GENFIT
TOWARDS BETTER MEDICINE

# Corporate Presentation

**December 2020**

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# GENFIT: Developing Innovative Therapeutic and Diagnostic Solutions

## PBC Therapeutics

**Elafibranor, a differentiated profile**

- ELATIVE™ Pivotal Phase 3 trial in PBC currently enrolling
- Breakthrough Therapy (FDA) and Orphan Drug Designation (FDA & EMA)[1]
- Activity on cholestatic, inflammatory, and pruritic effects[2]
- Safety and efficacy demonstrated in previous trials (P2 in PBC)[2]

**A growing PBC market estimated to be $1B in 2025**

- ~$315MM market in 2020, with double digit growth anticipated[3,4]

## NASH Diagnostics

**NIS4™ Technology for NASH Diagnosis**

- Pivotal publication of NIS4™ technology to identify patients with at-risk NASH in *The Lancet Gastroenterology & Hepatology*[5]

**NIS4™ Technology licensed to LabCorp in 3Q20**

- NIS4™ enabled test to be commercialized by LabCorp in early 2021
- NIS4™ enabled test to be publicly available for millions of patients

## Partnerships

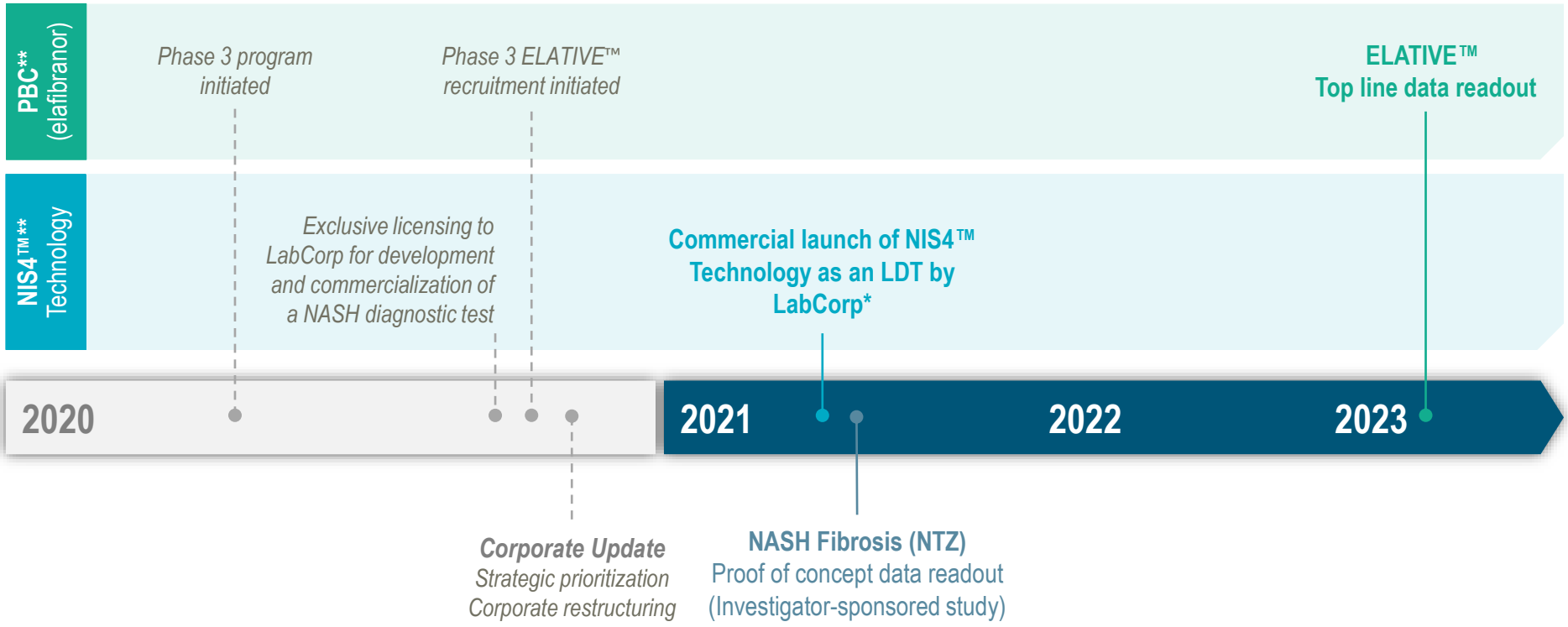
- Partnership with Terns Pharmaceuticals for commercialization of elafibranor in Greater China.
- Two Licensing agreements for NIS4™ Technology with LabCorp for commercial use in the clinical research and clinical management setting

## Financials

- OCEANEs convertible bond partial buyback in progress and final review/approval scheduled for the Extraordinary Shareholder Assembly – January 2021
- 3Q20 cash & equivalents of €199M
- Nasdaq and Euronext Paris (GNFT)

