

# CORPORATE PRESENTATION

- I. CORPORATE HIGHLIGHTS
  - II. LEADERSHIP IN NASH & PBC
-

# Disclaimer

## Forward Looking Statements

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# I. CORPORATE HIGHLIGHTS

# CORPORATE OVERVIEW

## BACKGROUND

- Founded in 1999 (Lille & Paris, FR and Cambridge, MA, U.S.A) – 180+ employees
- World-leading expert in nuclear receptor based drug discovery
- Developing therapies and diagnostic solutions for metabolic and liver related diseases, specifically NASH (the liver manifestation of the metabolic syndrome, closely associated with obesity and diabetes) and PBC (a severe cholestatic, chronic, autoimmune liver disease)
- Dual-listed public company : E.U. 2006 (Euronext Paris – GNFT) / U.S. 2019 (Nasdaq – GNFT)
- Market capitalization of ~€550M, €282 million cash balance (6/30/19) [not including the \$35 million upfront from the Terns licensing agreement to be recognized in H2]

## LEADERSHIP & CORPORATE GOVERNANCE

- CEO: Pascal Prigent; COO/CSO: Dean Hum
- Chairman of the Board: Jean-Francois Mouney

## LEAD PROGRAMS with retained rights in US/EU

- Elafibranor a PPAR alpha/delta, first-in-class molecule evaluated in NASH [ongoing Phase 3 under accelerated approval process and fast-track designation] and PBC [Phase 2 successfully completed, with breakthrough therapy designation granted by FDA and Orphan Drug granted by FDA & EMA]
- NIS4 In-Vitro Diagnostic (IVD) for non-invasive diagnosis of NASH

# Genfit Strategy

## Comprehensive and patient-centric

### 1. TREATMENT

- ▶ Providing  
THERAPEUTIC SOLUTIONS

### 2. DIAGNOSTIC TEST

- ▶ Identifying  
PATIENTS ELIGIBLE FOR TREATMENTS



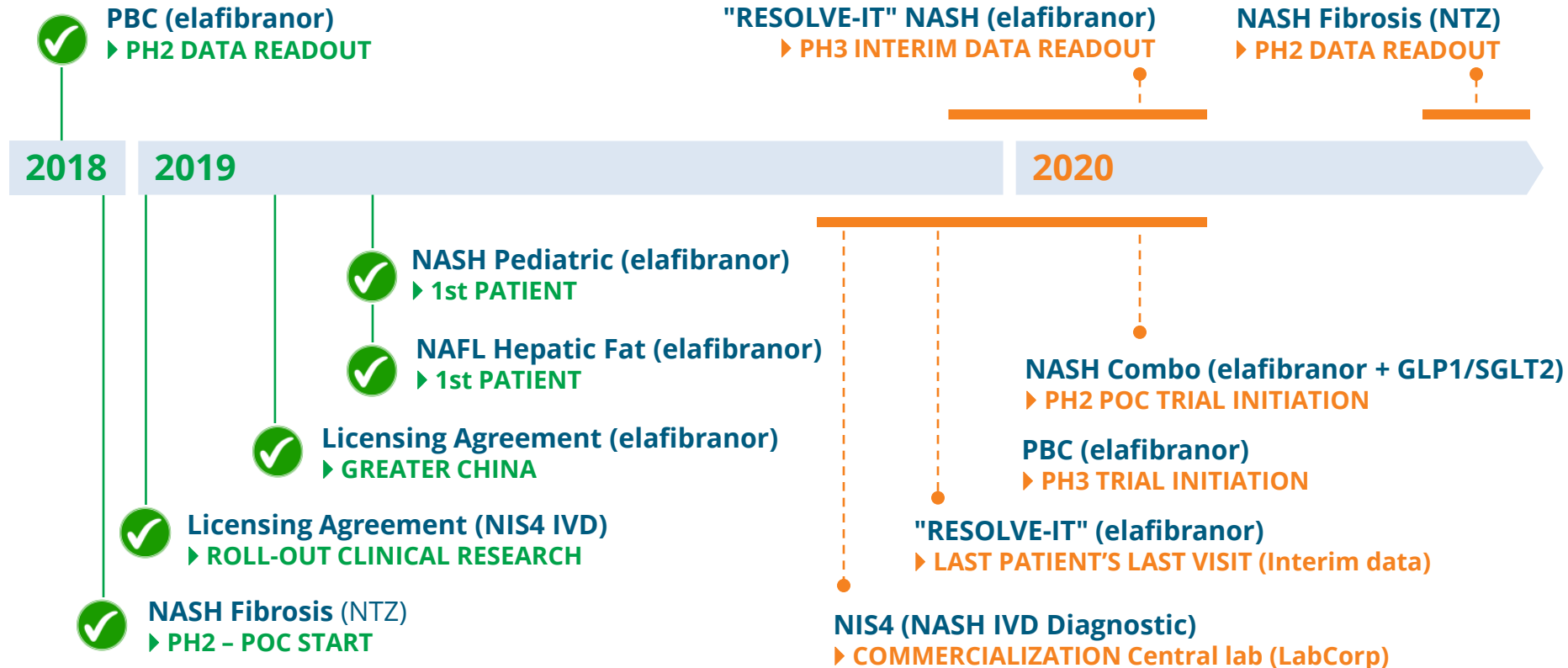
### 3. EDUCATION

- ▶ Improving  
AWARENESS & KNOWLEDGE

# A Robust Pipeline With Near-Term Clinical Milestones

PROGRAM	INDICATION	TARGET	DEVELOPMENT STAGE	TIMELINE
Elafibranor	ADULT NASH monotherapy	PPAR $\alpha/\delta$	PHASE 3	LAST PATIENT'S LAST BIOPSY – 4Q19 PHASE 3 INTERIM RESULTS – 1Q20
	PBC	PPAR $\alpha/\delta$	PHASE 2	PHASE 3 TRIAL INITIATION – 1Q20
	PEDIATRIC NASH	PPAR $\alpha/\delta$	PHASE 2	PHASE 2 - ENROLLING
	NAFL	PPAR $\alpha/\delta$	PHASE 2	PHASE 2 POC - ENROLLING
	ADUL TNASH Combination therapy	PPAR $\alpha/\delta$ SGLT2, GLP1	PHASE 2	PHASE 2 POC INITIATION – 1Q20
Nitazoxanide	FIBROSIS	Undisclosed	PHASE 2	PHASE 2 DATA READOUT – MID 2020
TGFTX1	AUTO-IMMUNE	ROR $\gamma$ t	PRECLIN	PRE-IND STUDIES
NIS4	NASH DIAGNOSTIC	NAS $\geq$ 4, F2+	CLINICAL COMMERCIAL	LDT COMMERCIALISATION CENTRAL LAB – 2H19 REGULATORY SUBMISSION for IVD – 2020

