IPSEN
Innovation for patient care

Investor and analyst call

Expanding the scope in Rare Disease

17 December 2021

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- All medicine names listed in this document are either licensed to Ipsen or are registered trademarks of Ipsen or its partners.
- The implementation of the strategy has to be submitted to the relevant staff representation authorities in each country concerned, in compliance with the specific procedures, terms and conditions set forth by each national legislation.
- In those countries in which public or private-health cover is provided, Ipsen is dependent on prices set for medicines, pricing and reimbursement-regime reforms and is vulnerable to the potential withdrawal of certain medicines from the list of reimbursable medicines by governments, and the relevant regulatory authorities in its locations. In light of the economic impact caused by the COVID-19 pandemic, there could be increased pressure on the pharmaceutical industry to lower medicine prices.
- Ipsen operates in certain geographical regions whose governmental finances, local currencies or inflation rates could erode the local competitiveness of Ipsen's medicines relative to competitors operating in local currency, and/or could be detrimental to Ipsen's margins in those regions where Ipsen's sales are billed in local currencies.
- In a number of countries, Ipsen markets its medicines via distributors or agents; some of these partners' financial strengths could be impacted by changing economic or market conditions, including impacts of the COVID-19 pandemic, potentially subjecting Ipsen to difficulties in recovering its receivables. Furthermore, in certain countries whose financial equilibrium is threatened by changing economic or market conditions, including impacts of the COVID-19 pandemic, and where Ipsen sells its medicines directly to hospitals, Ipsen could be forced to lengthen its payment terms or could experience difficulties in recovering its receivables in full.
- Ipsen also faces various risks and uncertainties inherent to its activities identified under the caption 'Risk Factors' in the Company's Universal Registration Document.
- All of the above risks could affect Ipsen's future ability to achieve its financial targets, which were set assuming reasonable macroeconomic conditions based on the information available today.