**Note:** PBC: Primary Biliary Cholangitis; NASH: Nonalcoholic Steatohepatitis. **References**: **1.** GENFIT Corporate Press Release. "GENFIT Announces FDA Grant of Breakthrough Therapy Designation to Elafibranor for the Treatment of PBC." 29 June 2019. **2.**Presented at EASL 2019; LBO-02; NCT03124108; Schattenberg et al. 2019 Journal of Hepatology, Vol. 70, Issue 1, e128. **3.** Intercept Corporate Press Release, November 9, 2020. **4.** Research on File, November 2019. **5.** Harrison SA, Ratziu V et al Nov 2020 The Lancet Gastroenterology and Hepatology, Vol 5, Issue 11, P970-985.

# Phase 3 Clinical Trial in Primary Biliary Cholangitis and Leading Non-invasive NASH Diagnostic Program




**Note:** ***LDT**= *Laboratory Develped Test.*

All PBC, NIS4™ Technology and outlicesened NIS4™ Technology to LabCorp, and NTZ upcoming milestones, data announcements and launch dates are anticipated and subject to change.

# Elafibranor in PBC

# Primary Biliary Cholangitis: A Significant Market Opportunity

## PBC: A severe, orphan, liver disease with a high unmet medical need

**Chronic, cholestatic, autoimmune** disease causing injury to the intrahepatic bile ducts[1,2]

Prevalence in general population: **0.04% (~1/2500)**[3,4]

Typically affects **Women 30-60 years old**[3]

New therapies are required to address the high **unmet medical needs in PBC**[5]

Disease symptoms - pruritus and fatigue - are **not** adequately addressed by current PBC therapies[6]

**~40% of patients** are **non/partial responders** to 1L and 2L therapies[9]

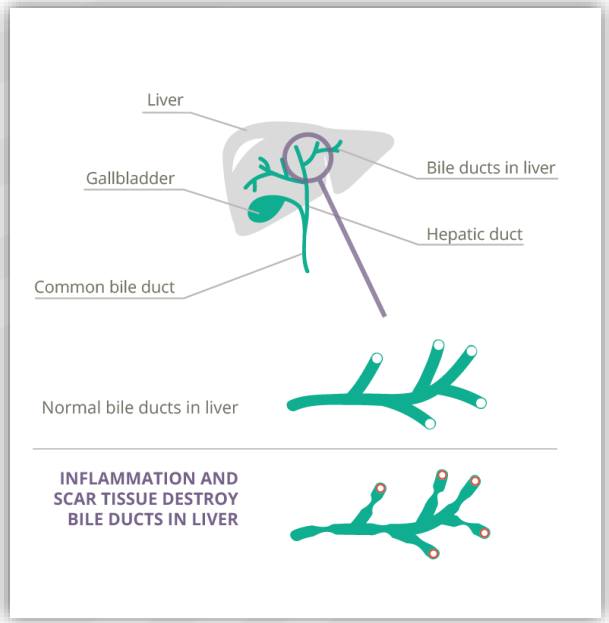
Existing **~$315MM PBC market**[7] with double-digit growth and market estimates of **$1B for 2025**[8]

**References**: **1.** Kuiper, E.M., et al., Relatively high risk for hepatocellular carcinoma in patients with primary biliary cirrhosis not responding to ursodeoxycholic acid. Eur J Gastroenterol Hepatol, 2010. 22(12): p. 1495-502.. **2.** Kumagi, T. and E.J. Heathcote, Primary biliary cirrhosis. Orphanet J Rare Dis, 2008. 3: p.1. **3.** Boonstra, K., et al., Epidemiology of primary sclerosing cholangitis and primary biliary cirrhosis: a systematic review. J Hepatol, 2012. 56(5): p. 1181-8. **4.**Kim, W.R., et al., Epidemiology and natural history of primary biliary cirrhosis in a US community. Gastroenterology, 2000. 119(6): p. 1631-6. **5.** Hirschfield, G.M.et al, The immunobiology and pathophysiology of primary biliary cirrhosis. Annu Rev Pathol, 2013. 8: p. 303-30. **6.** Lindor et al. Hepatol. 2019; 69 (1): 394-419. **7.** Intercept Corporate Press Release, November 9, 2020. **8.** Resarch on File, November 2019. **9.** Ali, A., et al., Orphan drugs in development for primary biliary cirrhosis: challenges and progress. 2015. 5: p. 83-97.

