



Corporate Presentation

Positive Results from Phase III ELATIVE[®]
Trial of elafibranor in Patients with
Primary Biliary Cholangitis

JUNE 2023

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About GENFIT

Mission & Expertise



GENFIT is a French **late-stage biopharmaceutical company** dedicated to improving the lives of patients with rare and/or severe liver diseases.



Expertise bringing early-stage assets into late development stages (*Phase 3, pre-commercialization*)



More than 20 years of expertise early stage to phase 3, with a **strong track record to develop long term collaboration**: *Ipsen, Genoscience Pharma, LabCorp, Seal Rock Therapeutics, Terns Pharmaceuticals*

Financials

- Listed on the **Nasdaq Global Select Market** and on compartment B of **Euronext's regulated market** in Paris (Nasdaq and Euronext: GNFT).
- In 2021, **IPSEN** became one of GENFIT's largest shareholders, acquiring 8% of the company's share capital.



- Cash, cash equivalents and current financial assets of **\$128.6M as of March 31, 2023**

Key information

150+
employees

800+
patents &
applications

100+
posters, abstracts, reviews,
and articles published*

- Facilities in **Lille** and **Paris**, France, **Zurich**, Switzerland, and **Cambridge**, MA, USA
- Committed continuous improvement of our **CSR performance**



United Nations
Global Compact

PAQTE



Our Mission

Our mission is to remain a **pioneer in the field of liver diseases**, *i.e.*, identify high potential assets to bring them **from discovery or early stages up to late development stages**, typically the end of Phase 3.

We capitalize on our **scientific, clinical and regulatory expertise** in the field of liver disease to build and expand a pipeline of innovative therapeutic and diagnostic solutions targeting **rare and severe liver diseases with high unmet medical** needs and representing a significant market potential in order to finance innovation to enable us to **sustain excellence in medical innovation, research and development** over time.



Our Purpose & Core Values

OUR PURPOSE

Our purpose supports our long-term commitment with regards to the role we want to play in society, not only as an economic player seeking to create long-term value for its ecosystem and partners but also as an innovative biotechnology company working to improve people's quality of life, and finally as a civic company striving to promote professional and personal development for its employees.

We intend to create general public benefit by generating a positive and significant social, societal and environmental impact through our activities. As part of this approach, our Board of Directors commits to taking into consideration (i) the social, societal and environmental consequences of its decisions on all the Company's stakeholders, and (ii) the consequences of its decisions on the environment.

OUR CORE VALUES

Our employees are driven by common principles that shape their actions.



**INNOVATION
TO SERVE PATIENTS**



**RESPECT
& DIVERSITY**



ETHICS

GENFIT 2023 EXTRA-FINANCIAL PERFORMANCE REPORT - 2022 ACTIVITY -



In 2023, we published our **Extra Financial Performance Report** to provide insight to our shareholders on our CSR policy and strategy, how we plan to meet our CSR objectives and the results obtained so far.

[Click here to download the report](#)

We Focus our R&D Efforts & Expertise on Critical Liver Diseases

Severe diseases

- Diseases are considered as severe when they exhibit significant impacts on an individual's health and well-being, and **high mortality**.
- They typically involve a high degree of intensity, seriousness, or **acuteness** in terms of symptoms, progression, or complications.
- Severe diseases often result in substantial **impairment** of bodily functions, substantial pain or discomfort, and a diminished quality of life for those affected.

Rare diseases

- Medical condition that affects a relatively small number of people in a population: US: **<200,000** individuals^{1,2} | EU: **<1 in 2,000** people^{1,2}
- 7 000 rare diseases | **400M patients** worldwide
- **95%** do not have an approved treatment

High unmet needs

- Arise when there is a **significant gap** between the existing therapies or interventions available and the level of care required to effectively manage or treat a condition.
- Several factors contribute to the classification of a medical need as "high unmet": **lack** of effective treatments, **limited** treatment options, severity of the condition or patient population.

Potentially eligible for expedited regulatory pathways provided by health authorities

There is an urgent and important need for **further research, innovation, and medical advancements** to improve the understanding, diagnosis, treatment, and management of the condition, with the ultimate goal of **addressing the unmet needs and improving patient outcomes**.

24 Years of Agile Corporate Strategy Evolution



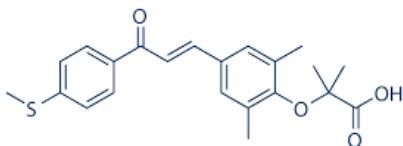
Inception & early years

1999

Development of **Research & Development know-how** via collaborations with Big Pharma*



In-house **discovery of elafibranor** (GFT505)



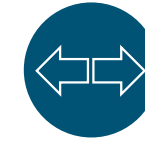
Clinical development in Non-Alcoholic Steatohepatitis (NASH)

Development of **elafibranor in NASH** up to and including Phase 3



Know-how and experience in liver diseases

- **Research** (collaborations with academia, liver disease models, spheroids, etc.)
- **Clinical** (large international trials, KOL networks, patient engagement, etc.)
- **Regulatory** (FDA/EMA interactions, etc.)