# Near-Term Catalysts



Achieved milestones

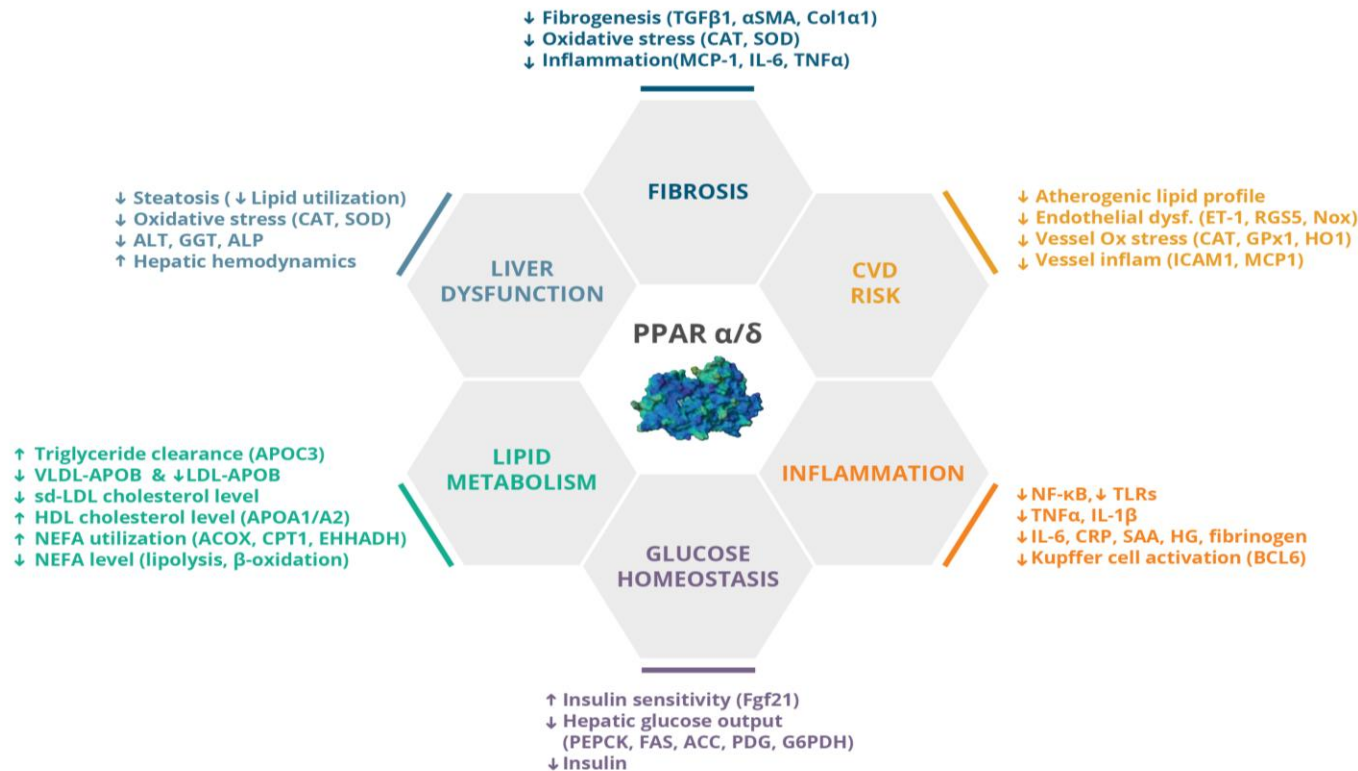
Near-term catalysts



## II. LEADERSHIP IN NASH & PBC



# Elafibranor, First-in-class PPAR Alpha/Delta, Has Pluripotent Activities Regulating Multiple Pathways Essential in PBC and NASH