# Elafibranor in PBC: A Promising Drug Candidate for Cholestatic Disease

## Elafibranor in PBC

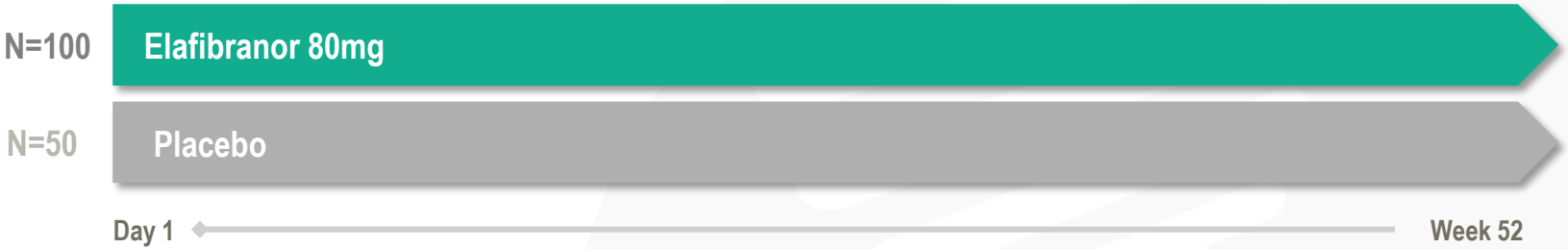
- Elafibranor is a PPAR Alpha/Delta agonist and has pluripotent effects[1]
- Elafibranor has demonstrated anti-cholestatic, anti-inflammatory, and anti-pruritic effects that may benefit the disease and symptoms of PBC[1]
- Successful Phase 2a trial in PBC demonstrating efficacy and safety of elafibranor 80mg[1,2]
- Awarded Breakthrough Therapy designation by the FDA and Orphan Drug Designation by the FDA & EMA for PBC[2]




**Note:** Elafibranor is an investigational compound and has not been approved by any regulatory authority in any indication.
Image adopted from Figure on Mayo Foundation for Medical Education and Research Website https://www.mayoclinic.org/diseases-conditions/primary-biliary-cholangitis-pbc/symptoms-causes/syc-20376874.
**References**: **1.** Schattenberg et al. 2019 Journal of Hepatology, Vol. 70, Issue 1, e128. **2.** GENFIT Corporate Press Release. "GENFIT Announces FDA Grant of Breakthrough Therapy Designation to Elafibranor for the Treatment of PBC." 29 June 2019.

# ELATIVE™ – a Pivotal Phase 3 Study in Patients with PBC

## Randomized 2:1, double blind, placebo-controlled, global study[1]




**Primary Endpoint**

*Response to treatment defined as **Alkaline phosphatase (ALP) < 1.67 x Upper Limit Normal (ULN) and Total Bilirubin (TB) ≤ ULN and ALP decrease ≥ 15 percent***

