



CORPORATE PRESENTATION

2020

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GENFIT: Pioneering Diagnostic and Therapeutic Solutions



A Glimpse of GENFIT

Developing innovative therapeutic and diagnostic solutions for metabolic and liver-related diseases

Key upcoming milestones

Phase 3 in NASH

- Biopsy re-read and in depth analyses of the interim dataset – 2H20

Phase 3 in PBC

- Trial initiation – 2H20*

NIS4™ commercialization

- Clinical diagnostics - 2H20

Corporate update

- Fall 2020

Multiple candidates and target indications

Elafibranor

- **NASH** liver manifestation of metabolic syndrome
- **PBC** severe cholestatic, chronic, autoimmune liver disease

NIS4™ NASH & Fibrosis Diagnostic

NTZ** in Fibrosis

A pipeline in development

Partnership with Terns for R&D and commercialization of elafibranor in Greater China

Licensing agreement with LabCorp-Covance for NIS4™

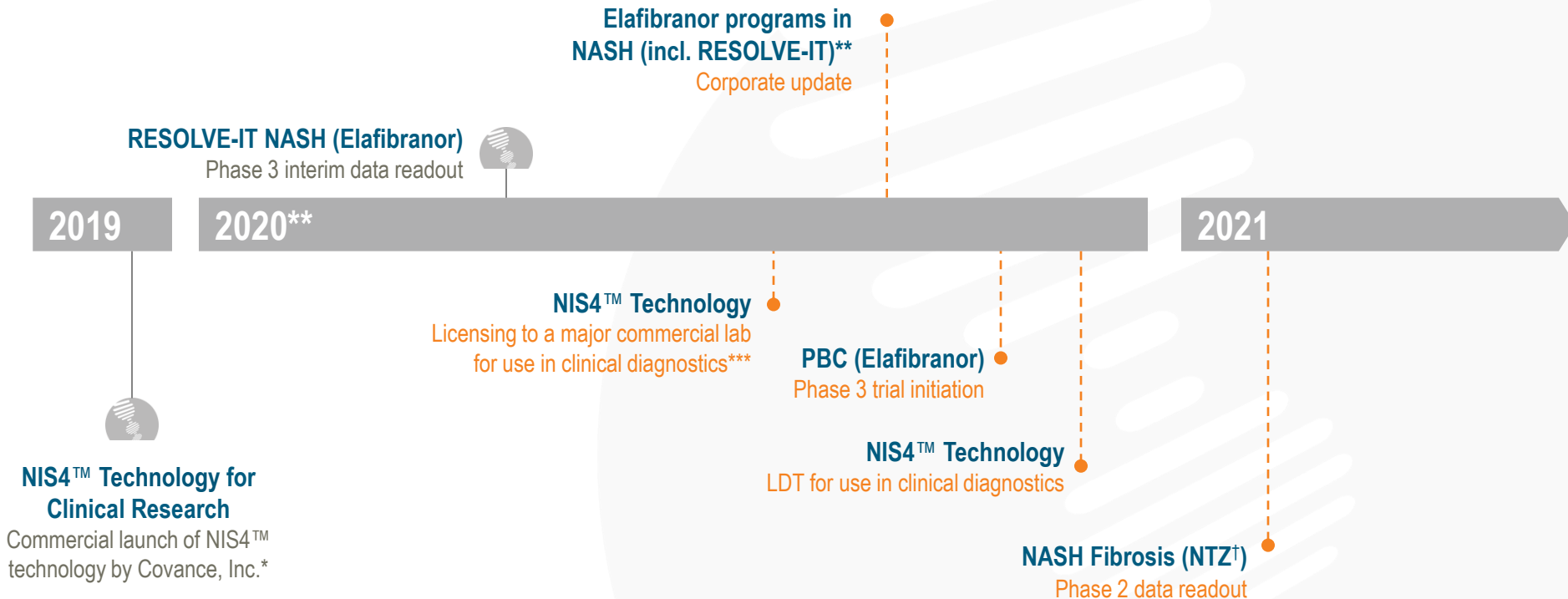
Solid financial position

- 1Q20 cash & equivalents of €252M
- Nasdaq and Euronext Paris (GNFT)

