GENFIT
TOWARDS BETTER MEDICINE

Corporate Presentation

April 2022

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About GENFIT

Mission & Expertise

- French late-stage biopharmaceutical company dedicated to **improving the lives of patients** with severe chronic liver diseases
- Pioneer in the field of nuclear receptor-based drug discovery, GENFIT has a **robust and diversified pipeline** leveraging the potential of innovative compounds and technologies
- More than 20 years of expertise **from discovery phase to late-stage development** with a strong track record to develop **long term collaboration**: Genoscience Pharma, Ipsen, Labcorp, Terns Pharmaceuticals
- Focused on areas with **high unmet medical needs & with significant market opportunities:**

Cholestatic Diseases Therapeutics | **ACLF Therapeutics** | **NASH Diagnostics**

Financials

- Cash position: **€258.8M** as of Dec 31, 2021
  - → including **€15M** non-dilutive French State-Guaranteed Loan
  - → Including **€120M upfront payment** and **€28M equity investment** from Ipsen[1]

120+ collaborators

400+ trademarks for key products and services

700+ patents & patents application

Fully committed in the continuous improvement of our **CSR & ESG Performance**[2]

WE SUPPORT

PACTE

EURONEXT

Nasdaq

Euronext & NASDAQ listed: GNFT

Based in Lille, Paris & Cambridge, MA

ACLF: Acute on Chronic Liver Failure NASH: Nonalcoholic steatohepatitis.

1. GENFIT is eligible to receive up to €360m in milestone payments as well as tiered double-digit royalties of up to 20%. **2**.Since 2021 GENFIT has been committed to the UN Global Compact corporate responsibility initiative and its principles in the areas of human rights, labour, the environment and anti-corruption.

Therapeutics: Cholestatic diseases

Therapeutics: ACLF

Diagnostics: NASH

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Cholestatic Diseases: Multiple Opportunities, from Preclinical Research to Market Access

Primary Biliary Cholangitis (PBC)

Description

- Chronic liver disease in which bile ducts in the liver are gradually destroyed.
- Bile accumulates in the liver, contributing to tissue damage and scarring, or fibrosis, leading to cirrhosis.
- Standard of Care (SoC): still unmet medical need calling for new differentiated therapies[1]

GENFIT's Rationale

- In-house expertise (discovery to late stage) in severe liver diseases
- Strong scientific rationale to support the effects of elafibranor* on cholestasis[2]
- Ongoing Late-stage clinical development in PBC: ELATIVE™ Phase 3 Study[3]

Market Opportunity

- **PBC orphan indication**: enhanced market exclusivity and clinical research subsidies[4]
- **Eligible population in PBC**: ~90,000 patients US+EU for second line treatment, representing a market potential of $1bn by 2025[5]

IPSEN Innovation for patient care

December 2021 - GENFIT | Ipsen:
Exclusive licensing agreement* for elafibranor as part of a **long-term global partnership**

Cholangiocarcinoma (CCA)

Description

- Cholangiocarcinoma is a rare liver malignancy with high mortality
- SoC: high unmet need for treatment – 5-year survival from presentation of symptoms concerns less than 20% of all untreated patients[6]

GENFIT's Rationale

- **In-licensing** of Genoscience Pharma asset: GNS561 (Autophagy inhibitor with a MoA of PPT-1 inhibition)
- GNS561 ***in vitro* and *in vivo* data support the rationale** for targeting cholangiocarcinoma[7]

Market Opportunity

- **Cholangiocarcinoma orphan indication**: EMA: 50 persons affected per 100k people | FDA: less than 200k persons affected in the total population ~60 per 100k people[8]
- Annual incidence of 0.3–6 per 100,000 people[9]

December 2021:
Acquisition of exclusive rights to develop and commercialize the investigational treatment GNS561 in cholangiocarcinoma**

Note: *Elafibranor is an investigational compound and has not been approved by any regulatory authority in any indication. Ipsen has global rights to develop and commercialize elafibranor in primary biliary cholangitis, with the exception of China, Hong Kong, Taiwan, and Macau where Terns Pharmaceuticals holds the exclusive license to develop and commercialize elafibranor **GNS561 is an investigational compound and has not been approved by any regulatory authority in any indication. GENFIT holds the exclusive rights for GNS651 in Cholangiocarcinoma in the United States, Canada and Europe, including the United Kingdom and Switzerland.

1. Onofrio et al. Gastroenterol. Hepatol. 2019, Vol.15, Issue 3:145-154; **2**. Schattenberg et al. J. of Hepatol. 2021, Vol. 74, Issue 6:1344-1354; **3**. NCT04526665; **4**. Orphan Drug Act of 1983, US Food and Drug Administration, 3 January 1983, PUBLIC LAW 97-414; **5**. Iqvia Commercial Opportunity Presentation, 2020 - Resarch on File, November 2019; **6**. Lamarca et al. 2021; **7**. S Brun et. al. Autophagy 2021 ; **8**. IQVIA Analysis, Research on file October 2021; **9**. J.M., Banales, Nat Rev Gastroenterol Hepatol. 2020; 17(9): 557–588.

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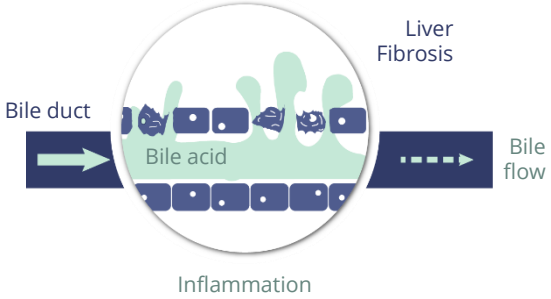
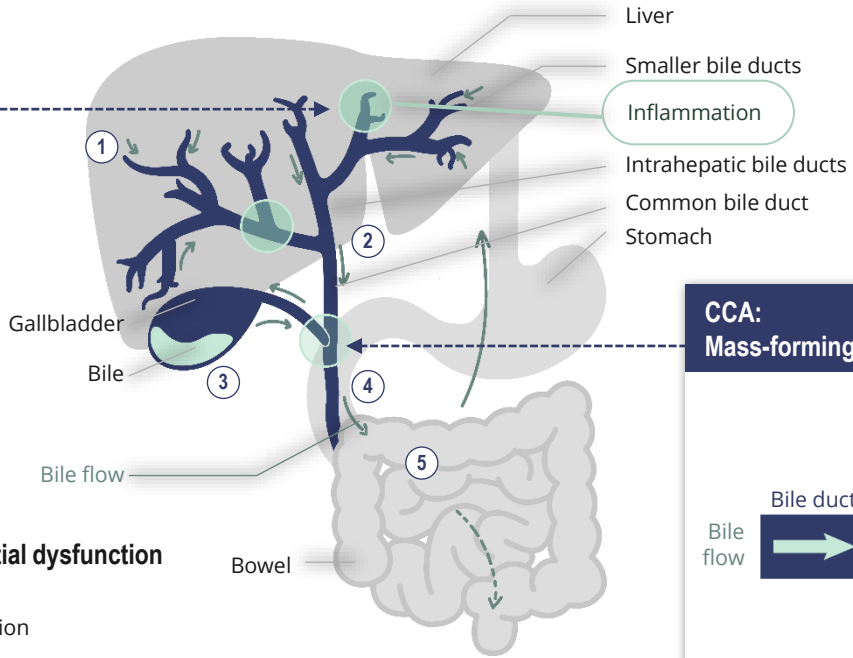
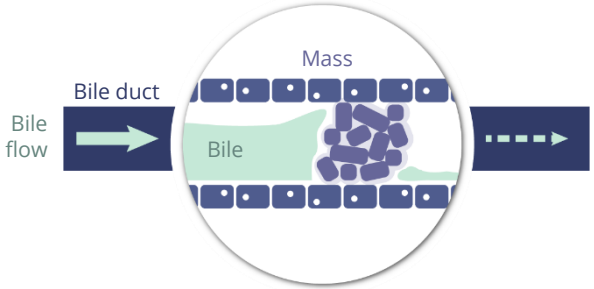
Cholestatic Diseases: Characterized by Inflammation and Destruction of Bile Ducts