**Secondary Endpoint**

*Response to treatment based on ALP normalization (At week 52)*

*Change in pruritus from baseline (Over 52 weeks of treatment)*

- *Based on PBC Worst Itch Numeric Rating Scale (NRS) score**

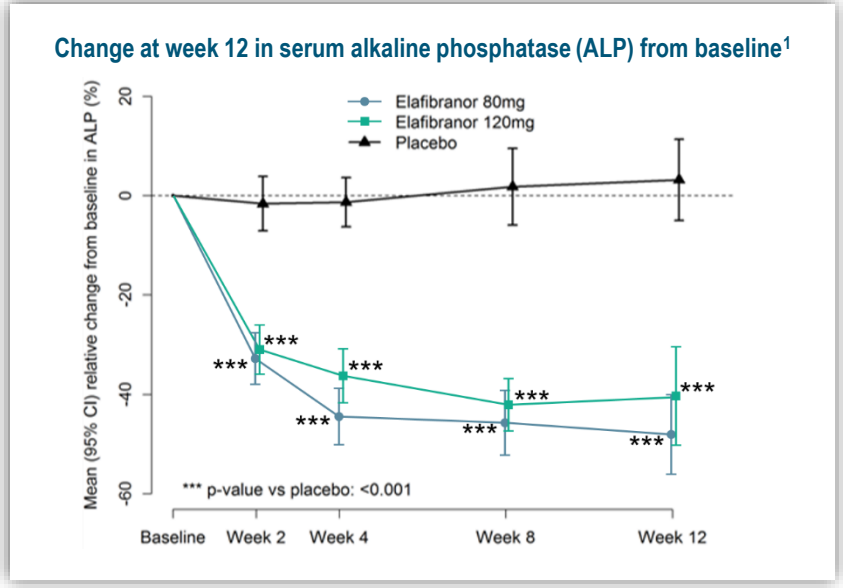
**2H 2020**
Enrollment

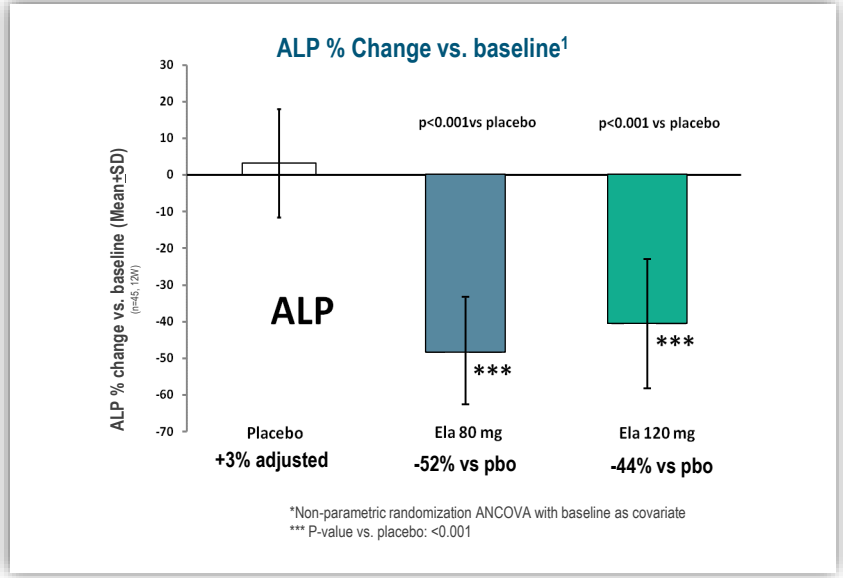
**1H 2023**
Anticipated Data readout

**Note:** *Measuring itch over the past 24 hours from 0 (no itch) to 10 (worst itch imaginable)

**References**: 1. NCT04526665

# Elafibranor Phase 2a PBC Study




**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**

**Note:*** mITT (All subjects w/ available baseline value and at least one post baseline value under treatment for ALP)=Placebo (N=15), Elafibranor 80mg (N=15), Elafibranor 120mg (N=14). Per Protocol Set = Placebo (N=14), Elafibranor 80mg (N=14), Elafibranor 120mg (N=13). ITT (intend to treat) = Placebo (N=15), Elafibranor 80mg (N=14), Elafibranor 120mg (N=15)

**References**: **1.** EASL 2019; Late Breaker Oral Session-02; NCT03124108; Elafibranor, a peroxisome proliferator-activted receptor alpha and delta agonist demonstrates favourable efficacy and safety in patients with primary biliary cholangitis and inadequate response to ursodeoxycholic acid treatment, Schattenberg et al. 2019 Journal of Hepatology, Vol. 70, Issue 1, e128.

# Phase 2a Efficacy and Safety Data Support ELATIVE™ Phase 3 PBC Trial

## Elafibranor demonstrated beneficial effects on clinically proven markers of PBC[1]…

**Cholestatic Markers** ↓
- **GGT**
  - - 39% (elafibranor 80mg, p=0.001)
- ↓ **5'-nucleotidase**

**Inflammation Markers** ↓
- **IgM**
- **hsCRP**

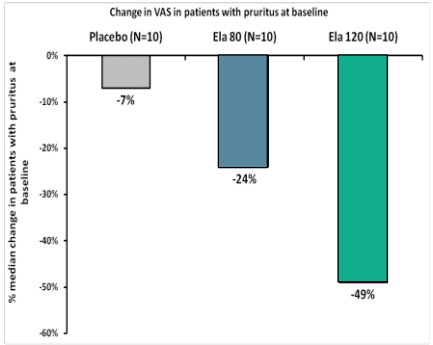
**Bile Acid Precursors** ↓
- **C4**

**Generally safe and well tolerated**

## Pruritus trend[1]

**VAS % change from baseline to W12**

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




**Note:GGT**= gamma-glutamyl transferase, **IgM**= immunoglobulin M, **hsCRP**= High sensitivity C-reactive protein, **C4**= serum 7α-hydroxy-4-cholesten-3-one, **VAS** = Visual Analog Score,
**References**: **1.** EASL 2019; Late Breaker Oral Session-02; NCT03124108; Elafibranor, a peroxisome proliferator-activted receptor alpha and delta agonist demonstrates favourable efficacy and safety in patients with primary biliary cholangitis and inadequate response to ursodeoxycholic acid treatment, Schattenberg et al. 2019 Journal of Hepatology, Vol. 70, Issue 1, e128.