# The Potential to Become a Leader in PBC & NASH

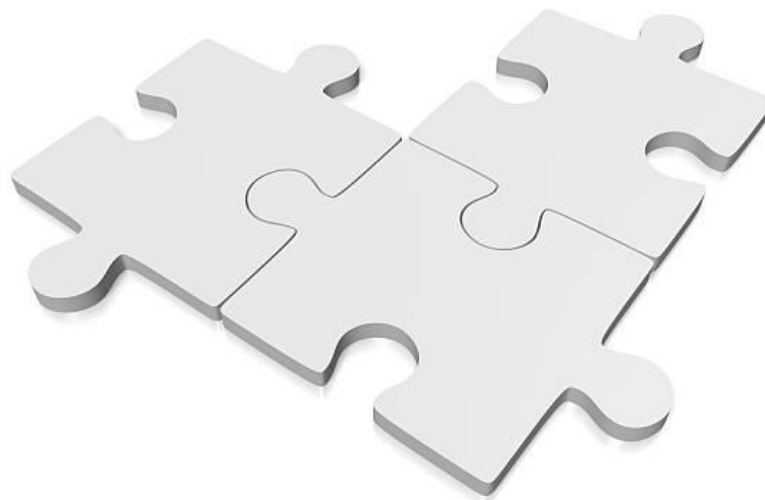
## 1. TREATMENT

### NASH & FIBROSIS

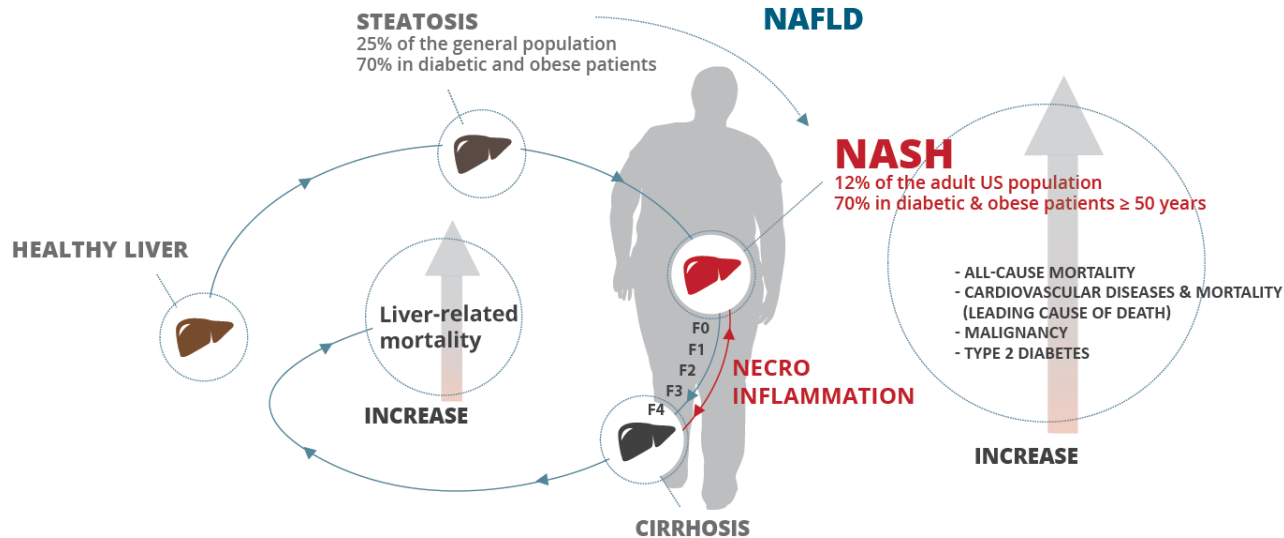
- ▶ *Elafibranor*
- ▶ *Combinations*
- ▶ *Nitazoxanide*

### PBC

- ▶ *Elafibranor*



# NASH, a Disease Leading to Cirrhosis and HCC, Represents a Large and Untapped Market



- > NASH is the **liver** manifestation of **metabolic syndrome**, and a **multifaceted disease**
- > Approvable endpoints are **NASH resolution** (disease engine) and **fibrosis improvement** (consequence of disease)
- > Leading cause of liver disease in developed countries; **~20 million in the United States**
- > **Cardiovascular events** are the leading cause of death in NASH (Patients F0-F3)
- > Market estimations (research analysts): **up to \$20bn by 2025**

# Elafibranor: Only Advanced Phase 3 Product Candidate Targeting "NASH Resolution Without Worsening of Fibrosis"

## Early stage PHASE 3

	NASH Resolution	Fibrosis Improvement
Cenicriviroc (ALLERGAN)	N/A	○ (PE)
MGL-3196 (MADRIGAL)	○ (PE)	○ (SE)