PBC:
Bile ducts gradually destroyed =
↘ bile acid circulation & ↗ toxicity





CCA:
Mass-forming in the bile duct = No bile circulation



Enterohepatic cycle (bile acid cycle) and potential dysfunction

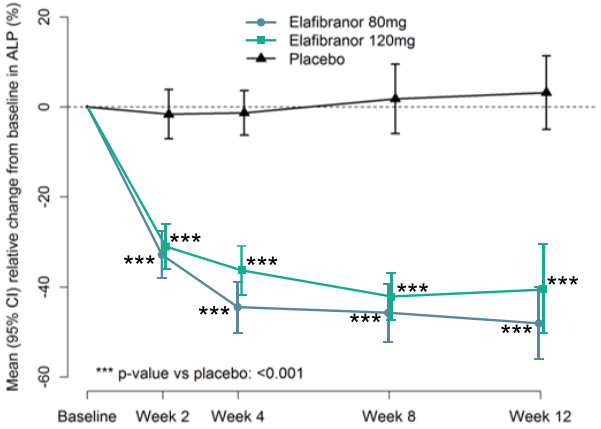
1. Synthesis by the liver
2. Transport to the bile duct and detoxification
3. Storage by gallbladder
4. Export to the intestine
5. Passive/active absorption by small intestine

Elafibranor as a Potential Treatment for PBC (1/3)

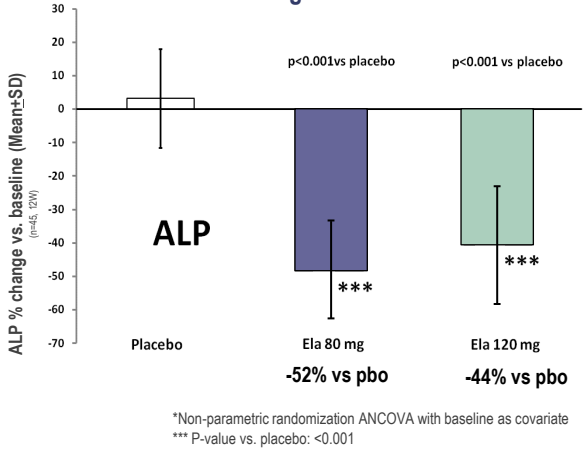
Elafibranor Phase 2a PBC Study

Statistically significant treatment effects with both 80mg and 120mg doses on the primary end-point* of serum alkaline phosphatase (ALP) change from baseline

Change from baseline in ALP at week 12[1]



ALP % Change vs. baseline[1]



*Non-parametric randomization ANCOVA with baseline as covariate
*** P-value vs. placebo: <0.001

Elafibranor awarded Breakthrough Therapy designation by the FDA and Orphan Drug Designation by the FDA & EMA for PBC[2]

JOURNAL OF HEPATOLOGY
The Home of Liver Research

A randomized placebo-controlled trial of elafibranor in patients with primary biliary cholangitis and incomplete response to UDCA[1]

Jörn Schattenberg *et. al.* | Journal of Hepatology. Feb. 2021

Note:* confirmed in mITT* set. 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).

1. Schattenberg et al. J. of Hepatol. 2021, Vol. 74, Issue 6:1344-1354; **2**. GENFIT Corporate Press Release June 29, 2019 "GENFIT Announces FDA Grant of Breakthrough Therapy Designation to Elafibranor for the Treatment of PBC.".

Elafibranor as a Potential Treatment for PBC (2/3)

Elafibranor is a Competitive 2L Candidate for PBC

	Elafibranor*[2] Phase 2a Week 12 Data NCT03124108 EudraCT2016-003817-80	
	80mg (N=15)	Placebo (N=14)
Composite endpoint *% responders, ALP<1.67 x ULN; Bili<ULN and ALP reduction >15%*	**67%** (p=0.001)	6.7%
Alkaline phosphatase *(% change vs baseline)*	**-48%** (p<0.001)	3%

	Ocaliva™[3], Phase 3 POISE Month 12 Data NCT01473524	
	10mg (N=73)	Placebo (N=72)
Composite endpoint *% responders, ALP<1.67 x ULN; Bili<ULN and ALP reduction >15%*	**47%** (p<0.001)	10%
Alkaline phosphatase *(% change vs baseline)*	**~-36%**** (p<0.001)	~-4%**

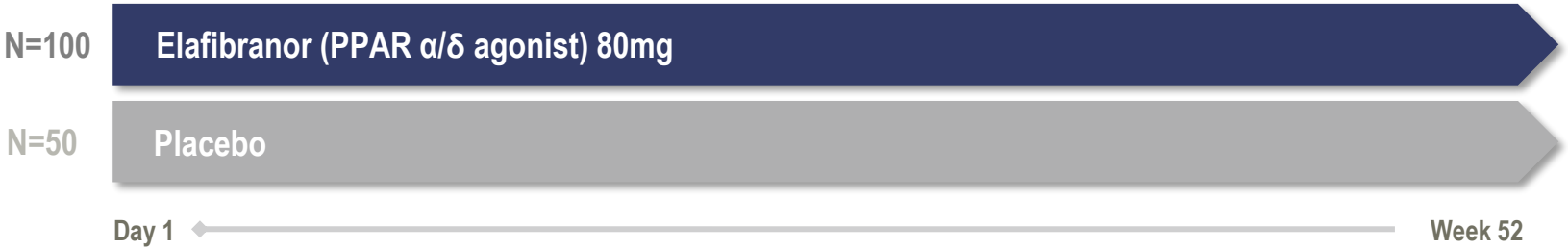
Note: Indirect Comparison of Selected Biochemical Endpoint[1]. Both studies were add-on investigational therapy to UDCA or monotherapy in patients unable to tolerate UDCA. 2L: Second-line. ***Elafibranor –** mITT: All subjects w/ available baseline value and at least one post baseline value under treatment for ALP. **These are estimations-based figures as reported data is based on actual change from Baseline n ALP (U/L) .Elafibranor is an investigational compound and has not been approved by any regulatory authority in any indication. Obeticholic acid is registered in US and EU under the trade name OCALIVA®, please refer to the approved PI and SmPC.