Development Pipeline

Program and indication	Target	Development stage*
Elafibranor programs in NASH (incl. RESOLVE-IT)**	PPAR α/δ	Phase 3 – Decision on continuation for clinical outcomes to be made in the Fall 2020
Elafibranor in PBC	PPAR α/δ	Phase 3
NIS4™ Diagnostic in NASH with fibrosis	NAS $\geq$ 4, F2+	Clinical research
Nitazoxanide (NTZ) in fibrosis***	Undisclosed	Phase 2
TGFTX1 in auto-immune diseases	ROR γ t	Preclinical

Corporate Timeline



Elafibranor in Clinical Development for Primary Biliary Cholangitis (PBC)

Cholestatic, autoimmune disease affecting intrahepatic bile ducts^{3,4}

Prevalence in general population: **0.04% (~40/100k)**³

Typically affects women **30-65** years old⁴

Successful Phase 2a trial in PBC⁶

PBC: A Severe, chronic liver condition

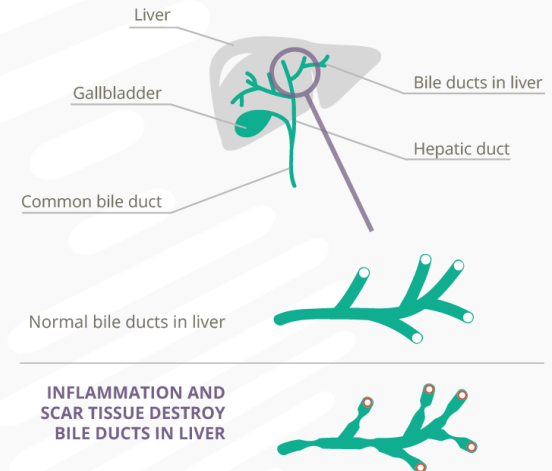
High unmet medical need

- High proportion of non/partial responders with current treatments
- Pruritus and fatigue, the most significant disease symptoms, are NOT addressed by current PBC therapies⁵

Elafibranor achieves positive efficacy and safety in a Phase 2a trial, justifying Phase 3 development⁶

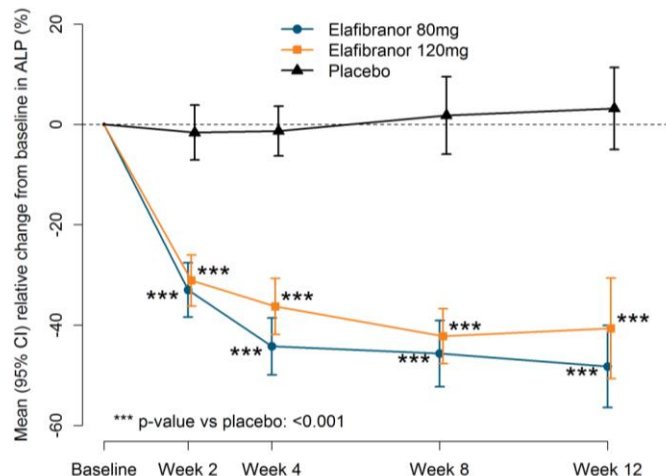
- Successful Elafibranor Phase 2a study results in adult patients with PBC with inadequate response to UDCA⁶

Breakthrough Therapy designation granted by FDA¹ and Orphan Drug designation granted by FDA & EMA¹