Pipeline expansion & diversification in rare/severe liver diseases with high unmet needs

Development of a diversified pipeline of innovative assets, with **4 clinical stage** and **3 preclinical stage programs****



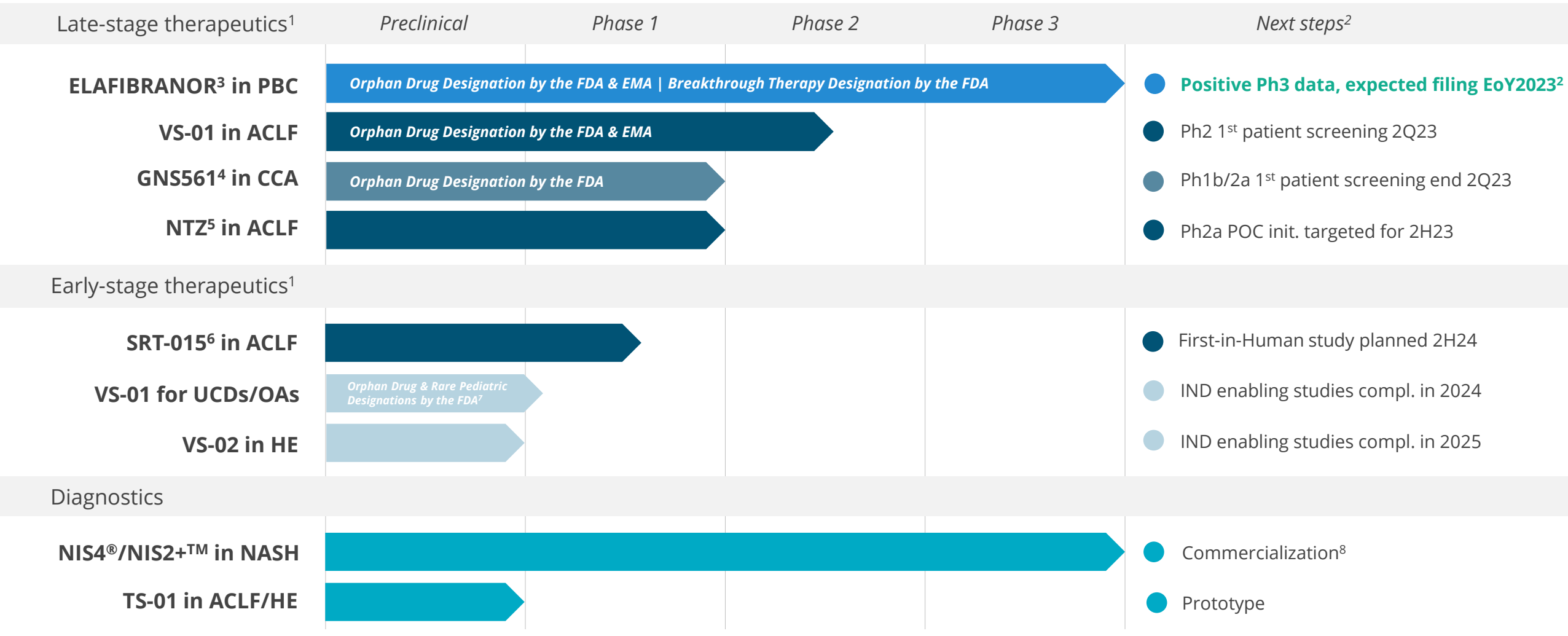
• **Primary Biliary Cholangitis (PBC)**

• **Acute on Chronic Liver Failure (ACLF)**

- Cholangiocarcinoma (CCA)
- Hepatic Encephalopathy (HE)
- Urea Cycle Disorders (UCD) & Organic Acidemias (OA)

7 Therapeutic Programs from Early to Late Development Stage

A regular **stream of clinical data** expected in the coming years



THERAPEUTICS

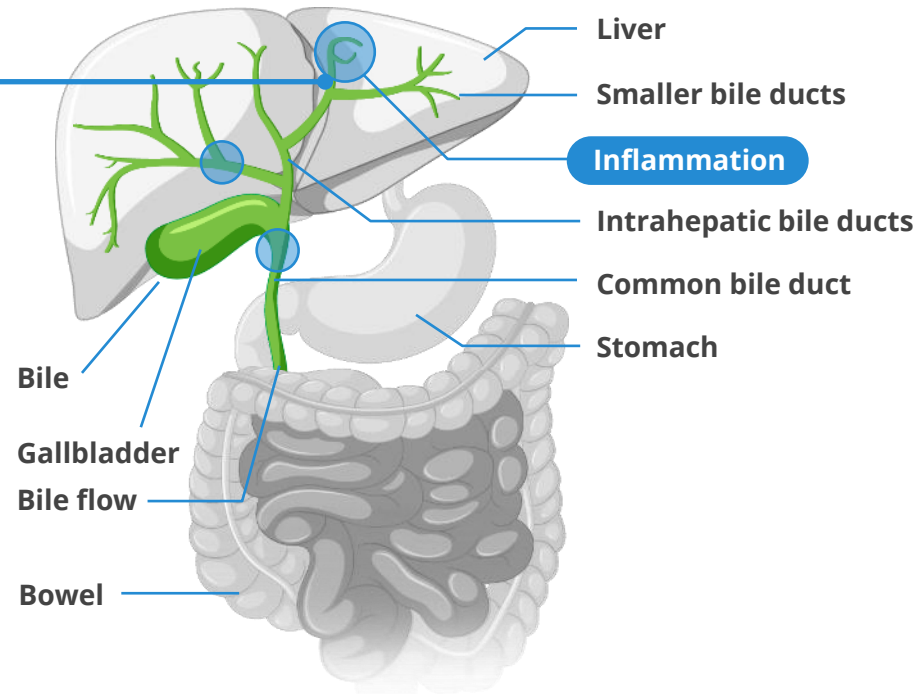
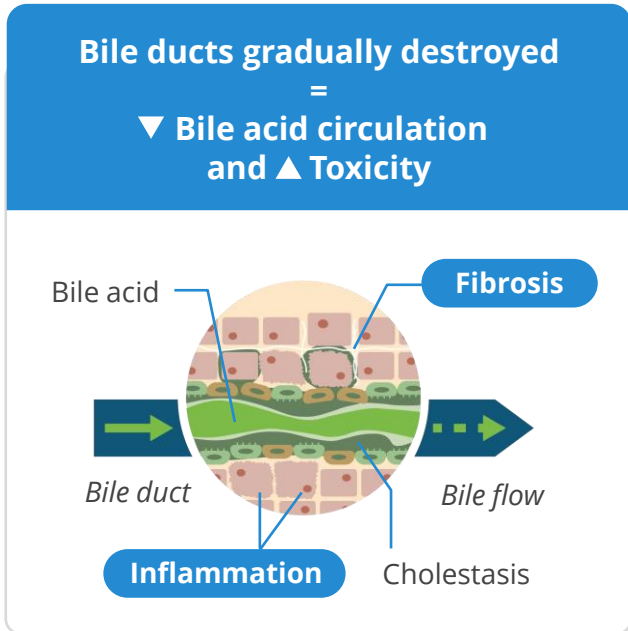
RARE DISEASES