1. Data from referenced clinical trials; **2.** Schattenberg et al. J. of Hepatol. 2021, Vol. 74, Issue 6:1344-1354; **3**. Nevens, et al. NEJM 2016, 375(7):631-43.

Elafibranor as a Potential Treatment for PBC (3/3)

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 at Week 52 defined as **Alkaline phosphatase (ALP) < 1.67 x Upper Limit Normal (ULN) and Total Bilirubin (TB) ≤ ULN and ALP decrease ≥ 15 percent***

Key Secondary Endpoints

- *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**

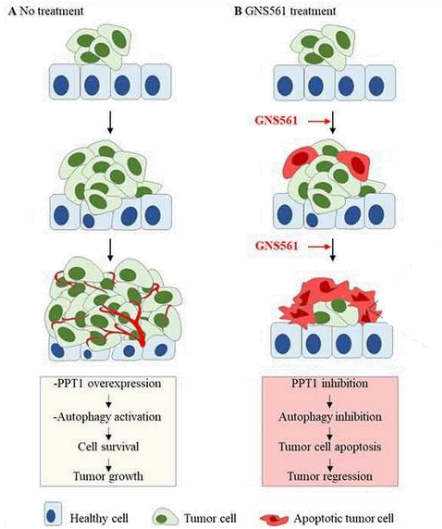
September 2020	**April 2022**	**2Q 2023**
Beginning of enrolment	End of patient screening[2]	Anticipated Topline Data readout

Note: *Measuring itch over the past 24 hours from 0 (no itch) to 10 (worst itch imaginable). Elafibranor is an investigational compound and has not been registered by any regulatory authority

1. NCT04526665 ; **2**. To be used to support accelerated approval. GENFIT Press Release "GENFIT Reports Strong Full-Year 2021 Financial Results and Provides Corporate Update" released on April 7, 2022

GNS561 as a Potential Treatment for CCA

GNS561 Mechanism of Action



- GNS561 is a clinical-stage candidate **inhibiting autophagy** which causes a cascade of events, leading to tumor cell apoptosis (cell death)[1]:
  - lysosomal accumulation of unbound zinc ion (Zn2+),
  - **inhibition of PPT-1** and cathepsin activity,
  - **blockage of autophagic** flux
  - MTOR displacement

- **Autophagy-related lysosomal cell death has been recognized as a major target** for cancer therapy
- Autophagy allows cancer cells to become resistant to the cellular stress induced by chemotherapy and targeted therapy
- By entering the lysosomes and binding to PPT-1, **GNS561 acts to block late-stage autophagy**, which can lead to tumor cell death

- GNS561 is a candidate for Breakthrough Therapy Designation, Orphan Drug Designation and Accelerated Approval.
- **GENFIT to start Phase 2 clinical trial by end of 2022**[2]

Autophagy

GNS561, a clinical-stage PPT1 inhibitor, is efficient against hepatocellular carcinoma via modulation of lysosomal functions[3]

S Brun *et. al.* | Nov 2021

PPT1: palmitoyl-protein thioesterase. MTOR: mammalian target of rapamycin.

1. S. Brun et.al. Invest New Drugs. 2019;37(6):1135–1145. **2**. GENFIT Press Release "GENFIT Reports Strong Full-Year 2021 Financial Results and Provides Corporate Update" released on April 7, 2022; **3.** S. Brun et.al. Autophagy, 2021.

Autophagy inhibition: Highlights from the Literature for Potential Treatment for CCA

Monotherapy

F. Bassissi et al.
GNS561 : a new quinoline derivative with high efficacy on cancer stem cells in liver metastases from colorectal cancer and hepatocellular carcinoma
Cancer Res 2017;77(13 Suppl):Abstract nr 5124. – March 2017

Sonia Brun et al.
GNS561, a new lysosomotropic small molecule, for the treatment of intrahepatic cholangiocarcinoma
Invest New Drugs 37(6):1135-1145 (Dec. 2019)

James J. Harding et al.
First-in-human phase I, pharmacokinetic (PK), and pharmacodynamic (PD) study of oral GNS561, a palmitoyl-protein thioesterase 1 (PPT1) inhibitor, in patients with primary and secondary liver malignancies.
Journal of Clinical Oncology Vol 39 issue 15 suppl. (2021)

Sonia Brun et al.
GNS561, a clinical-stage PPT1 inhibitor, is efficient against hepatocellular carcinoma via modulation of lysosomal functions
Autophagy (Nov. 2021)

Sonia Brun et al.
GNS561, a New Autophagy Inhibitor Active against Cancer Stem Cells in Hepatocellular Carcinoma and Hepatic Metastasis from Colorectal Cancer
J. Cancer 13;12(18):5432-5438 (Jul. 2021)

Combo with MEKi/ERKi

Chih-Shia Lee *et al.*
MAP kinase and autophagy pathways cooperate to maintain RAS mutant cancer cell survival
PNAS 116 (10) 4508-4517 (Mar. 2019)

Conan G. Kinsey *et al.*
Protective autophagy elicited by RAF→MEK→ERK inhibition suggests a treatment strategy for RAS-driven cancers
Nature Medicine volume 25, pages 620–627 (Mar. 2019)

Kirsten L. Bryant *et al.*
Combination of ERK and autophagy inhibition as a treatment approach for pancreatic cancer
Nature Medicine volume 25, pages 628–640 (2019)

Combo with chemotherapy

Yu-Jie Hou *et al.*
Inhibition of active autophagy induces apoptosis and increases chemosensitivity in cholangiocarcinoma
Laboratory Investigation 91, 1146-1157 (2011)

Hector Perez-Montoyo
Therapeutic Potential of Autophagy Modulation in Cholangiocarcinoma
Cells, 9, 614 (2020)

Linhe Gan *et al.*
Mesenchymal stem cells promote chemoresistance by activating autophagy in intrahepatic cholangiocarcinoma
Oncology Reports 45: 107-118 (2021)

Evangelos Koustas *et al.*
Role of autophagy in cholangiocarcinoma: An autophagy-based treatment strategy
World J Gastrointest Oncol; 13(10): 1229-1243 (Oct. 2021)

Autophagy-inhibition-Mechanism of action is a potential candidate for cholangiocarcinoma as monotherapy, in combination with MEKi/ERKi or for 2L-treatment with chemotherapy

CCA; Cholangiocarcinoma; ERKi: ERK (Extracellular Receptor Kinase) inhibitor ;MEKi: MEK (MAPK/ERK Cascade) inhibitor; MAPK: Mitogen activated protein kinase. There are 4 MAPK Cascads in humans: Ras (Small guanosin triphosphatases (GTPase), Raf, MEK, ERK.