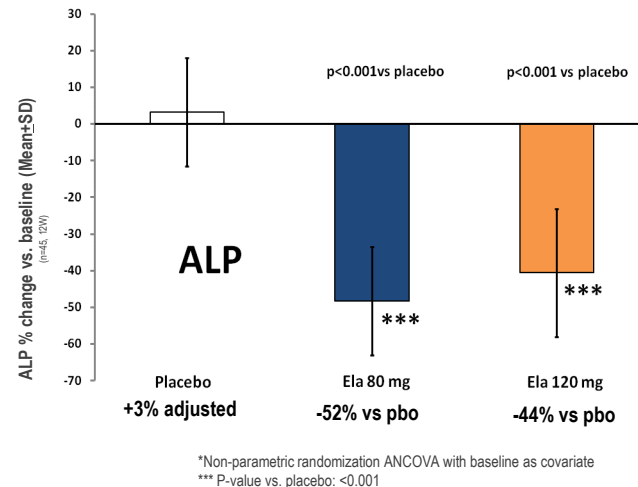


Elafibranor Achieved Primary Endpoint in Phase 2a PBC Study

Change at week 12 in serum alkaline phosphatase (ALP) from baseline¹



ALP % Change vs. baseline¹



Statistically significant ($p<0.001$) treatment effects in both 80mg and 120mg doses on the primary end-point (confirmed in mITT* set) of serum alkaline phosphatase (ALP) change from baseline

Elafibranor Shows Strong Competitive Profile on Composite Endpoint in Phase 2a PBC Study

Top-line comparison efficacy in Phase 2 (12-week data)					
Elafibranor ^{1,*} (GENFIT)			Ocaliva ^{2,**} (INTERCEPT)		
80mg	120mg	pbo	10mg	pbo	
Primary endpoint <i>ALP (% change vs baseline)</i>			-48%	-41%	3%
Composite endpoint <i>% responders</i> <i>ALP<1.67ULN; Bili<ULN and ALP reduction >15%</i>			-24%	-3%	
			67%	79%	6.7%
			23%	10%	

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

Achieved the composite endpoint previously used for regulatory approval^{3,4} of existing PBC therapies

Efficacy and Safety Data Support Progression of Elafibranor into a Phase 3 Trial in PBC

Beneficial effect on¹...

PBC markers

GGT

- - 39% (elafibranor 80mg)
- - 40% (elafibranor 120mg)
- (p=0.001, p=0.002)

5'-nucleotidase

Metabolic markers

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

Bile Acid Precursors

- C4

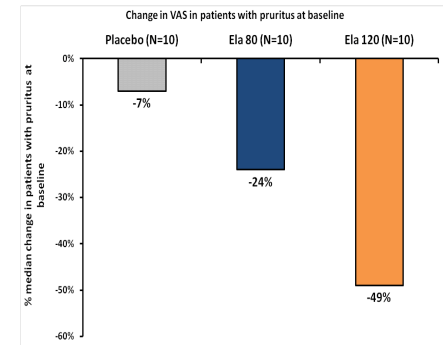
Safety & tolerability profile

Generally safe and well tolerated

Pruritus trend¹

VAS* % change from baseline to W12

- - 24% (elafibranor 80mg)
- - 49% (elafibranor 120mg)
- - 7% (PBO)



Phase 3 program underway and clinical study of elafibranor in patients with PBC to initiate 2H20**

Addressing Current NASH Identification Limitations to Improve NASH Diagnosis

Biopsy: the imperfect reference standard¹⁻⁹

- Significantly invasive and patient reluctance
- Potential complications
- Costly procedure
- Sampling errors
- Limited number of hepatologists and pathologists to interpret results

Liver biopsy: INVASIVE



Non-invasive blood tests (NITs) are supported and encouraged by the regulatory authorities¹⁰

Market need for a simple blood test¹⁰

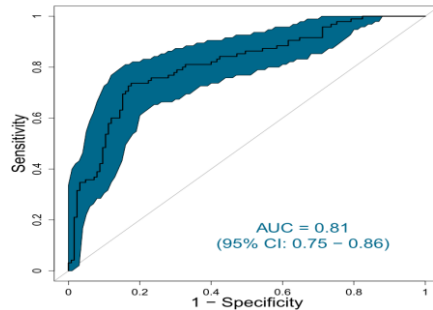
- A specific diagnosis of NASH activity and fibrosis stage
- Non-invasive, lower risk approach
- Easy-to-access, cost effective, with potential for large scale adoption
- Capacity for diagnosing and potentially monitoring disease progression

NIS4™ : A Clinically Validated* Diagnostic Blood Testing Technology to Identify Both NASH and Fibrosis²