Focus on Primary Biliary Cholangitis (PBC)



Disease State · Unmet Needs

GENFIT Program · Elafibranor in PBC



PBC in brief

PBC = rare autoimmune disease of the liver

- Causes the immune system to **mistakenly attack the bile ducts** inside and outside the liver
- Bile accumulates in the liver, contributing to tissue damage and scarring, or fibrosis, **leading to cirrhosis**
- If left untreated, may eventually cause **liver failure**
- PBC causes debilitating symptoms like pruritus and **affects patients' quality of life¹**

Unmet need

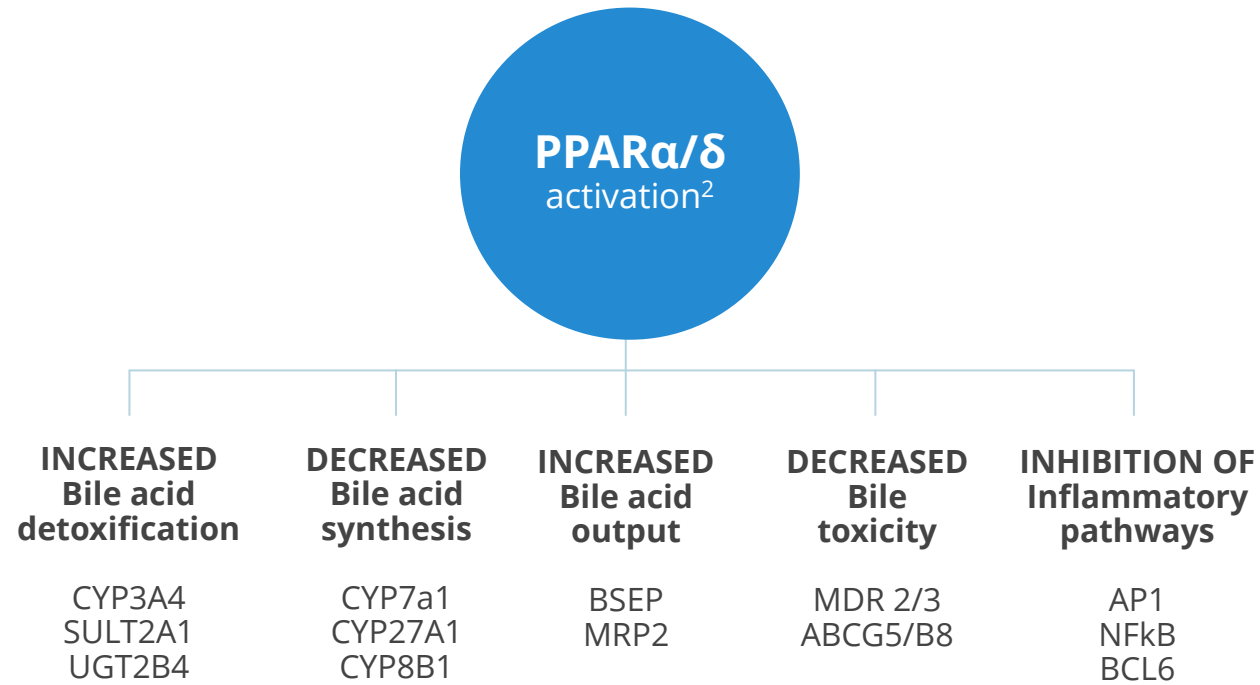
- Up to **40% of patients who take the most prescribed medication for PBC do not respond to it²**
- Amongst all PBC patients, **5-10% are not able to tolerate it²**

PBC risk factors

- 1** Of all PBC patients, **90% are female** and 10% male
- 2** Diagnosis typically occurs between **40-60 years of age**
- 3 Other:** Family history, smoking, exposure to toxins, history of UTI & other autoimmune diseases³