Next Wave Drugs

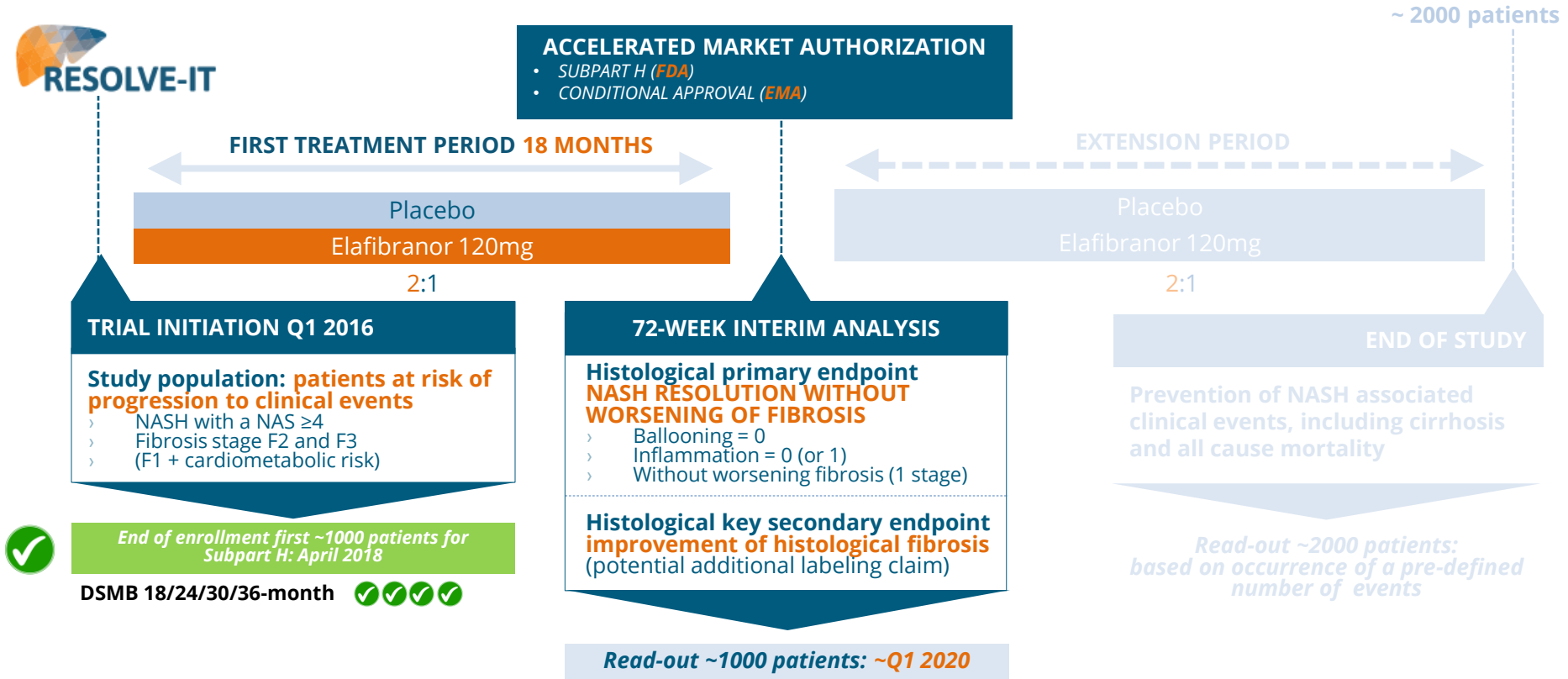
## Late stage PHASE 3

Subpart H Phase 3 cohort recruited

	NASH Resolution	Fibrosis Improvement
Elafibranor (GENFIT)	○ (PE)	○ (SE)
Obeticholic acid (INTERCEPT)	✗ (PE)	✓ (PE)
Selonsertib (GILEAD)	N/A	✗ (PE)

Wave 1 Drugs:  
NDA submission in 2019-2020

# Elafibranor Phase 3 Design: Details and Timing



# Elafibranor Phase 2b Results (1/3): Efficacy on Regulatory Endpoint for Phase 3

Elafibranor hits on "**NASH Resolution Without Worsening of Fibrosis**"  
in ITT and all other analyses

Population	120mg	Placebo	P-value
All / ITT	19%	12%	0.045
NAS $\geq$ 4	19%	9%	0.013
NAS $\geq$ 4 w/ fibrosis	20%	11%	0.009
<b>NAS<math>\geq</math>4 3 arms</b>	<b>26%</b>	<b>5%</b>	<b>0.02</b>

Based on the objective and approved definition of "NASH resolution"  
defined by regulators as **Ballooning = 0 & Inflammation = 0 (or 1)**

Data published in peer-review journal:

**Gastroenterology**

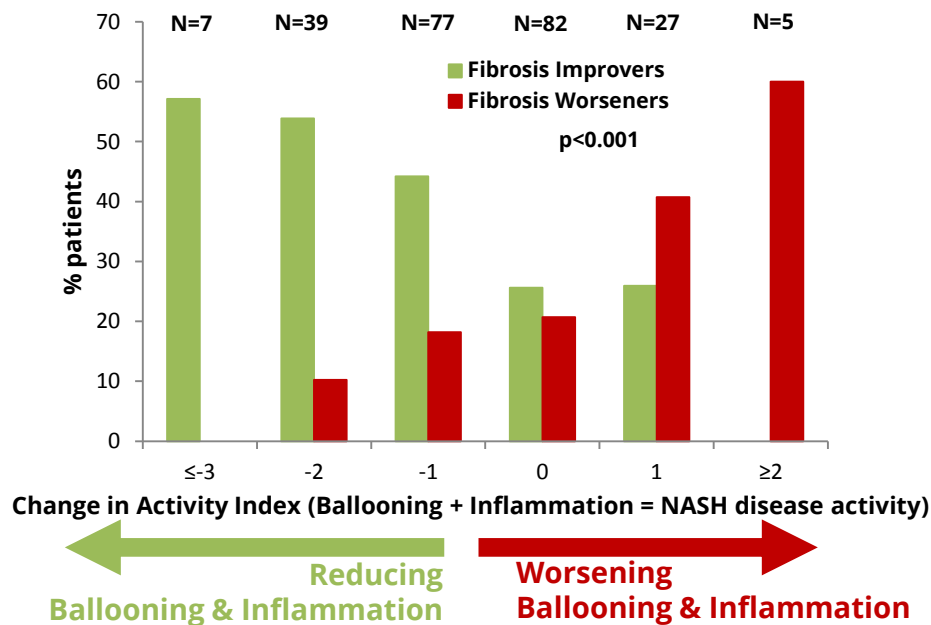
Ratziu et al. gastroenterology 2016

[https://www.gastrojournal.org/article/S0016-5085\(16\)00140-2/abstract](https://www.gastrojournal.org/article/S0016-5085(16)00140-2/abstract)



# Elafibranor Phase 2b Results (2/3): Change in Ballooning and Inflammation Correlates with Change in Fibrosis

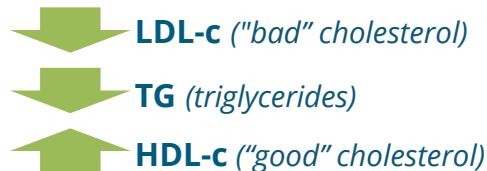
**Reducing Ballooning & Inflammation** correlates with **Fibrosis improvement**  
**Worsening Ballooning & Inflammation** correlates with **Fibrosis worsening**



# Elafibranor Phase 2b Results (3/3): Additional Key Benefits for NASH Patients

Beneficial effect on  
**Lipid Markers**  
in NASH patients

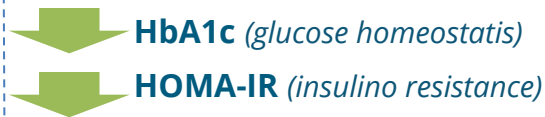
ON TOP OF STANDARD of CARE



"It is imperative that any drug developed for NASH be at least neutral from a cardiovascular risk perspective and ideally also reduce cardiovascular risks" (Hepatology 2015)

Beneficial effect on  
**- Glucose Homeostasis**  
**- Insulin Sensitivity**  
in T2D NASH Patients

ON TOP OF STANDARD of CARE



**Diabetes Care**

"Even using a low assumption for NAFLD prevalence in T2D patients, it is estimated that 84MM people in the U.S. live with prediabetes or T2D and NAFLD. Moreover, the coexistence of NAFLD and T2DM results in a worse metabolic profile and a higher cardiovascular risk." (Bril, Cusi, Diabetes Care 2017)