Speakers

David Loew
Chief Executive Officer

Aymeric Le Chatelier
Chief Financial Officer

Howard Mayer
Head of Research and Development

Agenda

01 **Strategic rationale**

David Loew

02 **The science: elafibranor**

Howard Mayer

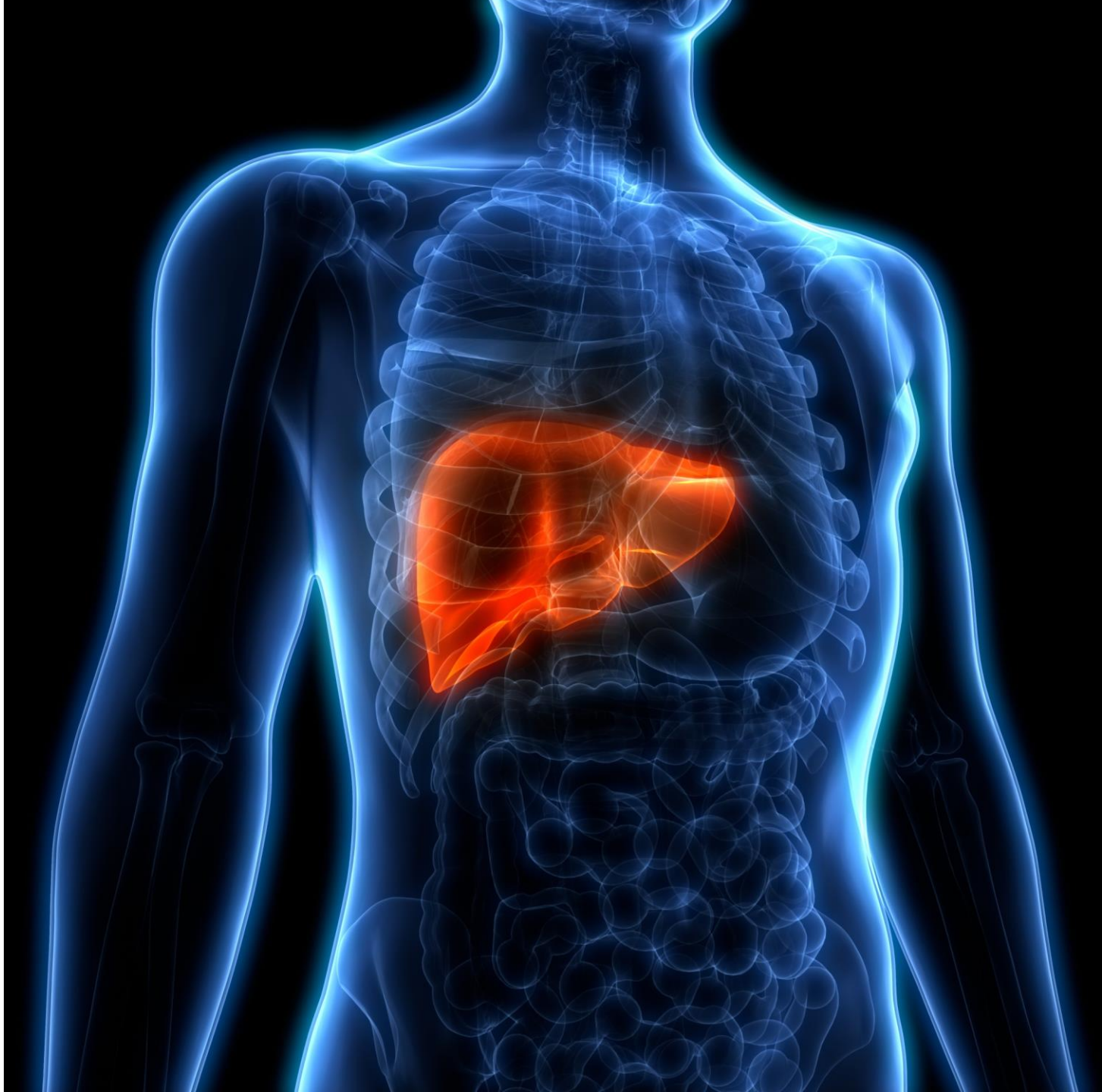
03 **Financials**

Aymeric Le Chatelier

04 **Questions**

Strategic rationale

David Loew



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Strong execution of the external-innovation strategy

Seven transactions completed in 2021: across the therapeutic areas

Accent Therapeutics METTL3	BAKX Therapeutics BKX-001	Queen's University FLIP-inhibitor program
Preclinical	Preclinical	Preclinical

GENFIT elafibranor
Phase III

IRLAB mesdopetam	Exicure Spherical Nucleic Acids	BCH/UOS BoNT/X
Phase II	Preclinical	Preclinical

BCH: Boston Children's Hospital; **UOS**: University of Stockholm; **BoNT/X**: a novel botulinum toxin serotype.

Today’s announcement: late-stage Phase III

A transaction central to expanding the scope in Rare Disease

Rare Disease

Elafibranor: in Phase III development for 2L PBC - data anticipated in 2023

Expands Ipsen’s position in Rare Disease
with a late-stage clinical asset in rare hepatic disorders with high unmet medical need

Exclusive worldwide licence[1]
to develop, manufacture and commercialize elafibranor: significant commercial potential

Compelling Phase II data
plus Breakthrough Therapy and Orphan Drug Designations

A first-in-class, innovative potential treatment option to help the PBC community

Access[2] to future programs led by GENFIT

1. Excludes China, Taiwan, Hong Kong and Macau. 2. Right of first negotiation. **2L**: second line; **PBC**: primary biliary cholangitis.

The science: elafibranor

Howard Mayer

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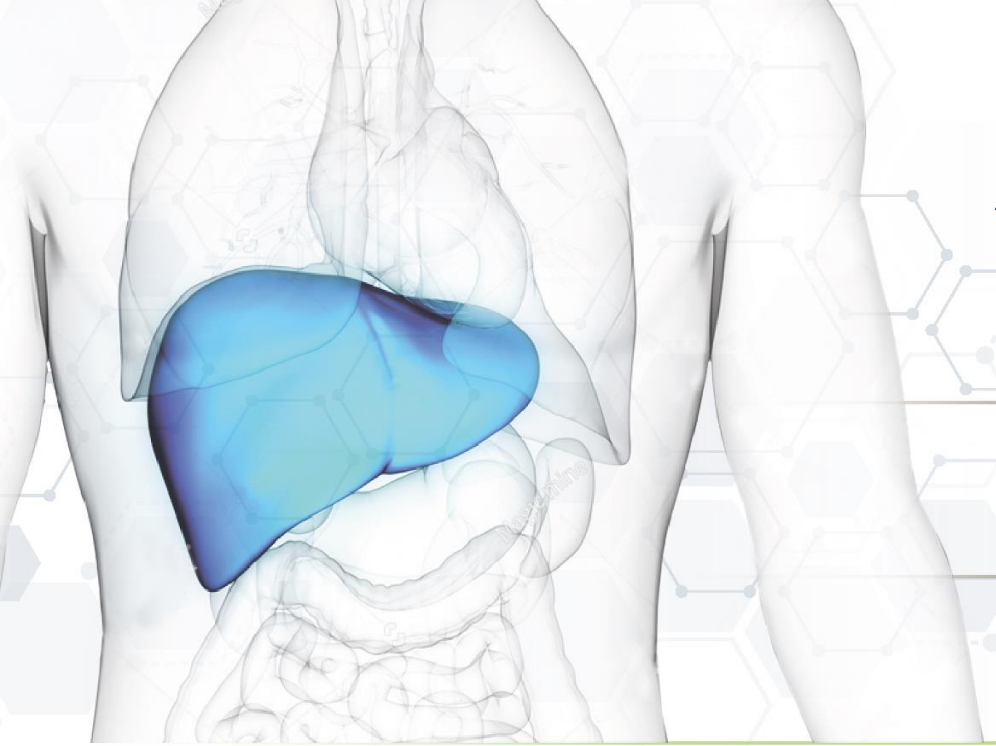
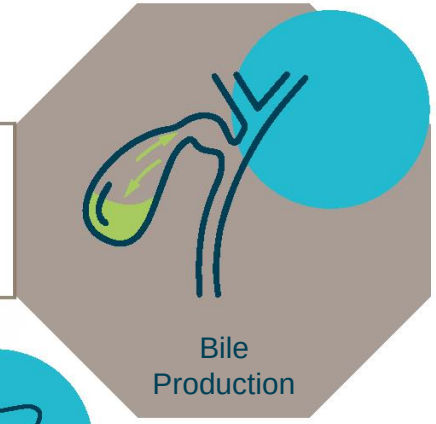