A Mechanism of Action Addressing Multiple Pathways

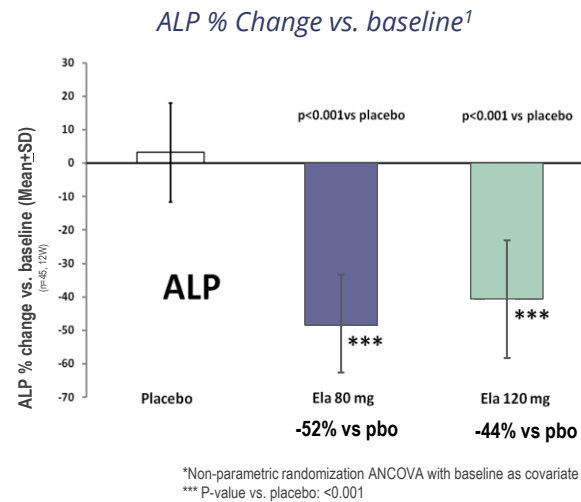
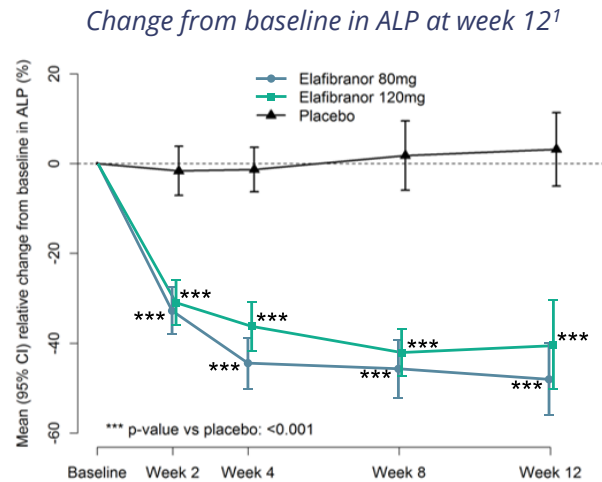
- Elafibranor is a **dual PPAR- α and PPAR- δ agonist**
- Strong mechanistic rationale for potential **benefit in cholestatic liver disease**



PPAR- α and PPAR- δ engage complementary pathways to drive potential efficacy in PBC

Compelling Results from the Phase 2b Study

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



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).

Elafibranor awarded Breakthrough Therapy designation by the FDA and Orphan Drug Designation by the FDA & EMA for PBC²

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 UDCA¹

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

Elafibranor is a **competitive 2L candidate** for PBC

Elafibranor ^{*1} Phase 2a Week 12 Data		Ocaliva ^{TM3} , Phase 3 POISE Month 12 Data	
		80mg (N=15)	Placebo (N=14)
		10mg (N=73)	Placebo (N=72)
Composite endpoint % responders, ALP<1.67 x ULN; Bilirubin and ALP reduction >15%		67% (p<0.001)	6.7%
Alkaline phosphatase (% change vs baseline)		-48% (p<0.001)	3%
Composite endpoint % responders, ALP<1.67 x ULN; Bilirubin 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 Endpoint¹. 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.

ELATIVE® – Pivotal Phase 3 Study in Patients with Primary Biliary Cholangitis

52 WEEKS

RANDOMIZED 2:1

DOUBLE BLIND

PLACEBO CONTROLLED

GLOBAL STUDY (>100 CENTERS)¹

Inclusion criteria

18-75 years old

•
Diagnosis of PBC

•
UDCA treatment for $\geq 12M$
+ stable dose for $\geq 3M$

•
Pts with inadequate response or
intolerance to UDCA (no UDCA for $\geq 3M$
before randomization)

•
If medication(s) for the management of
pruritus (stable dose for ≥ 3 months)
No mandatory liver biopsies

Number of Patients

n=150

N=100 | elafibranor (PPAR α/δ agonist) 80mg

N=50 | Placebo

Day 1

Week 52

+ 5 years extension period to be managed by
Ipsen, as per licensing agreement*

Primary Endpoint

Alkaline phosphatase (ALP) < 1.67
x Upper Limit of Normal (ULN) and Total
Bilirubin (TB) \leq ULN and ALP decrease
 $\geq 15\%$

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



GENFIT
TOWARDS BETTER MEDICINE

PRESS RELEASE

Ipsen and GENFIT Announce Positive Results from Phase III ELATIVE® trial of elafibranor in patients with primary biliary cholangitis, a rare cholestatic liver disease



IPSEN
Innovation for patient care


- Trial met primary endpoint with a statistically significant higher percentage of patients achieving a clinically meaningful cholestasis response compared to placebo
- Elafibranor was well tolerated with a safety profile consistent with previous studies
- Results position elafibranor as a potentially important new treatment option, where there is still high unmet need
- Ipsen intends to submit regulatory applications for elafibranor following discussions with the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA)


A Strong Partnership to Optimize Potential Commercialization





€120M
upfront payment


Up to €360M in
milestone payments


Tiered double-digit royalties of
up to 20%


8% shareholder
of GENFIT via equity investment
(€28M, at ~7€)


Responsibility for all additional
clinical development, including completion of the long-term extension period of the ELATIVE® trial, and global commercialization*