Favorable  
**- Safety profile**  
**- Tolerability profile**

Both crucial for a **chronic** and **silent** condition like NASH because safety can potentially be related to **clinical outcomes** and tolerability to **compliance** and therefore real world **efficacy**

# Clinical Requirements for Future Combinations: Elafibranor's Potential as Backbone Therapy

1

Addressing **NASH**  
(the underlying cause)

**ANTI-NASH**  
drug candidates



**PURE ANTI-FIBROTIC**  
drug candidates



2

Addressing **FIBROSIS**  
(the consequence)



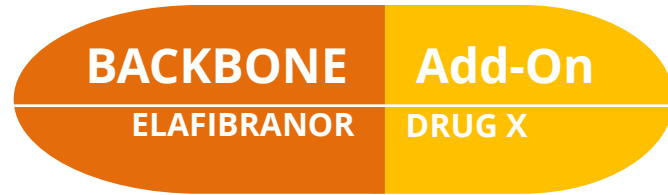
Among late-stage Phase 3 candidates, only **ELAFIBRANOR** has the potential to address both NASH resolution and fibrosis improvement






3

Ensuring a clean  
**SAFETY/TOLERABILITY**

**ELAFIBRANOR** has demonstrated a favorable safety and tolerability profile in Phase 1 and Phase 2 clinical trials

# Proactive Evaluation of Potential "Add-on" Drug Candidates for Elafibranor in NASH



		PRE-CLINICAL	CLINICAL
ELAFIBRANOR	+	NTZ	
ELAFIBRANOR	+	FXR	
ELAFIBRANOR	+	ACC	
ELAFIBRANOR	+	GLP-1/SGLT2	
			 Ph2 POC initiation 1Q20

# The Potential to Become a Leader in PBC & NASH

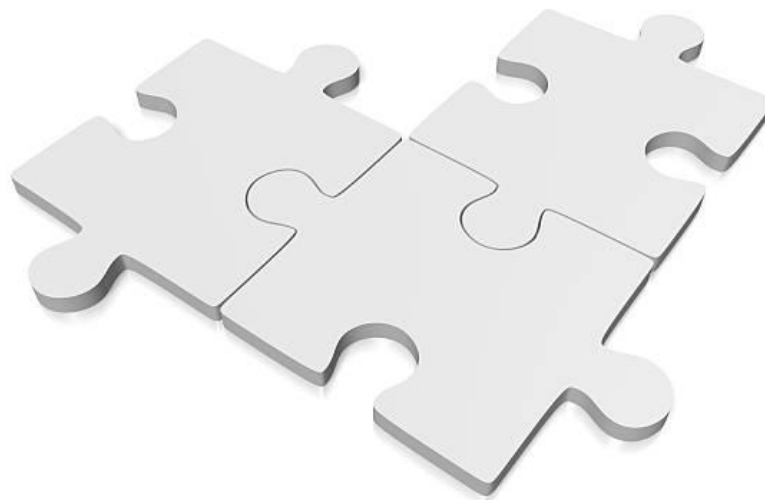
## 1. TREATMENT

### NASH & FIBROSIS

- ▶ *Elafibranor*
- ▶ *Combinations*
- ▶ *Nitazoxanide*

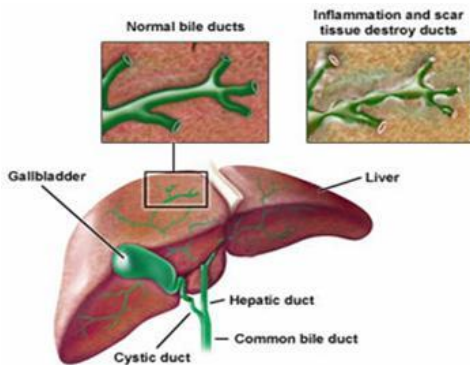
### PBC

- ▶ *Elafibranor*



# PBC (Primary Biliary Cholangitis): Elafibranor Well Positioned to Address Unmet Needs in this Severe Chronic Liver Condition

## High unmet needs



A cholestatic, chronic, autoimmune disease affecting intrahepatic bile ducts (prevalence general population: 0.05%; patient profile: women 40-60 years old)

- ▶ Significant proportion of non/partial responders with current treatments in PBC patient population
- ▶ Major symptom in PBC is pruritus and is not addressed by current PBC therapies

## Phase 2a study with elafibranor

**Treatment period 12 weeks, n=45**

UDCA + Placebo

UDCA + Elafibranor 80mg

UDCA + Elafibranor 120mg

### Primary endpoint

Effect of daily oral administration of elafibranor on serum alkaline phosphatase (ALP) from baseline

**Achieved – December 2018**



### Composite endpoint

% responders

ALP < 1.67ULN; Bili < ULN and Delta ALP < -15%

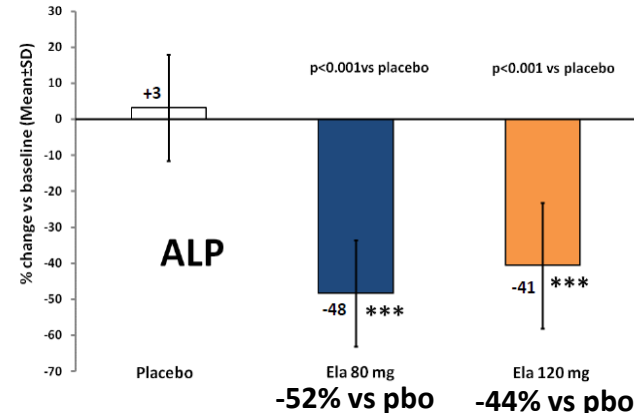
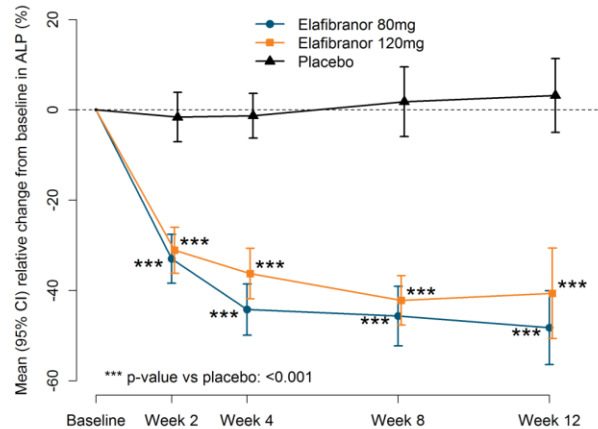
**Achieved – December 2018**