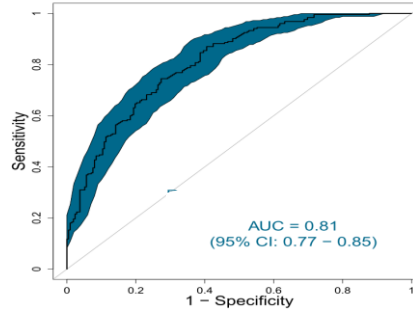
NIS4™ – an algorithm developed to identify patients with “at-risk NASH” (NAS≥4; F≥2)

- 4 biomarker panel: miR-34a, Alpha2-macroglobulin (A2M), YKL-40, Hemoglobin A1c (HbA1c), output score ranging from 0.00 to 1.00²
- Developed within the DISCOVERY cohort (N=239) and independently validated* in RESOLVE-IT-DIAG (N=475) and ANGERS cohorts (N=227)
- NIS4™-based test significantly outperformed other NITs for the detection of at-risk NASH³
- High specificity of rule-in configuration: corresponds to low false positive rate and high HCP confidence to identify those most in need of future therapeutic interventions

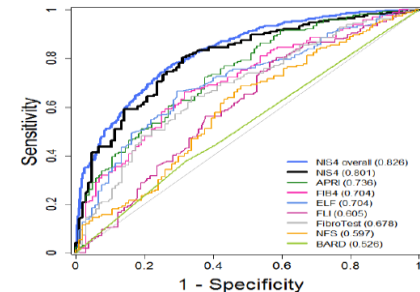
**Development:
DISCOVERY (N=239)²**



**Validation:
RESOLVE-IT-DIAG (N=475)² /
ANGERS (N=227)**

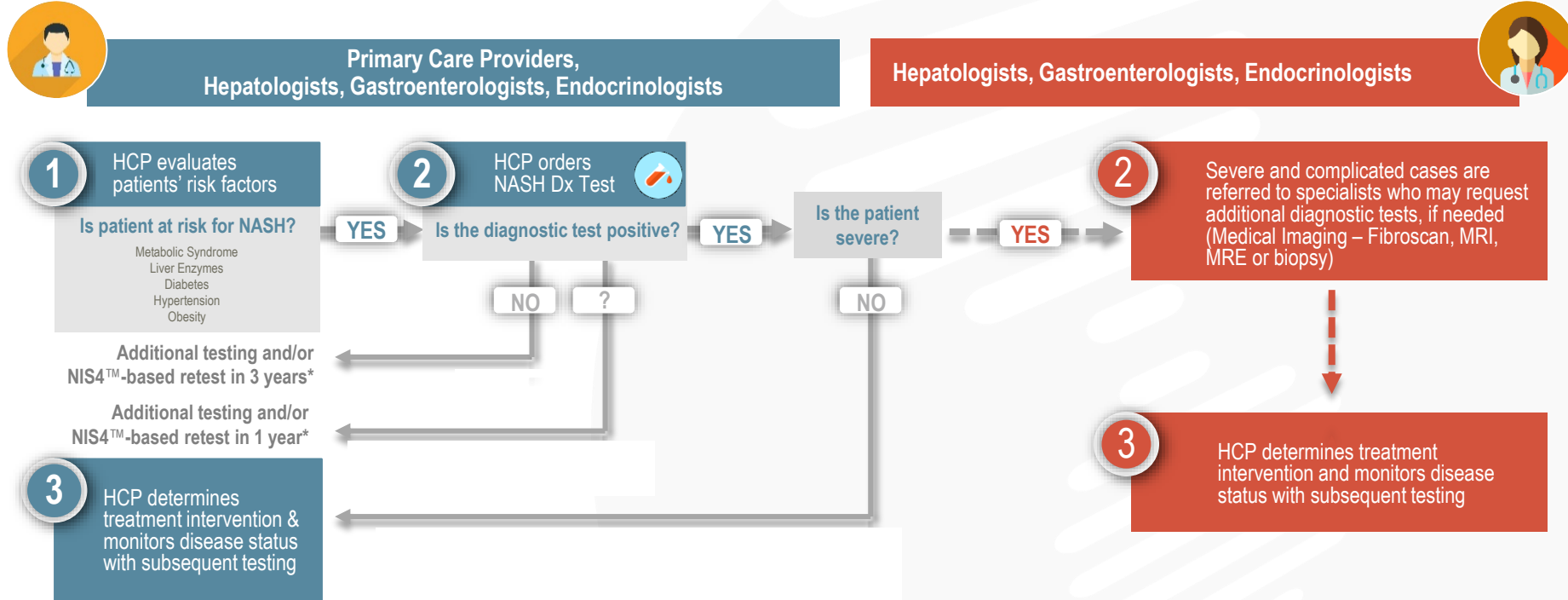


**Head-to-head AUROCs comparison:
NIS4™ vs. other NITs¹ (T2D N=275)³**



Patients with NASH (NAS≥4, with at least 1 point in sub-category: steatosis, ballooning, and inflammation) and fibrosis (F≥2). GENFIT internal data.

NIS4™ : A Diagnostic Technology to Aid in the Future Diagnosis and Treatment of NASH



Future Development and Commercialization of NIS4™ Technology

Achieved milestones and a clear plan

Accomplishments



- Licensing of NIS4™ technology to LabCorp-Covance for use by pharmaceutical companies in clinical research / clinical trials – 1Q19
- Development and commercialization of a NIS4™ – based blood test by Covance, a subsidiary of LabCorp, for use in clinical research – 4Q19

Market testing opportunity of target populations

- Diabetes patients in U.S.: 34M¹
- Obese (BMI>30) patients in U.S.: 94M²

Dual-track for regulatory development and commercialization

Potential to be the only clinically validated NIT for diagnosis of NASH activity and fibrosis stage

Upcoming projected development milestones

- Licensing of NIS4™ technology to a major commercial lab for use in clinical diagnostics*– 2H20