# Summary of Adverse, Treatment-Emergent Adverse, and Serious Adverse Events

| | Elafibranor[1, 2] (Phase 2a – 12W study) | | |
|---|---|---|---|
| | 80mg (N=15), N (%) [#AEs] | 120mg (N=15), N (%) [#AEs] | Placebo (N=15), N (%) [#AEs] |
| Patients with at any AE | 13 (86.7) [46] | 13 (86.7) [51] | 12 (80.0) [28] |
| Patients with at any TEAE | 12 (80.0) [41] | 13 (86.7) [46] | 12 (80.0) [25] |
| Patients with any treatment-related TEAE | 2 (13.3) [6] | 5 (33.3) [5] | 1 (6.7) [1] |
| Patients with any serious TEAE | 0 [0] | 2 (13.3) [3] | 0 [0] |
| Patients with any severe TEAE | 2 (13.3) [3] | 2 (13.3) [5] | 2 (13.3) [2] |
| Patients with any serious treatment related TEAE | 0 [0] | 1 (6.7) [1] | 0 [0] |
| Patients with any TEAE leading to study drug discontinuation | 0 [0] | 1 (6.7) [2] | 0 [0] |

**References**: **1.** Presented at EASL 2019; Late Breaker Oral Session-02; NCT03124108; Elafibranor, a peroxisome proliferator-activted receptor alpha and delta agonist demonstrates favourable efficacy and safety in patients with primary biliary cholangitis and inadequate response to ursodeoxycholic acid treatment, Schattenberg et al. 2019 Journal of Hepatology, Vol. 70, Issue 1, e128. **2.** Schattenberg et al., A randomized placebo-controlled trial of elafibranor in patients with primary biliary cholangitis and incomplete response to UDCA. J Hepatol, 2020 (submitted).

# Elafibranor is a Competitive and Differentiated 2L Candidate for PBC

## Cross Study Comparison of Top-Line Efficacy at 12 Weeks

| | Elafibranor[1,*] (Phase 2a – 12W study) | | Ocaliva[2,**] (Phase 3 – Month 3 Data) | | Seladelpar[5] (Phase 3 – Month 3 Data) | | |
|---|---|---|---|---|---|---|---|
| | 80mg (N=15) | Placebo (N=14) | 10mg (N=73) | Placebo (N=72) | 5mg | 10mg | Placebo |
| **Composite endpoint** *% responders, ALP<1.67 x ULN; Bili<ULN and ALP reduction >15%* | **67%** (p=0.001) | 6.7% | ~40% (p<0.001) | ~3% | 57% (n=56, p<0.0001) | 78% (n=55, p<0.0001) | 13% (n=56) |
| **Primary endpoint** *ALP (% change vs baseline)* | **- 48%** (p<0.001) | 3% | ~ - 36% (p<0.001) | -3% | - 36% (n=54, p<0.0001) | - 44% (n=53, p<0.0001) | -3.7% (n=56) |

**Note:** *Elafibranor – mITT: All subjects w/ available baseline value and at least one post baseline value under treatment for ALP. **These are estimation based figures due to the lack of 3mo data reporting. Elafibranor is an investigational compound and has not been approved by any regulatory authority in any indication.

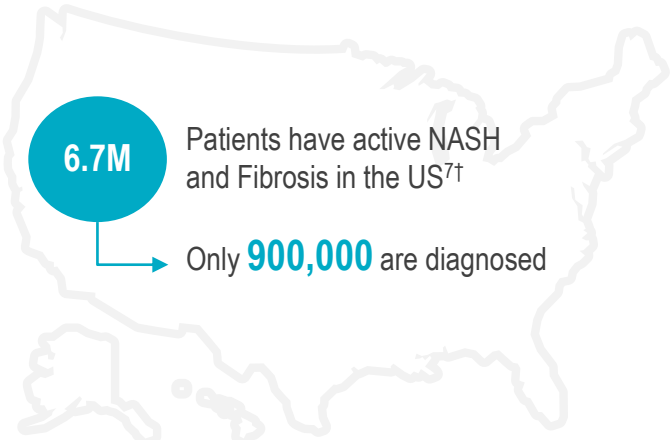
**Elafibranor met the composite endpoint previously used for regulatory approval of existing PBC therapies[3,4]**



**Note:** Elafibranor is an investigational compound and has not been approved by any regulatory authority in any indication. **References**: **1.** Presented at EASL 2019; Late Breaker Oral Session-02; NCT03124108; Elafibranor, a peroxisome proliferator-activted receptor alpha and delta agonist demonstrates favourable efficacy and safety in patients with primary biliary cholangitis and inadequate response to ursodeoxycholic acid treatment, Schattenberg et al. 2019 Journal of Hepatology, Vol. 70, Issue 1, e128. **2.** Nevens, et al. 2016 N Engl J Med; 375: 631-643. **3.** FDA CDER, "Application Number: 207999Orig1s000 Cross Discipline Team Leader Review for OCA Approval." 25 May 2016 **4.** FDA GIDAC Meeting, "FDA Introductory Remarks, NDA 207999: Obeticholic Acid." 7 April 2016. **5. Data** Presented by Cymabay in a Corporate Presentation and Press Release on August 3, 2020.