Phase 3 ELATIVE[®] in brief

4Q21 ● Signing of a licensing agreement with Ipsen for the global rights to develop and commercialize elafibranor



Mid-22 ● Recruitment of the last patient

2Q23 ● **Positive topline data**

EoY23 ● Expected filing*

2024 ● Expected approval/commercialization*

PBC market estimates

Potential elafibranor peak sales
\$500+ million**



Other development programs









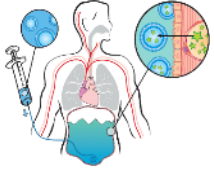


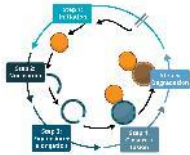
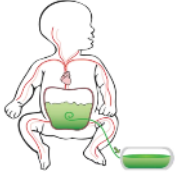
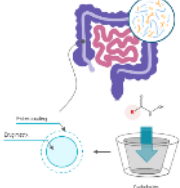
Program description · Mechanism of action

Current development phase · Available data

GENFIT pipeline | MoAs & Supporting Evidence

Expanded and **diversified pipeline in rare and severe liver diseases** with high unmet medical needs

ACLF franchise = 3 programs with complementary mechanisms of action

<p>VS-01 in ACLF</p>  <p>Potential first-in-class liposomal-based technology</p>	<p>NTZ in ACLF</p>  <p>Antibiotic and anti-inflammatory activities</p>	<p>SRT-015 in ACLF</p>  <p>Injectable formulation of ASK1 Inhibitor</p>	<p>GNS561 in CCA</p>  <p>Small molecule PPT1 inhibitor</p>	<p>VS-01 UCD/OA</p>  <p>Potential first-line peritoneal route treatment</p>	<p>VS-02 in HE</p>  <p>Urease inhibitor</p>
 <ul style="list-style-type: none"> Impact on overall liver disease severity Dose-dependent ammonia removal from the body Improvement in psychometric tests Reduction of ACLF metabolites Reduction of infection-related metabolites 	 <ul style="list-style-type: none"> Reduces LPS-induced inflammation in healthy rats Beneficial effects on liver function markers (bil, alb) in models of cirrhosis Reduces brain edema in models of ACLF (BDL) Reduces inflammation markers in models of ACLF (BDL) Improves survival in treatment models of Sepsis (CLP) In phase 1 studies, was generally well tolerated, with a favorable safety profile, in subjects with HI and RI 	 <ul style="list-style-type: none"> In kidney diseases, limits renal inflammation, apoptosis and fibrosis In liver diseases, prevents hepatocyte death, inflammation and fibrosis In brain disorders, limits neurodegeneration In inflammatory diseases, limits damaging immune responses In cardiopulmonary disease, slows the onset of heart failure 	<ul style="list-style-type: none"> Antitumor activity in human cell lines (HCC, iCCA*) Decreases tumor number and size in transgenic HCC mouse model First-in-human effects of PPT1 inhibition using GNS561/ Ezurpimtrostat in patients with primary/secondary liver cancers  <ul style="list-style-type: none"> Autophagy promotes cancer cell survival, tumor growth and treatment resistance 	 <ul style="list-style-type: none"> Potential first-line treatment for acute hyperammonemic crises Fast implementation - shorter lead time vs. SOC Gentle as less hemodynamic disturbances and no vascular access damage Administered outside the dialysis and intensive care units Ease of administration to children, allowing broader access to peripheral hospitals 	 <ul style="list-style-type: none"> Urease inhibitory activity in vitro over +15 screened hydroxamic acid derivatives Synthesis of lead candidate optimized and straightforward
<p>PHASE 1b data</p>	<p>Preclinical & PHASE 1 data</p>	<p>Preclinical & clinical data¹</p>	<p>PHASE 1b data²</p>	<p>Preclinical proof of concept</p>	<p>Preclinical proof of concept</p>

Conclusion

Positive Topline Data from Phase III ELATIVE® Trial of elafibranor in Patients with Primary Biliary Cholangitis



opportunity for near-term revenue streams (milestones payments, royalties, etc.)

A world **leadership position in ACLF**, with 3 clinical-stage assets, based on differentiated MoAs, potential for **expedited regulatory pathways**



expected to generate a **regular stream of clinical data** in the coming months/years

GENFIT – Market insights

IQVIA perspective on the commercial opportunity of GENFIT's pipeline

June 2023

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While keeping its footprint in hepatology, GENFIT is now moving to a diversified portfolio covering multiple rare liver related diseases with high unmet needs

Urea Cycle Disorders (UCDs)