Therapeutics:
Cholestatic diseases

Therapeutics:
ACLF

Diagnostics:
NASH

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Acute on Chronic Liver Failure: a New Growth Opportunity for GENFIT

High unmet medical need in ACLF

- **Life threatening disease** with high mortality at 30-90 days[1]
- **Standard of Care (SoC):** no approved drugs[2]
- **Medical need**: a therapy that helps patients to survive ACLF without liver transplantation

Market opportunity

- **Significant cost to the healthcare system**: in the U.S., in-hospital costs 3.5 times higher for an ACLF patient than for a decompensated cirrhosis patient without ACLF[3]
- **Hospital stays**: 16 days average for ACLF patient (vs 7 days for cirrhotic patient)[4]
- **Nb of patients**: 10-30% prevalence in cirrhotic patients hospitalized in the U.S.[5]
- **Market opportunity:** up to ~$4bn in the U.S. and ~$2bn in EU[6]
- **Orphan condition:** enhanced market exclusivity and clinical research subsidies[7]

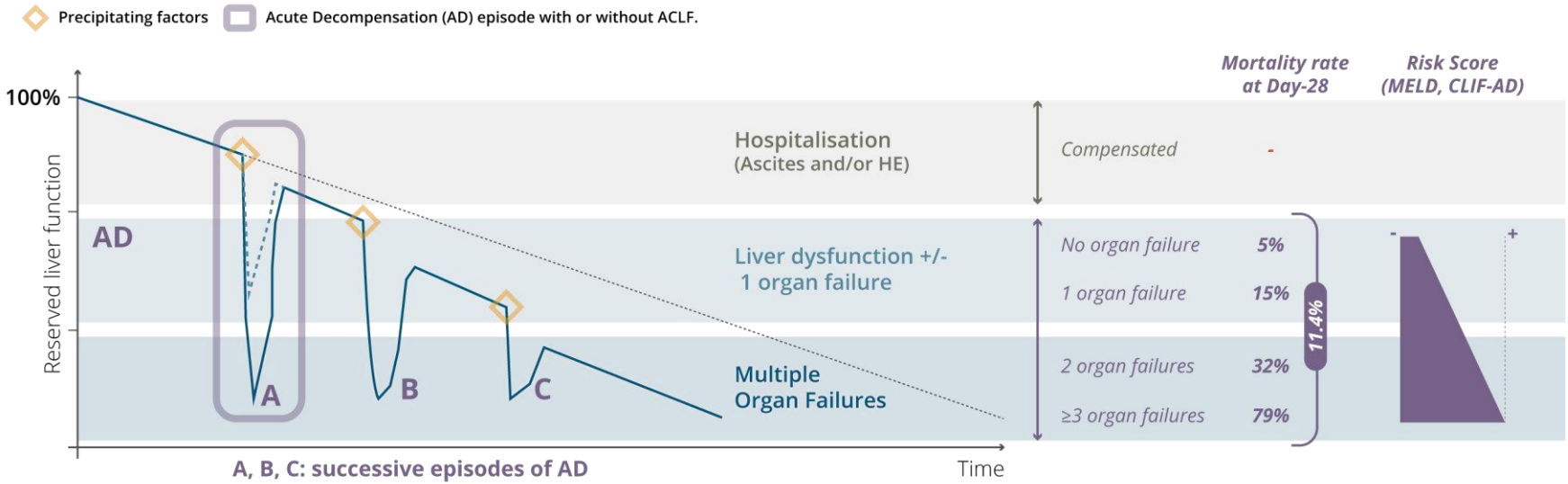
GENFIT's rationale

- **In-house expertise (discovery to late stage) in severe liver diseases**
- **Strong scientific rationale based upon supportive preclinical data for NTZ**[8]
- **Initiation of clinical program for NTZ in ACLF in 4Q21 with first clinical data expected in 3Q22** (Phase 1)[9]

ACLF: Acute on Chronic Liver Failure. NTZ is an investigational compound and has not been registered in the indication ACLF by any regulatory authority.

1. Jalan R et al. World Gastroenterol. Org. Working Party. Gastroenterology 2014;147:4-10; **2**. Allen, A. Kim, WR. Moriarty, JP. Shah, ND. Larson, JJ. Kamath, PS. Time trends in the health care burden and mortality of ACLF in the US. Hepatology. 2016. Dec.64(6):2165-2172; **3**. Allen et al. Hepatology, 2016;64:2165-2172; **4**. Kamath, Acute on Chronic Liver Failure. 2017; **5**. Hernaez et al. J. of Hepatol. 2019; **6**. Derived from assumptions taken from Delveinsight, ACLF Market Insight, Epidemiology and Market Forecast -2030 Report published in Oct. 2020; **7**. Orphan Drug Act of 1983, US Food and Drug Administration. 4 January 1983, PUBLIC LAW 97-414; **8**. Shou et al. Inflammation Vol. 42:1336–1349(2019), data on file. **9**. GENFIT Press Release

Natural History of AD and ACLF in Cirrhotic Patients



- ACLF Definition : **acute deterioration of preexisting chronic liver disease**, usually related to a **precipitating event** and associated with **increased mortality at three months due to multi-system organ failure.**
- Precipitating factors **: Infection (bacterial, fungal or viral)** / Reactivation of hepatitis B (or C) or superimposed viral hepatitis (e.g hepatitis E in India) / Alcohol / Drug Induced Liver Injury (DILI, herbal medicine) / Gastrointestinal bleeding / Portal vein thrombosis / Surgery / Ischemia / Flare of autoimmune hepatitis or Wilson disease.
- ACLF patient with known chronic liver disease experiencing sudden **multiple organ failures affecting liver, kidney, coagulation, brain and lung functions**

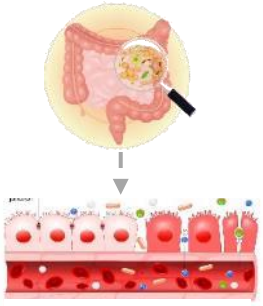
AD: Acute Decompensation. MELD: Model for End-stage Liver Disease. Clif-AD: Chronic Liver Failure with Acute Decompensation
Adapted from: **1**. Kim TY, Kim DJ. Clin Mol Hepatol. 2013 Dec;19(4):349-59; **2**. Moreau et al. Gastroenterology.