# NIS4™ Technology

# NIS4™ Technology to Diagnose Millions of Patients with Active NASH and Fibrosis



**6.7M** Patients have active NASH and Fibrosis in the US[7†]

Only **900,000** are diagnosed

**Poor disease awareness** among patients with NAFLD due to nonspecific symptoms[1,2]

Liver biopsy, the reference standard for NASH, poses **risks for patients and has technical limitations**[3]

Patients who have **NAS≥4 and F≥2 (i.e. at-risk NASH)** are at increased risk of developing cirrhosis and/or complications of severe liver disease [4-6]

There are **NO non-invasive diagnostic tests** specifically developed to identify at-risk NASH

## NIS4™ Technology research and development program

**To identify patients with at-risk NASH, GENFIT has invested in a strategic R&D program**

- Statistical analysis of **>100** circulating **blood-based biomarkers**[4]
- Comparison of results against **liver biopsy** results[4]
- **Testing and validation** in 3 independent cohorts with suspected NAFLD[4]
- **Designed for utilization and commercialization in clinical research and clinical management settings**

**Note**: †Case numbers for the specified populations are approximated as follows: Active NASH and fibrosis, i.e. at-risk NASH is F2 + F3 + F4, NASH with cirrhosis is F4, and ESLD is decompensated cirrhosis.

**References**: **1.** Chalasani N, et al. *Hepatology*. 2018;67(1):328-357. **2.** Bugianesi E. *J Hepatol*. 2005;42(5):784-785. **3.** Cleveland E, et al. *Clin Liver Dis (Hoboken)*. 2018;11(4):98-104. **4.** Harrison SA, et al. Lancet Gastroenterol Hepatol. 2020; 5(11):970-985, https://doi.org/10.1016/S2468-1253(20)30252-1. **5.** Angulo P, et al. *Gastroenterology*. 2015;149(2):389-397.e10. **6.** Sanyal AJ, et al. Presented at: American Association for the Study of Liver Diseases Annual Meeting. 2019 (abstr 1190). **7.** Estes C, et al. Hepatology. 2018;67(1):123-133

# NIS4™: A Proprietary and Differentiated Technology for the Diagnosis of At-Risk NASH

| Diagnostic method | NASH Activity | Fibrosis | Standard Ordering HCP | Method | Designed for NASH |
|---|---|---|---|---|---|
| **NIS4™,1** | ✓ | ✓ | **Any healthcare provider** | **Non-invasive** | ✓ |
| **BIOPSY** | ✓ | ✓ | **Hepatologist/GI** | Invasive | - |
| **ULTRASOUND** | ✓ Steatosis Only | - | **Any healthcare provider** | **Non-invasive** | - |
| **FibroScan®** | ✓ Steatosis Only | ✓ | **Hepatologist or GI** | **Non-invasive** | - |
| **NFS** | - | ✓ | **Hepatologist/GI/Specialist** | **Non-invasive** | - |
| **FIB-4** | - | ✓ | **Hepatologist/GI** | **Non-invasive** | - |
| **APRI** | - | ✓ | **Any healthcare provider** | **Non-invasive** | - |
| **ELF™** | - | ✓ | **Hepatologist/GI** | **Non-invasive** | - |

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**Note**: At-risk NASH as defined by NASH Activity Score (NAS)≥4 and Fibrosis stage (F)≥ 2.
NFS (NAFLD fibrosis score), FIB-4 Index (Fibrosis-4), APRI (AST / platelet ratio index), FibroScan® is a registered trademark of EchoSens™, Paris. ELF™ (Enhanced Liver Fibrosis) is a trademark of Siemens Healthineers and is not commercially available in the U.S. but used widely outside of the U.S.
**References: 1**. Harrison SA, et al. Lancet Gastroenterol Hepatol. 2020; 5(11):970-985, https://doi.org/10.1016/S2468-1253(20)30252-1

# NIS4™ Technology: An Innovative Approach Built Upon miRNA Science

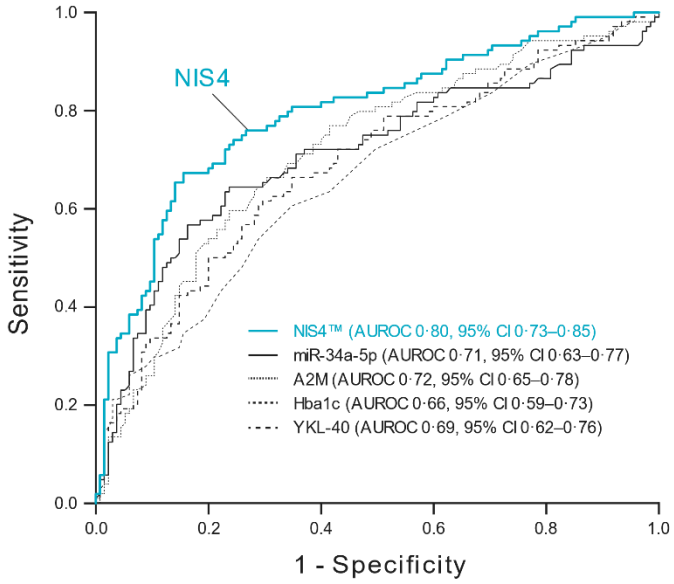
**NIS4™ is the only non-invasive, blood-based technology specifically designed to assess both NASH activity and liver fibrosis among patients with metabolic risk factors**

