT505 Can Meet the Need

- ▶ GFT505, New dual PPAR α/δ -non PPAR γ product
 - ▶ Over 450 patients or healthy volunteers treated with GFT505 to date
 - ▶ Beneficial properties for NASH & cardiovascular risk reduction

▶ Improvement of
glucose homeostasis & insulin sensitivity ◀

▶ Improvement of markers
of **liver dysfunction** ◀

▶ Favorable effects
on **plasma lipids** ◀

NASH
CV risk Prevention

▶ **Efficacy on histological NASH**
parameters in disease models
(fibrosis, steatosis,...) ◀

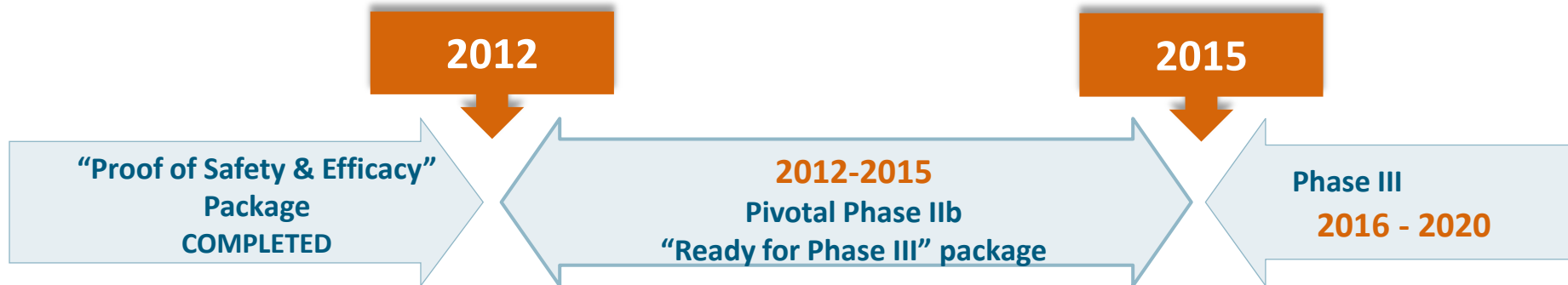
▶ **Absence of safety concern,**
▶ **Absence of PPAR deleterious effect** ◀

▶ **Anti-inflammatory** properties ◀

DIABETES

➤ GFT505 Development Plan

Aligned to Register GFT505 Among the 1st Approved Drugs for NASH



Pivotal phase IIb in Europe & US 1-year treatment liver biopsy-based trial

270 patients / 74-90 centers
2 doses (80mg & 120mg) + placebo

FDA IND approval: OK
EMA Scientific Advice: OK

Submission US & Europe.....June-Oct 2012
First patient, First Visit.....Sept 2012
End of treatment analysis.....Dec 2014



Questions les plus fréquemment posées <

- ▶ GFT505, Développement clinique et Perspectives
- ▶ Pipeline et Business Development
- ▶ Vie Financière
- ▶ Divers ?



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Thank you <



www.genfit.com