# Elafibranor Phase 2 Results (1/3): Elafibranor Successfully Meets Primary Endpoint

**Primary endpoint** “Change at week 12 in serum alkaline phosphatase (ALP) from baseline”  
achieved with high statistical significance ( $p < 0.001$ )



\*Non-parametric randomization ANCOVA with baseline as covariate

# Elafibranor Phase 2 Results (2/3): Strong Competitive Profile on Composite Endpoint Used for Registration

**Composite endpoint** previously used for **regulatory approval** of existing PBC therapies achieved with high statistical significance ( $p<0.001$ )

TOP LINE COMPARISON EFFICACY in PHASE 2 (12-week data)								
	Elafibranor <sup>1</sup> (GENFIT)			Ocaliva <sup>2</sup> (INTERCEPT)		Seladelpar <sup>3</sup> (CYMABAY)		
	80mg	120mg	pbo	10mg	pbo	5mg	10mg	pbo
<b>PRIMARY ENDPOINT</b> <i>ALP (% change vs baseline)</i>	<b>-48%</b>	<b>-41%</b>	<b>+3%</b>	<b>-24%</b>	<b>+3%</b>	<b>-33%</b>	<b>-45%</b>	<b>N/A</b>
<b>COMPOSITE ENDPOINT</b> <i>% responders ALP&lt;1.67ULN; Bili&lt;ULN and Delta ALP&lt;-15%</i>	<b>67%</b>	<b>79%</b>	<b>+6.7%</b>	<b>23%</b>	<b>+10%</b>	<b>N/A</b>		

Data taken from different clinical trials (no head-to-head comparative data available)

# Elafibranor Phase 2 Results (3/3): Elafibranor Provides Other Benefits to PBC Patients

## PBC MARKERS

- › **GGT**
  - 39% (ela 80mg)
  - 40% (ela 120mg)
  - (p=0.001, p=0.002)
- › **5'-nucleotidase**

## METABOLIC MARKERS

- › **Total cholesterol**
- › **Low-density lipoprotein-C**
- › **Triglycerides**

## BILE ACID PRECURSORS

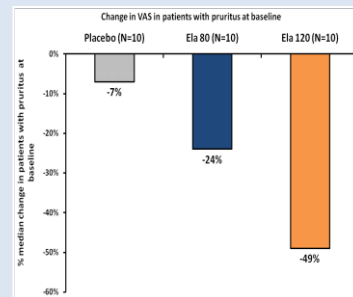
- › **C4**

## SAFETY & TOLERABILITY

- › **Clean profile**

## PRURITUS TREND

- › **VAS % change from baseline to W12**
  - 24% (80mg),
  - 49% (120mg),
  - 7% (PBO)

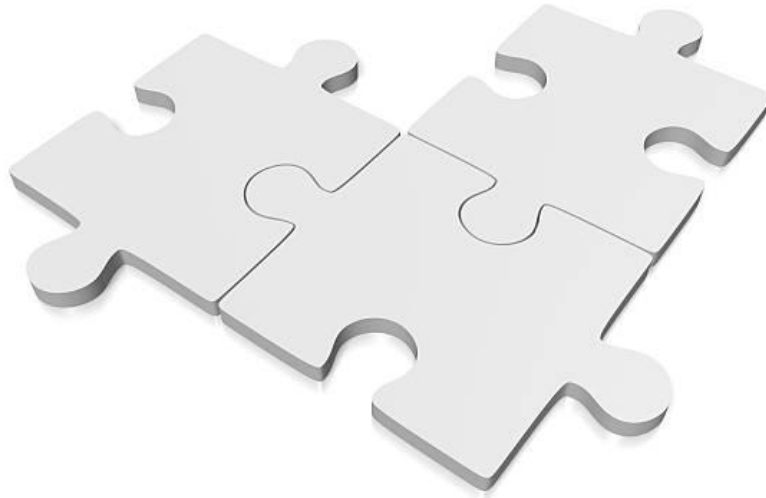


ELAFIBRANOR READY FOR **PHASE 3**, BASED ON CLEAR CLINICAL EVIDENCE

# A Pioneering & Proactive Approach to Unlock the NASH Market

## 2. DIAGNOSTIC TEST

► *Towards a large scale industrial solution*



# NASH Diagnosis: A Need for Simple Blood Test

Current bottleneck	
BIOPSY	Imperfect "Gold Standard"
IMAGING TECHNIQUES	Non-invasive, but limited

Ideal situation	
BLOOD TEST	Potential for large scale adoption in the clinic
<p>Challenges and Opportunities in Drug and Biomarker Development for Nonalcoholic Steatohepatitis: Findings and Recommendations From an American Association for the Study of Liver Diseases–U.S. Food and Drug Administration Joint Workshop</p> <p><small>Arun J. Sanyal,<sup>1</sup> Scott L. Friedman,<sup>2</sup> Arthur J. McCallough,<sup>3</sup> and Lara Dimick-Santos<sup>4</sup></small></p> <p>(HEPATOLOGY 2015;61:1392-1405)</p> <p><i>"...there is an urgent unmet need to develop <b>biomarkers</b> that facilitate the diagnosis, identification of populations at risk, assessment of disease progression or regression, and/or response to treatment."</i></p> <p><i>Page 1401</i></p>	