**NIS4™ assigns a single score that ranges from 0.00 to 1.00 based on blood/serum levels of 4 biomarkers:**

- **miR-34a-5p**
- **Alpha2-macroglobulin (A2M),**
- **YKL-40,**
- **Hemoglobin A1c (HbA1c),**

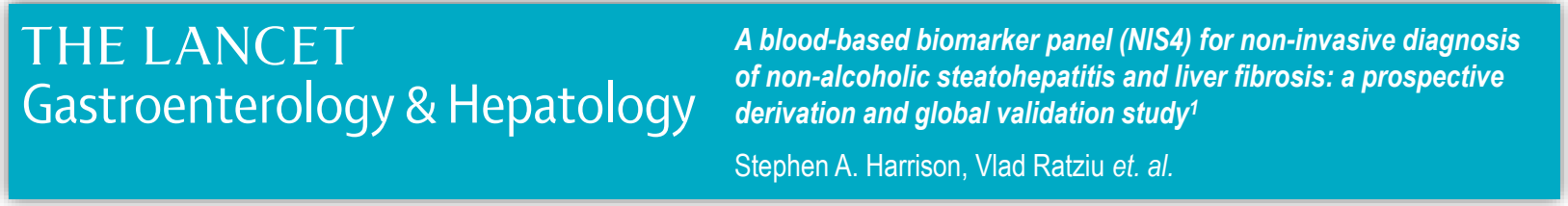
- NIS4™ significantly outperformed other blood biomarker-based NASH or fibrosis diagnostics, including FIB-4, NFS, APRI, and ELF for the detection of at-risk NASH
- NIS4™ performance data have been generated against liver biopsy in more than 900 patients across the NASH/NAFLD spectrum

**Comparison of NIS4 vs individual biomarker components to identify patients with at-risk NASH within the discovery cohort (n=239)***




**Note**: At-risk NASH (NAS≥4,F≥2), NAS, non-alcoholic fatty liver disease activity score; AUROC, area under the receiver operating characteristics curve.
**References:** Harrison SA, et al. Lancet Gastroenterol Hepatol. 2020; 5(11):970-985, https://doi.org/10.1016/S2468-1253(20)30252-1

# NIS4™ Technology Published in *The Lancet Gastroenterology & Hepatology*




## NIS4™ Technology

- High diagnostic performance with low misclassification rates to rule in and rule out at-risk NASH
- Consistent test performance vs. other tests – more consistent results irrespective of BMI, gender, presence or absence of diabetes, dyslipidemia, hypertension, or aminotransferase levels
- Provides a definitive diagnosis of at-risk NASH for over 72% of patients with high accuracy

## Tests powered by NIS4™ technology can be adapted to different clinical trial or clinical goals

- Potential to reduce unnecessary liver biopsies in patients with lower risk of disease progression
- May improve referral pathways amongst multiple patient sub-populations to liver specialty care
- May enable earlier identification of higher risk patients and allow for focused patient management to mitigate disease progression

**Note:** *There is currently no NIS4-based test approved as an IVD. NIS4™technology has been licensed to LabCorp, which has used it to develop and launch its own NIS4-based for use in the commercial setting.

**References**: **1.** Harrison SA, et al. Lancet Gastroenterol Hepatol. 2020; 5(11):970-985, https://doi.org/10.1016/S2468-1253(20)30252-1

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# The Progression and Future of NIS4™ Technology

## A test powered by clinically validated NIS4™ technology is the simple solution to identify at-risk NASH patients

**Licensing of NIS4™ Technology for research use in clinical trials**
Signed with LabCorp-Covance
**1Q19**

**Commercialization of NIS4™ Technology for clinical research (LabCorp-Covance)**
Utilization in clinical trials
**4Q19**

**NIS4™ Technology Pivotal Publication in *The Lancet G&H*[3]**
NIS4™ derivation and validation
**3Q20**

**Licensing of NIS4™ Technology for Commercialization of a NASH Diagnostic Test**
Agreement with LabCorp
**3Q20**

**A development and commercialization plan for an untapped market**

**LabCorp to commercialize the only non-invasive, blood-based, molecular LDT for diagnosis of at-risk NASH based on NIS4™ Technology**

### Target Populations with Suspected NASH

- Diabetes patients in U.S.: 34M[1]
- Obese (BMI>30) patients in U.S.: 94M[2]