NTZ and PPARs May Address Multiple Relevant Pathways in ACLF

NTZ effects
PPARs effects

Gut microbiota dysbiosis
(>90% anaerobic Gram negative)
Bacterial overgrowth
Decreased bacterial diversity

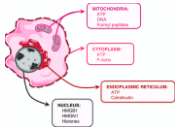
Impaired intestinal barrier and increased bacteria translocation:
Bacterial products (PAMPs: LPS, peptidoglycan....)
Non-pathogen and pathogen bacteria



PAMPs
(LPS, peptidoglycan...)

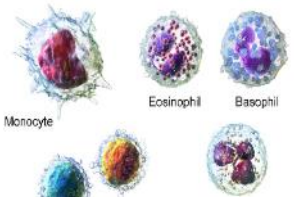
Cirrhotic liver

Dying cell



DAMPs
(HMGB1, mitDNA,ATP...)

Overactivation of innate immune system by PAMPs and DAMPs



Cytokine storm:
- Increased TNFa, IL6, IL1b, IL8
- Increased ROS NOS

Exacerbated Metabolic stress
- Increased aerobic glycolysis
- FFA accumulation and lipotoxicity
- Mitochondrial dysfunction
- Decreased beta-oxidation
- Decreased OXPHOS

Multiple Organ Failures (MOFs)
➔ ACLF ➔ Death

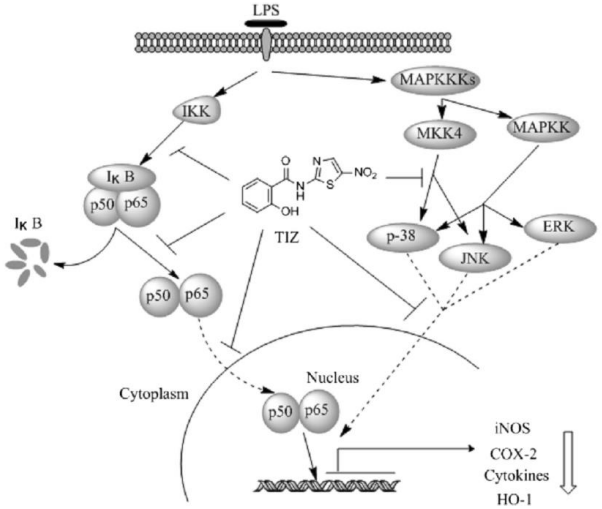
Organ injury and acute loss of function
Oxidative stress, Apoptosis, Necrosis

PAMP: pathogen-associated molecular patterns; DAMP: damage-associated molecular patterns
Adapted from: **1**. Arroyo V et al. J. Hepatol, 2021 Mar;74(3):670-685; **2**. Trebicka J et al. Nat Rev Gastroenterol Hepatol 2021 Mar;18(3):167-180.

Highlights from the Literature on NTZ and PPARs in ACLF

NTZ

- **Anti-infectious** properties may act on intestinal microbiota dysbiosis/overgrowth and improve intestinal barrier.
- Direct dose-dependent **anti-inflammatory** effects on immune cells (macrophages and PMN).



1. Shou et al. Inflammation Vol. 42:1336–1349(2019); **2**. Dubreuil et al. Antimicrob Agents Chemother 1996 Vol.40:2266–2270; **3**. Hecht et al. Antimicrob Agents Chemother 2007 Vol.51:2716–2719; **4**. Hoffman et al. Antimicrob Agents Chemother 2007 Vol.51:868–876; **5**. MacVay et al. Antimicrob Agents Chemother 2000 Vol.44: 2254-2258; **6**. Megraud et al. Antimicrob.Agents Chemother. 1998 Vol. 42:2836-2840; **7**. Musher et al. Clinical Infectious Diseases 2006 Vol.43:421-427; **8**. Pankuch et al. Antimicrob Agents Chemother. 2006 Vol.50(3):1112-7.

PPARs

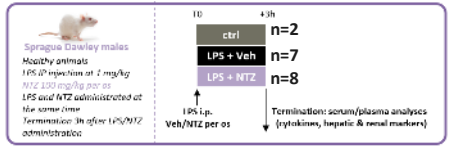
- In ACLF, an over-activation of the innate immune-system induces a **critical energetic adaptation** i) increased aerobic glycolysis ii) profound decrease in FFA beta-oxidation[1,2]
- In the liver and other peripheral organs, an over-metabolic adaptation leads to:
  - Energy deprivation
  - FFA acid accumulation and lipotoxicity
  - Mitochondrial dysfunction and ER stress
  - Oxidative stress
  - Hepatocyte necrosis and apoptosis…[1,2]
- **PPARs are master switches of energetic adaptation**, and their activation directly **modulates inflammatory response** of immune cells. [3]
- In animal models, over-activation of the immune system, some selective agonists (PPARα, PPARγ and PPARδ) have shown certain **favorable effects on MOF's and mortality.** [4]

Notes: MOF=Multiple organ failures

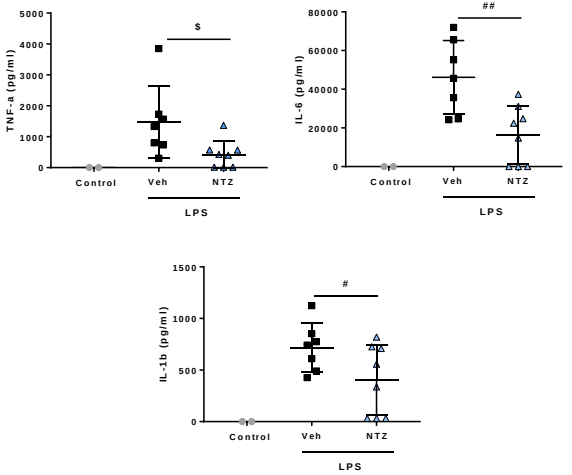
1. Zaccherini G. JHEP Reports 2021 Vol.3:100176; **2**. Moreau et al. J. of Hepatol. 2020 Vol.72(4):688-701; **3.** Standage et al. Critical Care Medicine 2016 Vol. 44(6):594-603; **4**. Paumelle et al. J. of Hepatol. 2019 Vol.70(5):963-973.