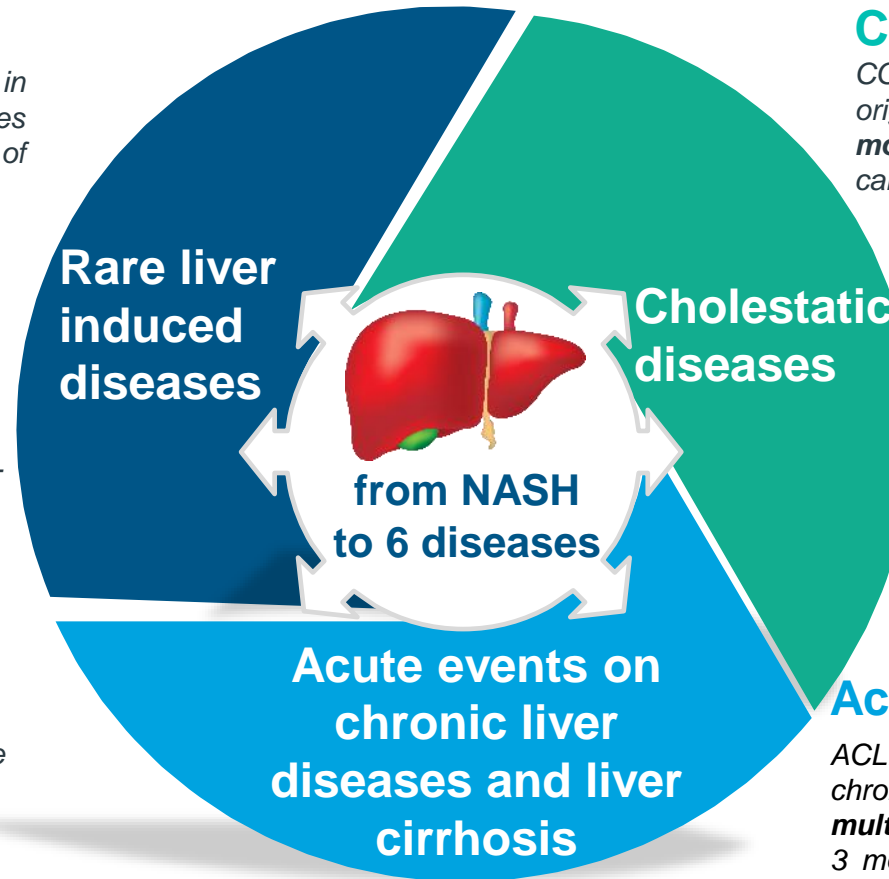
UCDs are a set of **rare inherited metabolic conditions** in which there is a **full or partial deficiency** in the enzymes of the **urea cycle**, causing a defect in the metabolism of excess nitrogen, and leading to **hyperammonemia**.

Organic Acidemias (OAs)

OADS are a spectrum of **rare inherited disorders** characterized by **enzymatic defects** in metabolism of amino-acids or some fatty acids leading to **toxic, and potentially life-threatening accumulation** of by-products

Hepatic Encephalopathy (HE)

HE is **deterioration in brain** function when liver is unable to adequately remove **toxins** from the blood. It is often associated with **cirrhosis** and potentially **fatal**



Cholangiocarcinoma (CCA)

CCA are malignancies of the biliary duct system that may originate in the liver or extrahepatic bile ducts . It is the **second most common liver cancer**, accounting for 10-20% of all liver cancers

Primary Biliary Cholangitis (PBC)

Primary biliary cholangitis (PBC) is **chronic and progressive cholestatic disease** of the liver. It is a rare autoimmune disease that can lead to **cirrhosis** if untreated

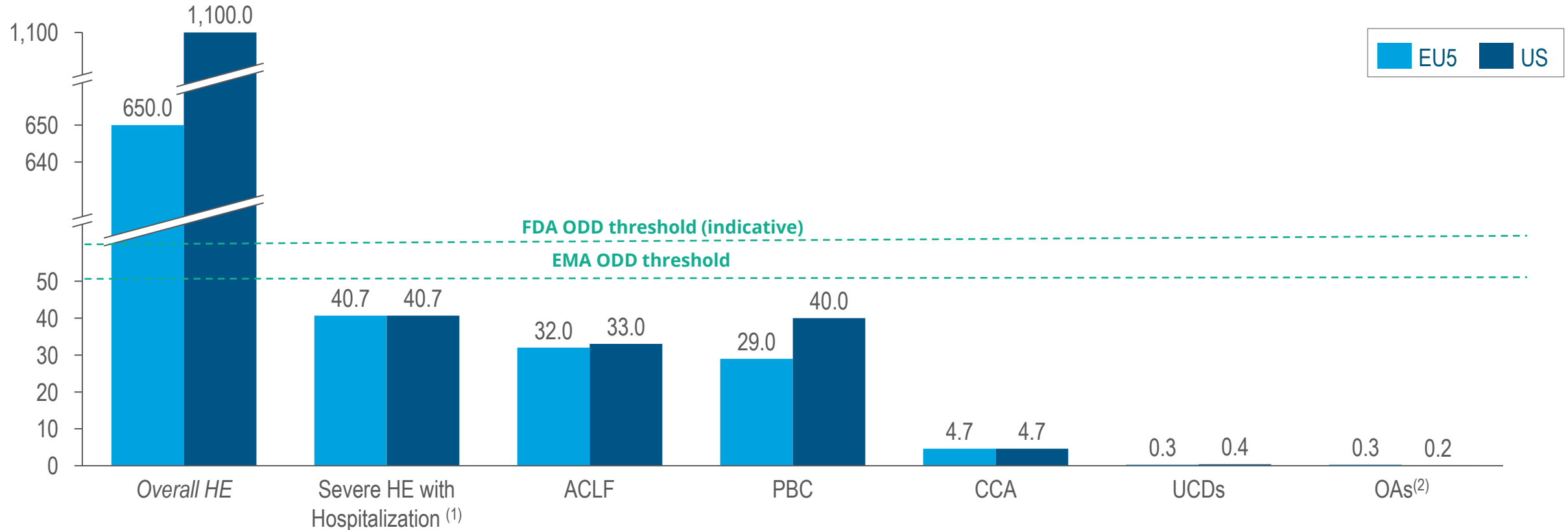
Acute on Chronic Liver Failure (ACLF)