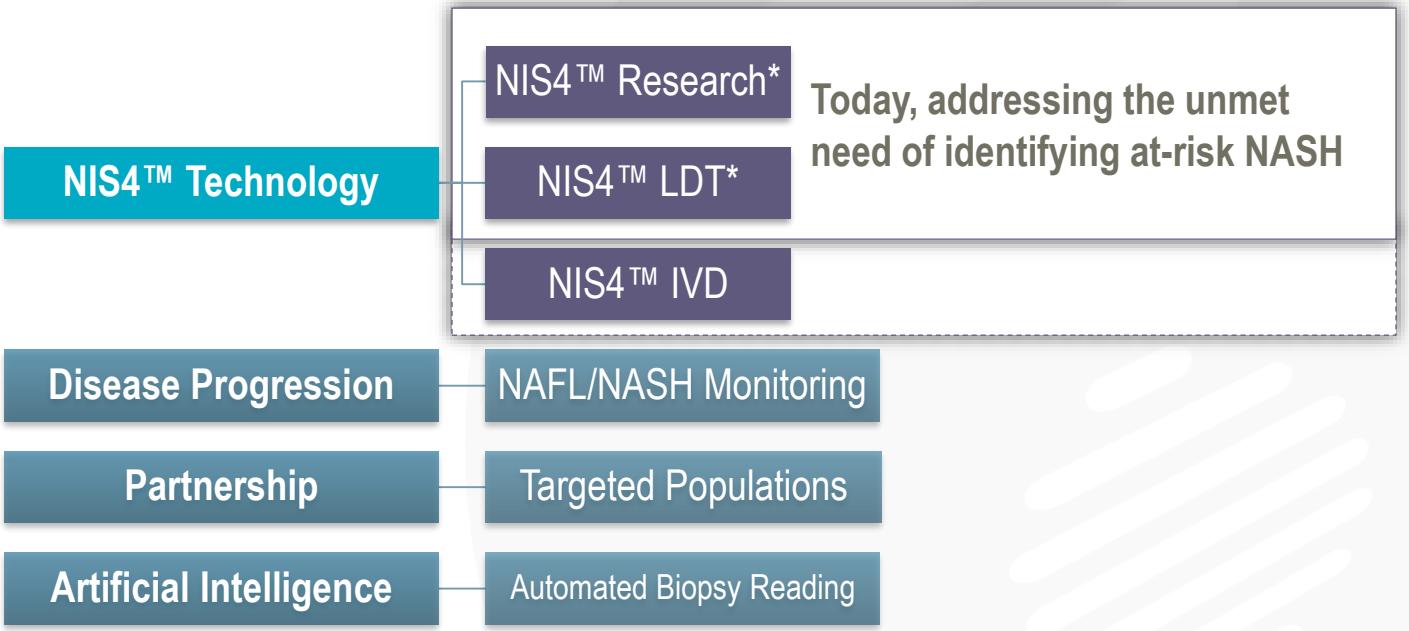
### Upcoming projected development milestones

- LabCorp to commercialize LDT for clinical care in U.S. & CA – 1H21
- Future Submission to FDA for IVD approval
- Future Submission to EU Notified Body for CE mark

**References**: **1.** National Diabetes Statistics Report 2020 (13% = prevalence of diabetes in U.S. population) ; +2010 US Census: (308,745,538 U.S. population – 74,181,467 U.S. population under age 18 = 234,564,071 U.S. adults). **2.** National Center for Health Statistics (39.8% = prevalence of obesity in U.S.). **3.** Harrison SA, et al. Lancet Gastroenterol Hepatol. 2020; 5(11):970-985, https://doi.org/10.1016/S2468-1253(20)30252-1

# NASH Diagnostics: Accelerating Technology

## A platform of fit-for-purpose NASH diagnostic solutions




**Note:** *NIS4™Technology has been licensed to LabCorp, which has used it to develop and launch its own NIS4™Technology-based research tool and NIS4™Technology-based LDT for use in the commercial setting. There is currently no NIS4™Technology-based test approved as an IVD.

# GENFIT: A Pioneer in the Diagnosis and Treatment of Liver Disorders

| Organizational Pillars | Target Indications |
| --- | --- |
| PBC Therapeutics | Elafibranor for treatment of PBC |
| NASH Diagnostics | NIS4™ technology for at-risk NASH identification |

## Expertise

- Leader in PPAR research
- Pioneer in NASH and PBC
- Proven team with global scientific, regulatory, and commercialization expertise

## Milestones

- Partnership with Terns Pharmaceuticals for commercialization of elafibranor in Greater China (PBC)
- Licensing agreement with LabCorp-Covance for use of NIS4™ technology in clinical research
- Exclusive licensing agreement with LabCorp for NIS4™ Technology development and commercialization of a NASH diagnostic test

## Next Steps

- Restructuring of corporate debt
- Evolving corporate structure
- Pursuing novel business development opportunities
- Exploring NTZ potential in several hepatic conditions