Pre-clinical Evidence Generated by GNFT – NTZ in ACLF (1/2)

In vivo model #1

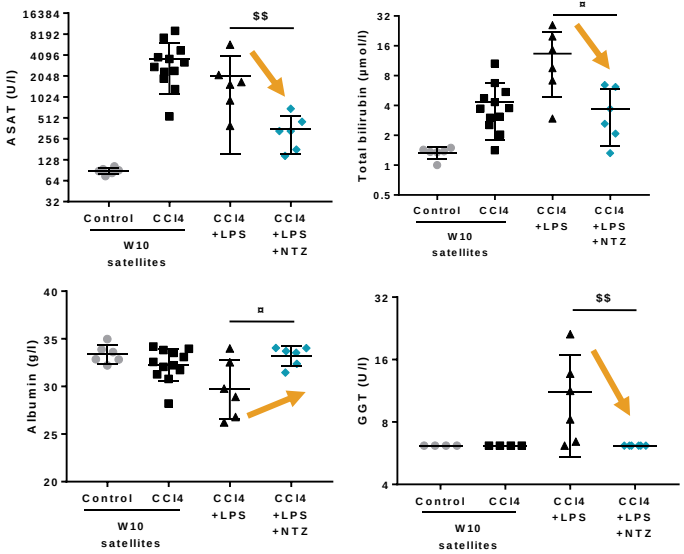


Activity on inflammatory markers

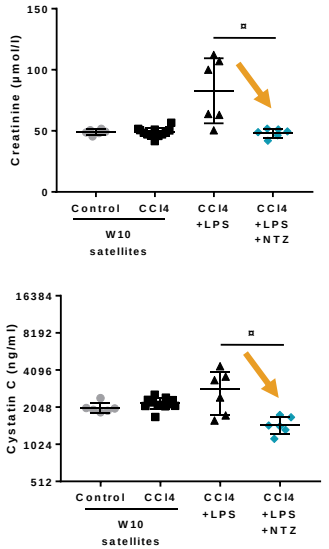


In vivo model #2 (ACLF)

Activity on liver failure markers



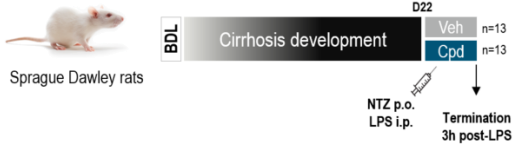
Activity on kidney failure markers



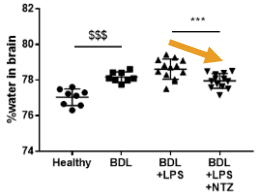
In this experiment, 40% mortality was observed in each group. Liver and kidney failure markers were measured on the remaining 60% survivors.

Pre-clinical Evidence Generated by GNFT – NTZ in ACLF (2/2)

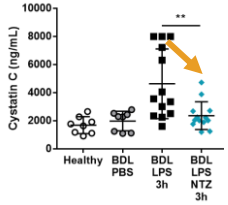
In vivo model #3 (ACLF)



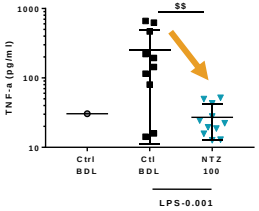
Brain edema



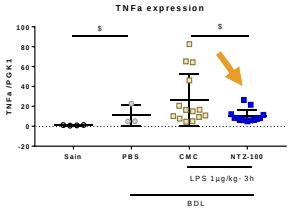
Kidney function marker



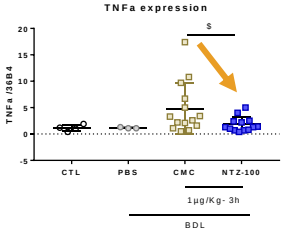
Circulating cytokines



Hepatic TNFα expression

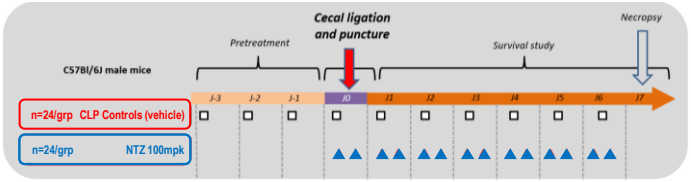


Renal TNFα expression

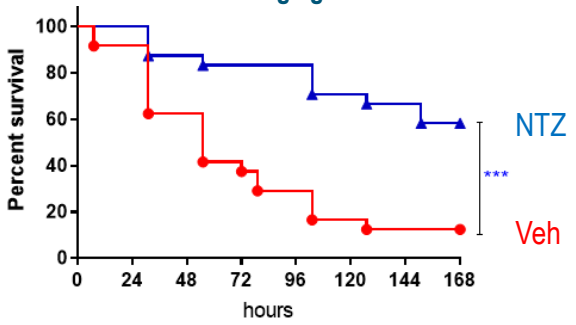


Similar results with IL1b, MCP1 and F4/80 expression

In vivo model #4 (sepsis)



NTZ treatment 100 mg/kg/d



Impact of NTZ to decrease mortality

GENFIT data on file. *In vivo* model #3: sample size of 13 subjects. *In vivo* model #4: sample size increased to 24 subjects.

Therapeutics:
Cholestatic diseases

Therapeutics:
ACLF

Diagnostics:
NASH

GENFIT
TOWARDS BETTER MEDICINE

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

High unmet medical need in NASH diagnostics

- 6.7M patients have NASH and significant fibrosis (F≥2) in the US[1†], only 900,000 are diagnosed
- Poor disease awareness among patients with NAFLD due to nonspecific symptoms[2,3]
- Liver biopsy, the reference standard for NASH, poses risks for patients and has technical limitations[4]
- Patients who have NASH and Significant Fibrosis (F≥2), also referred to as at-risk NASH, are at increased risk of developing cirrhosis and/or complications of severe liver disease [5-7]
- There are no non-invasive diagnostic tests specifically developed to identify at-risk NASH

GENFIT's rationale

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

- **Statistical analysis of >100 circulating blood-based biomarkers[5]**
- **Comparison of results against liver biopsy results[5]**
- **Testing and validation in 3 independent cohorts with suspected NAFLD[5]**
- **Designed for utilization and commercialization in clinical research and clinical management settings**

Market opportunity

- Prevalence of NASH among patients with diabetes: 25 to 30%[8]
  - Diabetes patients in U.S.: 34M (13% = prevalence of diabetes in U.S. population) 2020 US Census: 308,745,538 U.S. population (74,181,467 U.S. population under age 18 + 234,564,071 U.S. adults)[9]
- Prevalence of NASH among patients with obesity (BMI>30): 25 to 30%[8]
  - Obese patients in U.S.: 94M- (39.8% = prevalence of obesity in U.S.)[10]

Go To Market

- NASHnext® clinical diagnostic launched by Labcorp in April 2021.

Test is powered by GENFIT's NIS4® Technology

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.

1. Estes et al. Hepatology. 2018;67(1):123-133; **2**. Chalasani et al. Hepatology. 2018;67(1):328-357; **3**. Bugianesi et al. J. of Hepatol. 2005;42(5):784-785; **4**. Cleveland et al. Clin Liver Dis (Hoboken). 2018;11(4):98-104; **5**. Harrison et al. Lancet Gastroenterol Hepatol. 2020; 5(11):970-985; **6**. Angulo et al. Gastroenterology. 2015;149(2):389-397.e10; **7**. Sanyal et al. Presented at: The Liver Meeting 2019 (abstr 1190); **8**. Anstee, Q. M. & Day, C. P. Nat. Rev. Gastroenterol. Hepatol. 10, 645–655 (2013); **9**. National Diabetes Statistics Report 2020; **10**. National Center for Health Statistics.