PBC

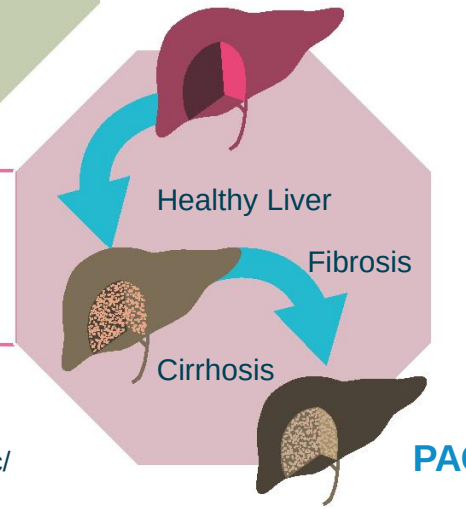
A rare, chronic autoimmune disease of the liver[1]

Bile is a liquid produced inside the liver to help digest fats and remove waste products from the body[2]



PBC leads to a slow, progressive destruction of the small bile ducts of the liver, causing bile and other toxins to build up in the liver (known as cholestasis)[1]

Further damage can lead to scarring, fibrosis and eventually cirrhosis of the liver[1]



1. Kimagi T, Heathcote EJ. Orphanet J Rare Dis. 2008; 3:1.
2. NHS. Primary Biliary Cirrhosis.https://www.nhs.uk/conditions/primary-biliary-cirrhosis-pbc/

The importance of PBC treatment options

Improving the lives of people living with rare conditions

A high unmet medical need

PBC impacts patient's daily lives through debilitating symptoms (fatigue, itching), jaundice and progressive liver damage (liver fibrosis, cirrhosis and liver failure)[1]