- LDT for use in clinical diagnostics – 2H20
- Submission to FDA for IVD approval
- Submission to EU Notified Body for CE mark

RESOLVE-IT: Phase 3 Clinical Trial Design for Elafibranor in Adults with NASH and Fibrosis



INTERIM ANALYSIS 2Q 2020

~1000+ Patients

For Accelerated Market Authorization
Subpart H (FDA) / Conditional approval (EMA)

Initiation
Q1 2016

Phase 3 Trial: 72w

Phase 3 Extension Phase: Event Driven

End of
Study



Endpoint Histology at 72w (18mo)

- Primary: NASH resolution without worsening of fibrosis
- Key Secondary:
 - Improvement of histological fibrosis
 - Composite of metabolic parameters

Design 1,000 biopsy defined NASH patients at risk of progression to clinical events

- NASH with a NAS ≥ 4 , Fibrosis stage F2/F3
- (F1 + metabolic risk)

DSMB 18/24/30/36/42-month ✓

Reduction in NASH associated clinical events, including cirrhosis and all cause mortality based on a pre-defined number of events, vs. placebo

~2,000 biopsy defined NASH patients at risk of progression to clinical events

Decision on continuation of RESOLVE-IT for clinical outcomes
to be made in the Fall 2020

RESOLVE-IT: Baseline Characteristics

Interim efficacy results at 72 weeks¹

Characteristics	Statistics	Elafibranor	Placebo	Overall
ITT* Set (F2/F3)	N	717	353	1070
Age (Years)	Mean (SD)	54.35 (12.06)	55.04 (11.10)	54.58 (11.75)
Sex				
- Female	N (%)	283 (39.5)	137 (38.8)	420 (39.3)
- Male	N (%)	434 (60.5)	216 (61.2)	650 (60.7)
Fibrosis Stage				
- Stage 2	N (%)	338 (47.1)	167 (47.3)	505 (47.2)
- Stage 3	N (%)	379 (52.9)	186 (52.7)	565 (52.8)
Type 2 Diabetes				
- No	N (%)	361 (50.3)	178 (50.4)	539 (50.4)
- Yes	N (%)	356 (49.7)	175 (49.6)	531 (49.6)
NAFLD Activity Score (NAS)				
- 4	N (%)	104 (14.5)	45 (12.7)	149 (13.9)
- 5	N (%)	209 (29.1)	90 (25.5)	299 (27.9)
- 6	N (%)	239 (33.3)	120 (34.0)	359 (33.6)
- 7	N (%)	146 (20.4)	92 (26.1)	238 (22.2)
- 8	N (%)	19 (2.6)	6 (1.7)	25 (2.3)