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

Currently Available 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	-	✓	Any healthcare provider	Non-invasive	-
FIB-4	-	✓	Any healthcare provider	Non-invasive	-
APRI	-	✓	Any healthcare provider	Non-invasive	-
ELF™	-	✓	Hepatologist/GI	Non-invasive	-

FNIH Foundation for the National Institutes of Health

NIS4® technology's utility has been recognized in a Stage 1 study[2] undertaken by the Non-Invasive Biomarkers of Metabolic Liver Disease (NIMBLE) initiative of the Foundation for the National Institutes of Health's Biomarkers Consortium as **demonstrating a unique performance in identifying patients with "at-risk" NASH** (NASH + NAS≥4 and F≥2)

Note: At-risk NASH as defined by NASH Activity Score (NAS)≥4 and Fibrosis stage (F)≥ 2. NIMBLE: Non-Invasive Biomarkers of Metabolic Liver Disease. 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.

1. Harrison et al. Lancet Gastroenterol Hepatol. 2020; 5(11):970-985; **2**. Sanyal et al. Hepatology. 2021 Vol 74 Issue 6 – Suppl: 1383A – Presented at The Liver Meeting® 2021 as a Late Breking Oral Presentation

NIS4® Technology: An Innovative Approach Built Upon a Blood Test[1]

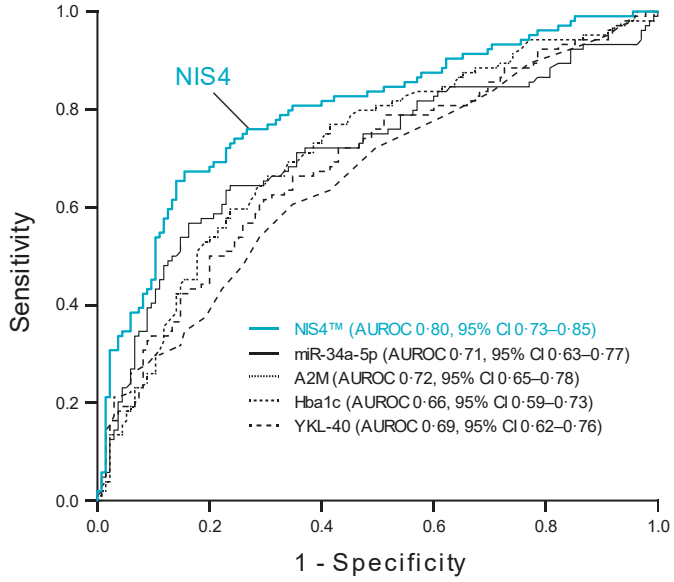
NIS4® is the only non-invasive, blood-based technology specifically designed to assess both NASH activity and liver fibrosis among patients with metabolic risk factors

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[2]
- 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.

1. Harrison et al. Lancet Gastroenterol Hepatol. 2020; 5(11):970-985; **2**. Sanyal et al. Hepatology. 2021 Vol 74 Issue 6 – Suppl: 1383A – Presented at The Liver Meeting® 2021 as a Late Breking Oral Presentation

NIS4® Technology Published in The Lancet Gastroenterology & Hepatology

THE LANCET
Gastroenterology & Hepatology

A blood-based biomarker panel (NIS4) for non-invasive diagnosis of non-alcoholic steatohepatitis and liver fibrosis: a prospective derivation and global validation study[1]

Stephen A. Harrison, Vlad Ratziu *et. al.* | Accepted for publication in *The Lancet Gastroenterology & Hepatology* Aug. 5, 2020

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.
Harrison et al. Lancet Gastroenterol Hepatol. 2020; 5(11):970-985

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 Drug Development
1Q19

Commercial availability of NIS4® Technology in clinical research (Labcorp Drug Development)
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
Signed with Labcorp
3Q20

Launch of NASHnext® based on NIS4® Technology
By Labcorp
2Q21

A development and commercialization plan for an untapped market

Large scale commercial launch of NASHnext® by Labcorp: a non-invasive, blood-based, molecular LDT for the identification of patients with at-risk NASH powered by GENFIT's NIS4® Technology:

Target Populations with Suspected NASH

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

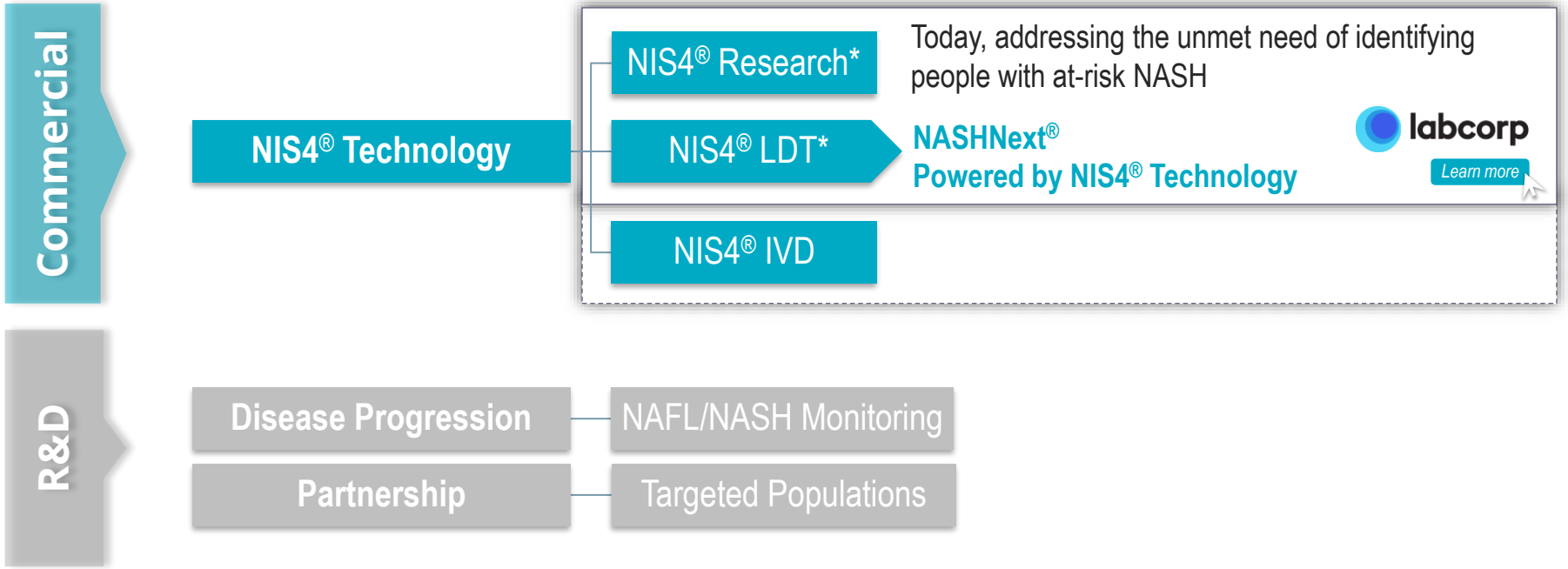
Upcoming GENFIT's projected development milestones:

- Future Submission to FDA for IVD approval
- Future Submission to EU Notified Body for CE mark

LDT: Laboratory Developed Test ; **IVD:** In vitro Diagnostic ; **CE mark:** (*Conformité Européenne)* mandatory conformity marking for certain products sold within the European Economic Area (EEA) since 1985.
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 et al. Lancet Gastroenterol. Hepatol. 2020; 5(11):970-985.