# GENFIT's Approach Designed to Ensure the NASH Market Can Reach its Full Potential

Focus on a specific and relevant clinical question:



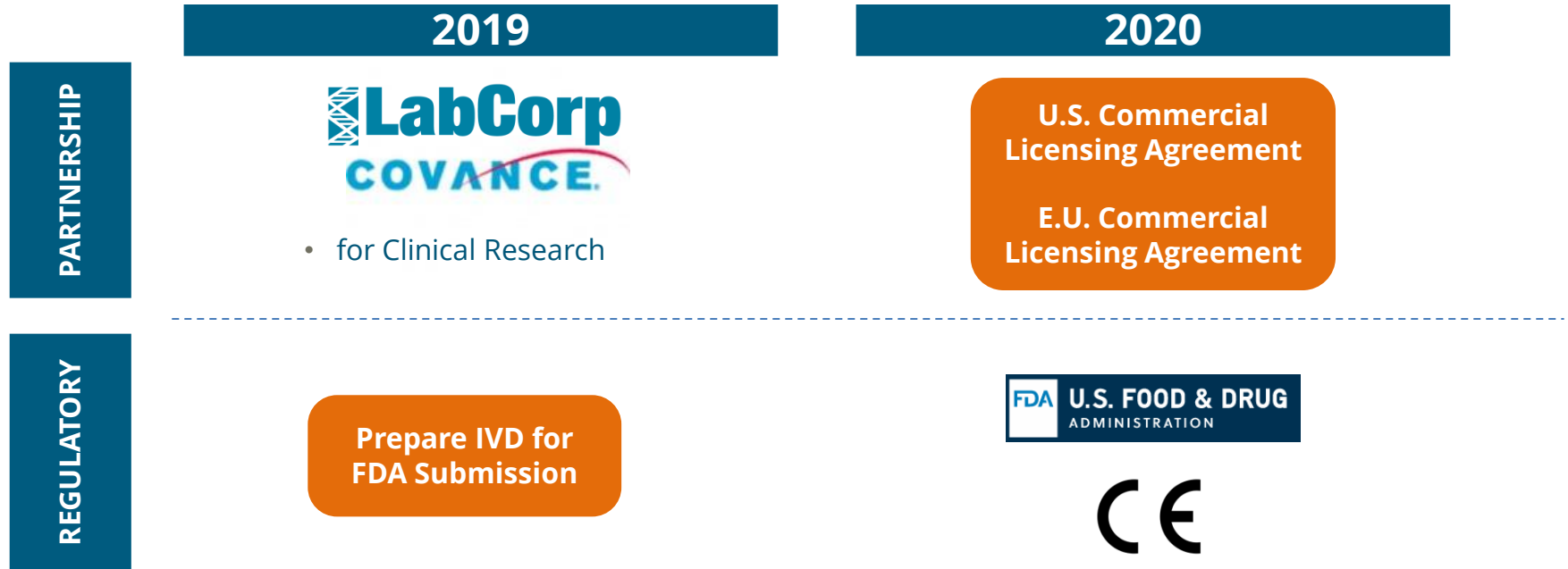
## NIS4 – an algorithm to identify patients with “at-risk NASH”

- **4 biomarker panel:** Mir-34a, Alpha2-macroglobulin, YKL-40, Hemoglobin A1c, risk probability (0.00 to 1.00)
- NIS4 panel and algorithm discovered through GOLDEN p2b trial cohort, **validated** in first 467 patients screened for inclusion in RESOLVE-IT
- High specificity of rule-in configuration: corresponds to **low false positive rate** and **high physician confidence** to either initiate treatment or refer to specialist