RESOLVE-IT: Surrogate Efficacy Analysis

Phase 3 Data Results¹

- Evaluation of the effect of elafibranor 120mg compared to placebo in 1,070 patients (ITT population) at 72 weeks, randomized 2:1
- Biopsy was collected for inclusion into the trial and a follow-up liver biopsy was collected at week 72 to evaluate histologic endpoints. Patients without a repeat biopsy were evaluated as non-responders in the complete efficacy analysis.
- The trial did not achieve statistical significance on the primary or secondary endpoints, including the composite metabolic endpoint.

Intent to Treat Population (ITT)		Elafibranor 120mg		Placebo		p-value
		N	%	N	%	
Primary Endpoint	Resolution of NASH without worsening of fibrosis	138 / 717	19.2	52 / 353	14.7	0.0659
Key Secondary Endpoint	Fibrosis improvement of at least one stage	176 / 717	24.5	79 / 353	22.4	0.4457

RESOLVE-IT: Surrogate Efficacy Analysis Continued and Next Steps

Results

Key Findings

- Top-line results do not support an application for accelerated approval by the FDA under Subpart H or conditional approval by the EMA
- A detailed review is underway to gain further clarity on high placebo response and performance in subpopulations
- GENFIT will engage with the regulatory agencies, and determine to discontinue, amend or continue of the RESOLVE-IT

Full RESOLVE-IT data will be available at an upcoming scientific congress in 2H20.

Favorable Safety and Tolerability Profile

Elafibranor was generally well tolerated over 72 weeks

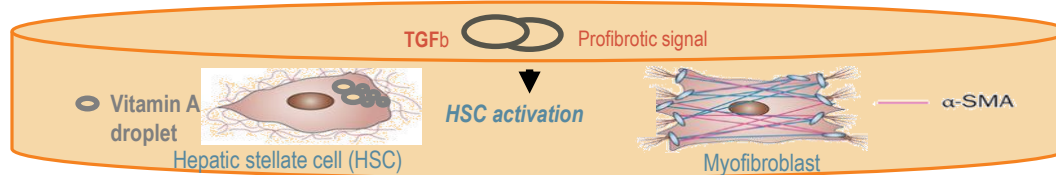
- Performance was in-line with previous studies
- DSMB recommended continuation of the trial without modification based upon available data at the time of surrogate efficacy analysis
- Elafibranor's safety and tolerability profile could support additional trial exploration and use in other liver diseases, such as PBC

Elafibranor's development programs in pediatric NASH and in NASH combination studies with SGLT2/GLP-1 are under review. A comprehensive corporate update will be provided in the Fall 2020.

NTZ Advancing in a Phase 2a Investigator-led Study for NASH Induced Fibrosis

Identified by a phenotypic screen

Using primary human stellate cells



Established safety

as approved antiparasitic

Potential for accelerated time-to-market

for fibrosis

Phase 2a Study in NASH induced fibrosis

Stage 2/3 fibrosis patients

Potential use in other fibrotic diseases

GENFIT: Driving Identification, Diagnosis and Treatment of Liver Disorders

Pipeline

Elafibranor in NASH
Elafibranor in PBC
NIS4™ for NASH identification
NTZ for NASH Fibrosis

Target Indications

NASH, PBC, and fibrosis
Diagnosis of NASH with fibrosis

Milestones

Partnership with Terns:
- R&D collaboration
- Elafibranor's rights in Greater China (NASH/PBC)

Licensing agreement with LabCorp-Covance for NIS4™

Next Steps

Exploring business development opportunities and capitalizing on in-house assets

Engagement with agencies on future of elafibranor in NASH

Corporate update in Fall 2020

Pioneer

Leader in PPAR research

Proven team with global, NASH expertise: scientific, regulatory, commercialization