ACLF is **acute and life-threatening** condition in patients with chronic liver disease with or without cirrhosis that may progress into **multiple organ failure** with associated **high risk of mortality** within 3 months if not treated. However, it is potentially reversible with treatment

The recent Versantis investment is transformative, creating a sustainable platform for future therapies in liver and related disorders. GENFIT's know-how and expertise in physiopathology of liver failure and dysfunction will be the driving force in this success

The six pursued indications have low prevalence and could potentially be eligible for orphan designation

Estimated current prevalence (1:100,000)



- **PBC:** Elafibranor has been granted orphan designation and breakthrough therapy designation
- **CCA:** Pemigatinib, Infigratinib and Futibatinib (FGFR2 mutation) have had accelerated approval from FDA. GNS561 granted ODD
- **UCD:** DTX301 and Pegzilarginase have been granted ODD
- **OAs:** HST-5040 granted FDA Orphan Drug, Fast Track and Rare Pediatric Disease designations for the treatment of MMA⁽²⁾ and PA⁽³⁾

Note ⁽¹⁾ Defined as the number of cirrhosis patients with HE events leading to hospitalization per year ⁽²⁾ 1:100,000 new born (<18 years old) Source: Robert S. Rahimi, MD Et Al. AJM, ⁽²⁾ methylmalonic acidemia; ⁽³⁾ PA - propionic acidemia
GENFIT - Corporate Access and Biotech Showcase during JP Morgan Healthcare Conference - January 2023

All 6 diseases have a high impact on patients' lives and high unmet needs

	Burden of disease	Unmet needs & approved therapies
HE	<ul style="list-style-type: none"> Potentially life-threatening condition Significant impairments in multiple health-related quality of life domains (sleep disturbances, functional impairments) 	<ul style="list-style-type: none"> Current approved HE treatments are associated with significant side effects and low compliance
ACLF	<ul style="list-style-type: none"> Mortality rate of 50% at 90 days High cost per hospitalization of 50k US\$ 	<ul style="list-style-type: none"> No approved treatments for ACLF
PBC	<ul style="list-style-type: none"> After development of symptoms (cholestasis), and without treatment, survival duration ranges from 5 to 12 years Associated with symptoms that impair quality of life such as fatigue and pruritus. 	<ul style="list-style-type: none"> UDCA in first line (40% suboptimal response). Only OCA in second line with contraindications
CCA	<ul style="list-style-type: none"> The prognosis is poor, with median survival of ~6 months in unresectable advanced CCA patients 	<ul style="list-style-type: none"> Despite increasing targeted therapies (e.g.: FGFR2, IDH1), many patients with advanced CCA do not initiate therapy after chemo due to lack of efficacy
OAs	<ul style="list-style-type: none"> Children are at constant risk of having episodes of decompensation and encephalopathy throughout lives and life-threatening symptoms Newborns who do not receive treatment are at risk of death 	<ul style="list-style-type: none"> No current approved therapy
UCDs	<ul style="list-style-type: none"> Symptoms like lethargy, abnormal motor function, which precedes first hyperammonemia are associated with reduction of patient's QoL 5y Mortality rate in neonatal onset UCD cases was 24% 	<ul style="list-style-type: none"> Current approved UCDs treatments are not effective or not approved for acute hyperammonemia



GENFIT has a well-balanced portfolio across disease areas with limited treatment options and lower development costs(1)

Portfolio



- **Diversified portfolio** with multiple assets and modes of action across various indications

Diseases areas



- **Six liver-related diseases** most⁽²⁾ of which are **life threatening, late-stage** with high unmet needs
- **Easy diagnosis** with standard tests

Clinical development



- **Smaller trials** (in comparison to NASH)
- **Short clinical development timelines**, leading to shorter time to inflection points