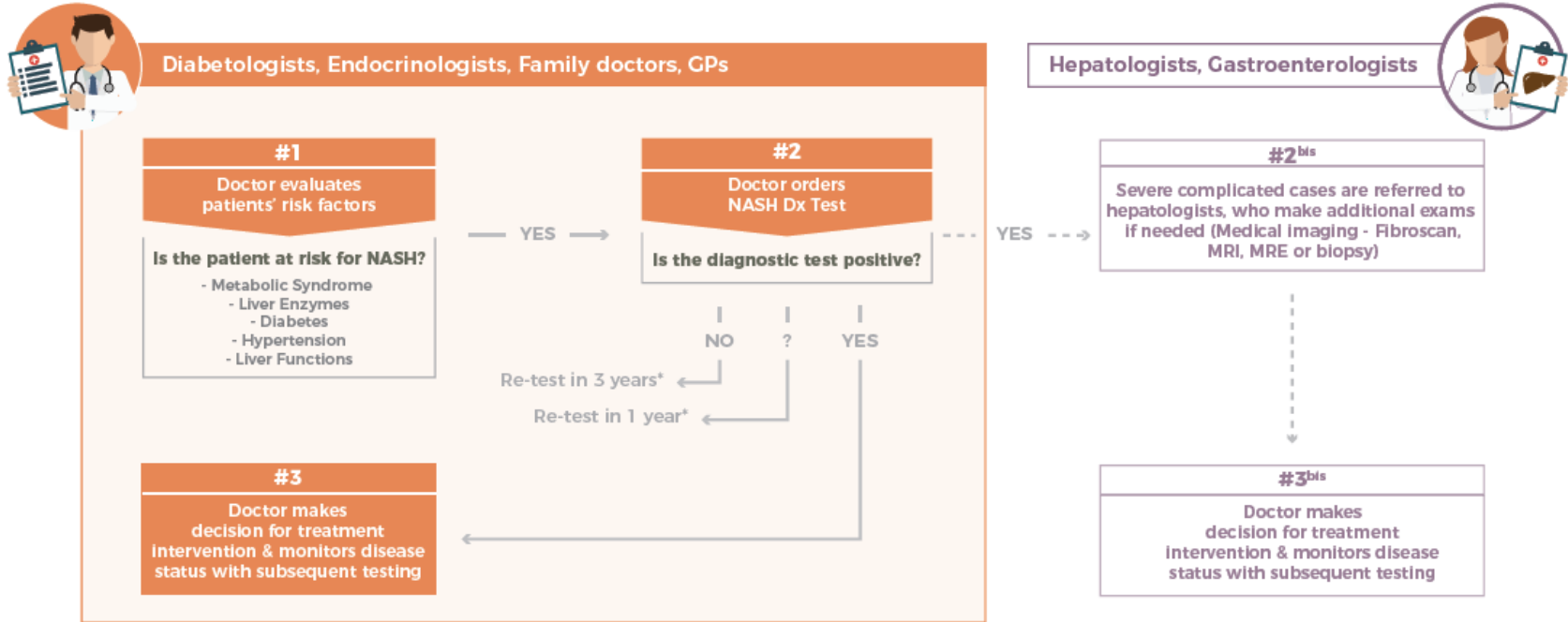


# NIS4 Commercialization

Regulatory submission for approval anticipated in **2020** (US, EU)

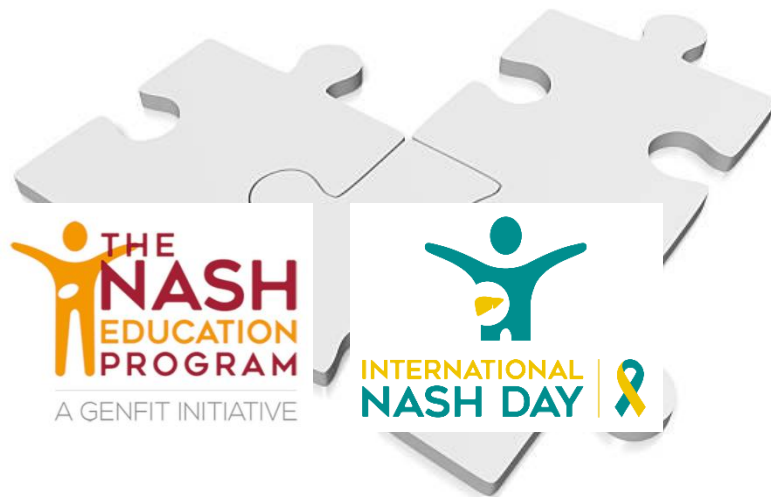


# A Vision of the Future Patient Journey and Optimized Clinical Management



*\*Interval time to be defined*

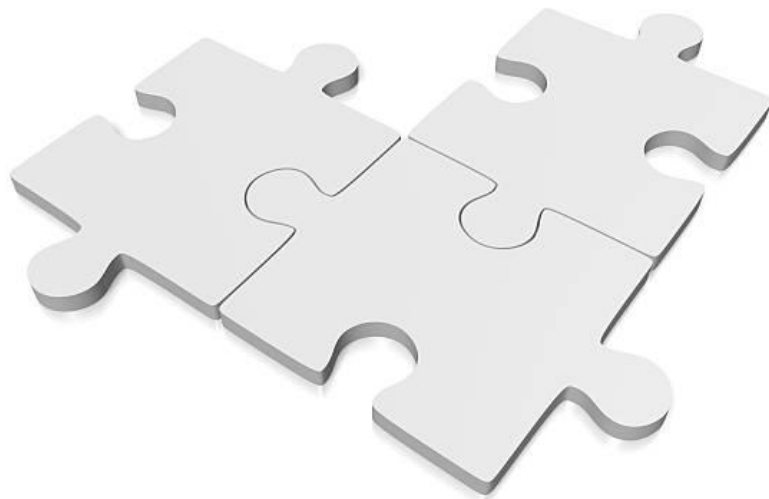
# GENFIT Committed to Improving Awareness, for Better Patient Outcomes



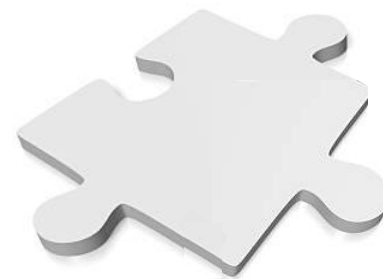
## 3. EDUCATION

► *Improving AWARENESS & KNOWLEDGE*

# Towards Commercialization



## 4. LAUNCH EXCELLENCE



# Gearing-Up for Commercialization

- ▶ **Building within – creating a team with significant commercial expertise**
  - Recruiting a team of experienced pharma leaders in the fields of Clinical development, marketing and market access, commercialization, diagnostics, external affairs and MSLS
  - New GENFIT executives have worked on multiple global launches and have years of combined experience in big pharma in Europe and the U.S.
- ▶ **Establishing key external partnerships**
  - Selected and initiated work with ad agencies, market research, and strategic consultancy
  - Discussions to develop services beyond the pill
- ▶ **Open to exploring potential alliances with large pharma**
  - Current market access work surely places GENFIT in a competitive position allowing for informed discussions based on a deep understanding of the market
  - All options possible: global or regional, licensing or M&A

# Stand Alone Licensing Agreement in Greater China: a Clear Vote of Confidence



## ► A positive signal from NASH experts

- \$35MM upfront and \$228MM total value to develop, register and market elafibranor in NASH & PBC
- One of the largest deal ever signed in Greater China for one single product

## ► An ideal partner for commercialization and R&D

- Terns backed by Eli Lilly Ventures, Orbimed, Vivo – healthcare and metabolic disease experts
- Seasoned management team with track-record at big pharmas such as Gilead, Novartis
- Dual footprint in the U.S. and Shanghai
- Additional R&D collaboration agreement to leverage a larger NASH portfolio

## ► The right timing

- To capitalize on new CFDA regulations and take a leadership in NASH in Greater China



# Key Takeaways



- ▶ **Data milestone 1Q20**
- ▶ **Highly experienced and successful team**
  - ▶ **Preparing for commercial launch success of elafibranor and NIS4 to address a large unmet medical need**
- ▶ **Driving identification, diagnosis and treatment of liver disorders**

OCTOBER 2019



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# THANK YOU

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