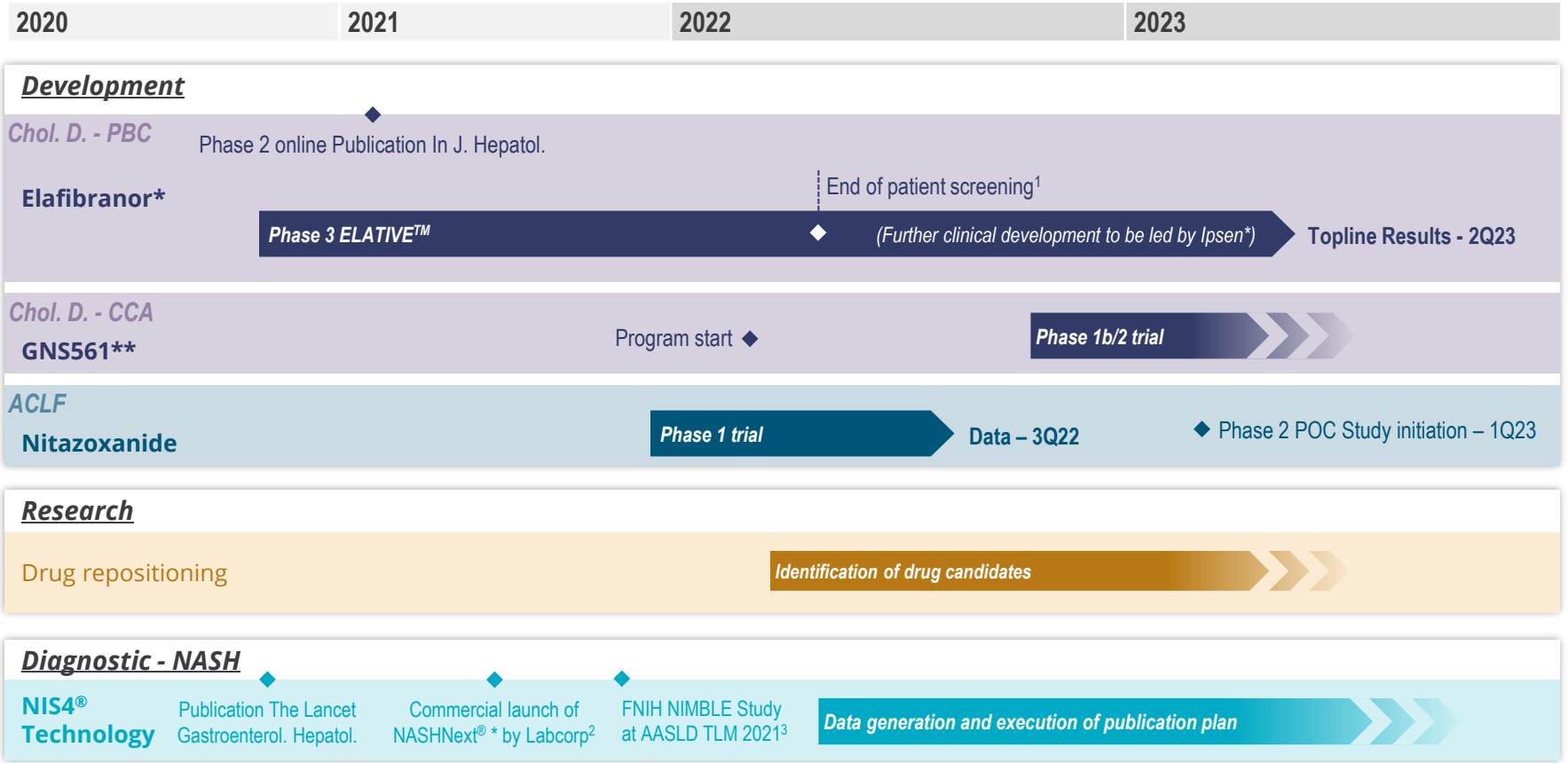
NASH Diagnostics: Accelerating Technology

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.

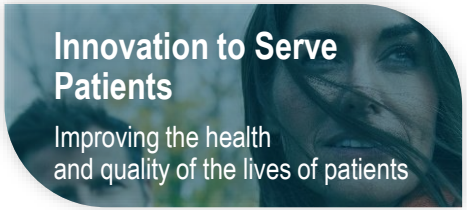
R&D Roadmap

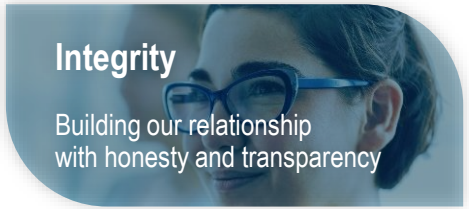


Upcoming milestones, data announcements and launch dates are anticipated and subject to change. ACLF: Acute on Chronic Liver Failure. CCA: Cholangiocarcinoma. NASH: Non-Alcoholic Steatohepatitis. PBC: Primary Biliary Cholangitis. POC: Proof-of-Concept. *Elafibranor is an investigational compound and has not been approved by any regulatory authority in any indication. Ipsen has global rights to develop and commercialize elafibranor in primary biliary cholangitis (including open-label extension, confirmatory PBC study and life cycle management), with the exception of China, Hong Kong, Taiwan, and Macau where Terns Pharmaceuticals holds the exclusive license to develop and commercialize elafibranor. **GNS561 is an investigational compound and has not been approved by any regulatory authority in any indication. GENFIT holds the exclusive rights for GNS651 in Cholangiocarcinoma in the United States, Canada and Europe. 1. **1**. Exclusive licensing to Labcorp for development and commercialization of NIS4® Technology to power a next-generation NASH diagnostic test. **2**. Sanyal et al. Hepatology. 2021 Vol 74 Issue 6 – Suppl: 1383A.

Our Core Values

Drive our Mission to be a Pioneer in the Diagnosis and Treatment of Liver Disorders





A portfolio focused on disease areas with high unmet needs and highest market potential

A recognized expertise in bringing early-stage assets into late development stages

Partners with a strong international track-record

A robust financial situation with a strong cash position

Our Strengths

Are Consolidated Everyday to Achieve our Objectives