Regulatory & reimbursement



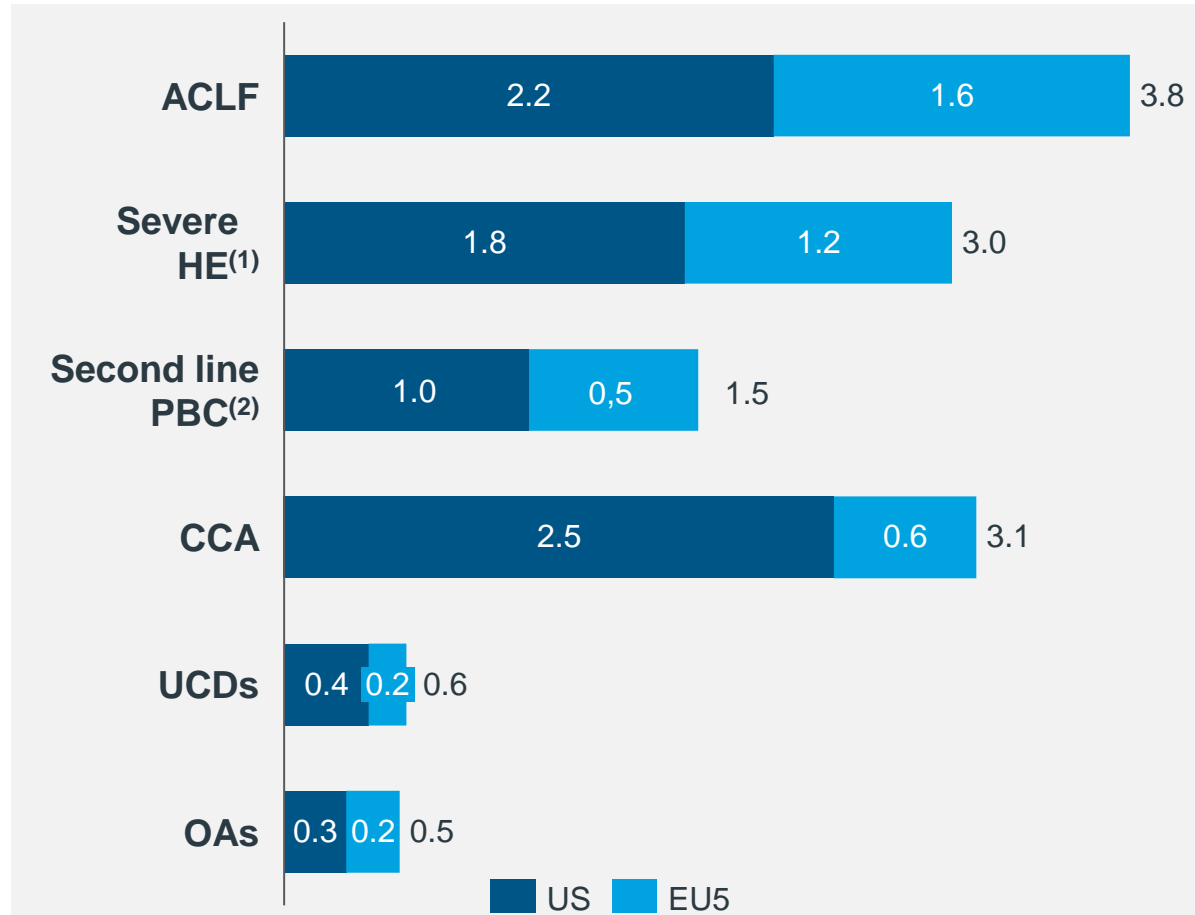
- **Potential orphan designation and accelerated regulatory pathway**
- Some are **pediatric indications** with high unmet need

Moving from one asset in NASH into pipeline of assets across several diseases

Given high unmet needs and lower prevalence, the indications may qualify for accelerated regulatory pathways and lower development costs

These 6 indications represent an overall ~12,5 bn USD market opportunity

Estimated overall market size (US+UE5) by 2030, bnUSD



Assumptions⁽³⁾

- Prevalence: 155K (EU5) / 80k (US) for grade 1 / 2 ACLF patients
- Drug price could amount to \$30-40k per patient in US in secondary prevention for ACLF1/2. With restricted subpopulation in ACLF2 for acute life-threatening event, drug price could amount up to ~\$50-150k ⁽⁴⁾

- Hospitalizations per year: 195k (EU5) / 200k (US)
- Drug price ranges: analogues in acute ICU costs would potentially range from \$15-20k in US and \$7-15k in EU5 based on economic burden of hospitalizations

- Prevalence: 52k (EU5) / 54k (US) for 40% of patients moving to 2L
- Drug gross price ranges per year: ~\$30k in EU5 in 2022 and ~\$84k in US expected to slightly evolve as competition will arise in second line

- Prevalence: 15k (EU5) / 15k (US)
- Drug price ranges per month: [\$500 – \$9k] in EU5 and [\$k – \$30k] in US

- Prevalence: 1k (EU5) / 1.3k (US)
- Drug price ranges per year: [\$500k - \$700k] in US and [\$300k - \$500k] in EU5

- Incidence in newborns: 129 (US), 198 (EU5)
- Drug price ranges per year: [\$96 – \$81k] in EU5 and [\$200 – \$300k] in US

(1) Only acute HE considered in estimations (2) Addressable market for second Line post UDCA (3) Estimation calculations include duration of treatment, potential eligibility to drug treatment, compliance rates based on analogues in rare diseases, gross-to-net price estimate depending on therapeutic area & disease (4) Acquired aplastic anemia could be a relevant analogue, treatments that include blood transfusions, stem cell transplant, immunosuppressants and bone marrow stimulants cost: approx. \$72k/patient per year
Genfit - JP Morgan presentation - January 2023

Conclusion



Novel mechanisms of action

- **Elafibranor**: only asset targeting both PPAR α/δ receptors for PBC
- **VS-01**: First-in-class liposomal-based technology
- **VS-02**: novel urease inhibitor bringing a unique oral and colon active formulation for HE
- **GNS561**: novel MoA with autophagy inhibition for CCA



Potential expedited approval pathways

- **Orphan drug designation** granted for elafibranor in PBC (FDA/EMA), VS-01 in ACLF (FDA) and GNS561 in CCA (FDA)
- **Breakthrough therapy designation** (elafibranor in PBC)
- **Rare pediatric disease designation** (VS-01 in UCDs & OAs)
- Potential **priority review voucher** (VS-01 in UCDs & OAs)



Sizable commercial opportunity

- **~12,5 bn USD** cumulative market across all disease areas
- Limited competitive intensity in OAs, UCD and ACLF



We thank you for
your attention

JUNE 2023