Untreated, it can result in liver failure, transplant or death

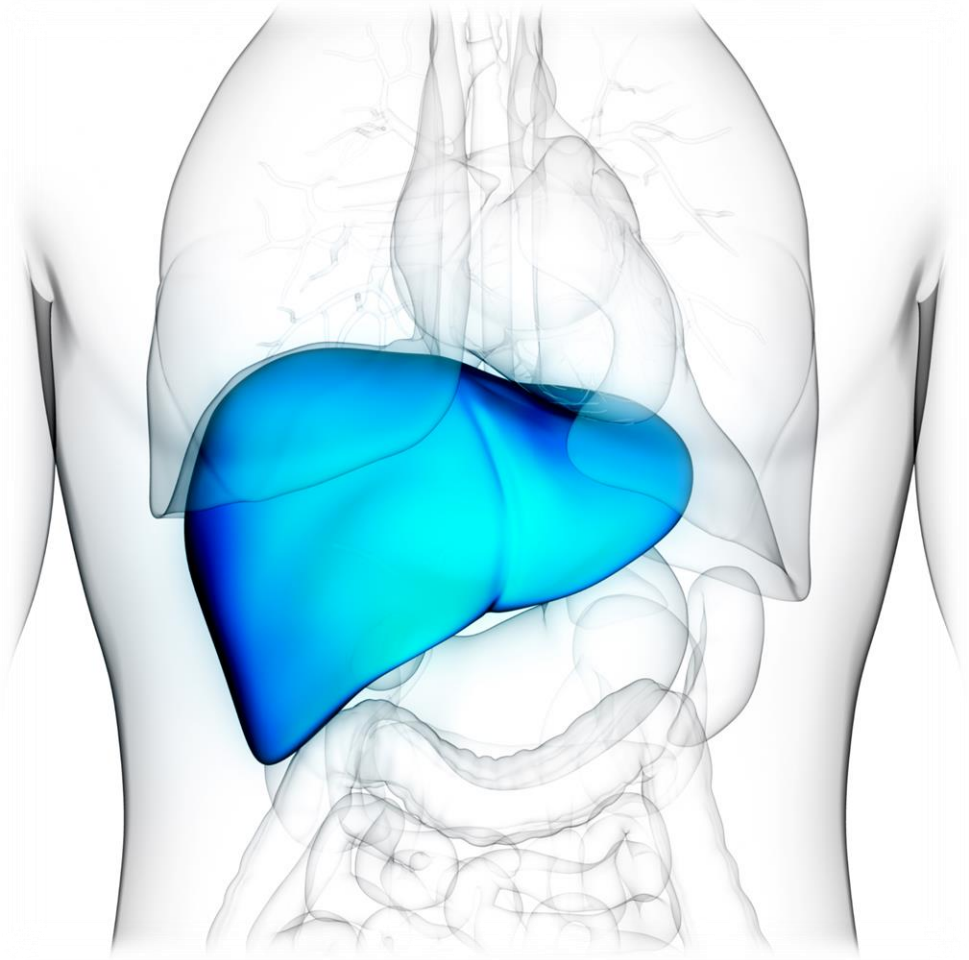
Serologic hallmark of PBC is the antimitochondrial antibody, a highly disease-specific autoantibody found in 90-95% of patients and less than 1% of controls

Higher incidence in women, and a leading cause of liver transplantation

The prevalence of people living with PBC in the US is estimated to be between 23.9-39.2 per 100,000[2, 3]

1. EASL Guidelines. Journal of Hepatology 2017 vol. 67 j 145–172
2. Lu et al Clinical Gastro and Hepatol 2018; 16:1342-1350
3. Galoosian et al. Journal of Clinical and Transplantation Hepatology 2020; 8:49-60

Treatment options: PBC



First line

Backbone: UDCA (13-15 mg/kg/day): not curative

Generally safe, may improve clinical symptoms, delay progression and improve quality of life

1L in treatment-naïve patients since 1999:
30-40% non-responders
5% intolerant (GI effects)

Second line

Obeticholic Acid: approved therapy

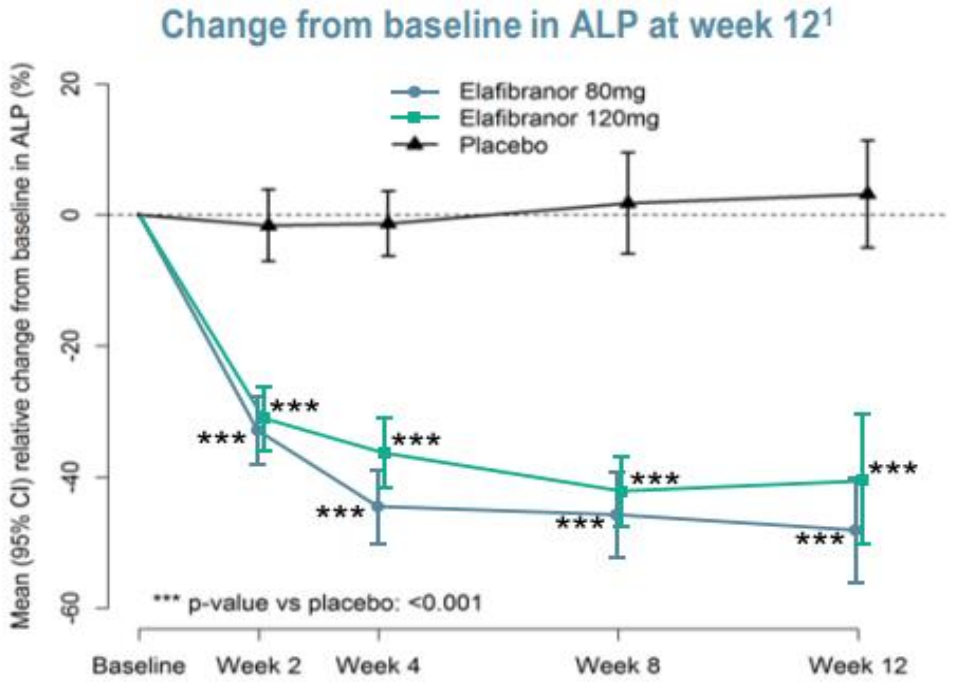
Boxed warning for hepatic decompensation and failure.
Warning for severe pruritis[1]

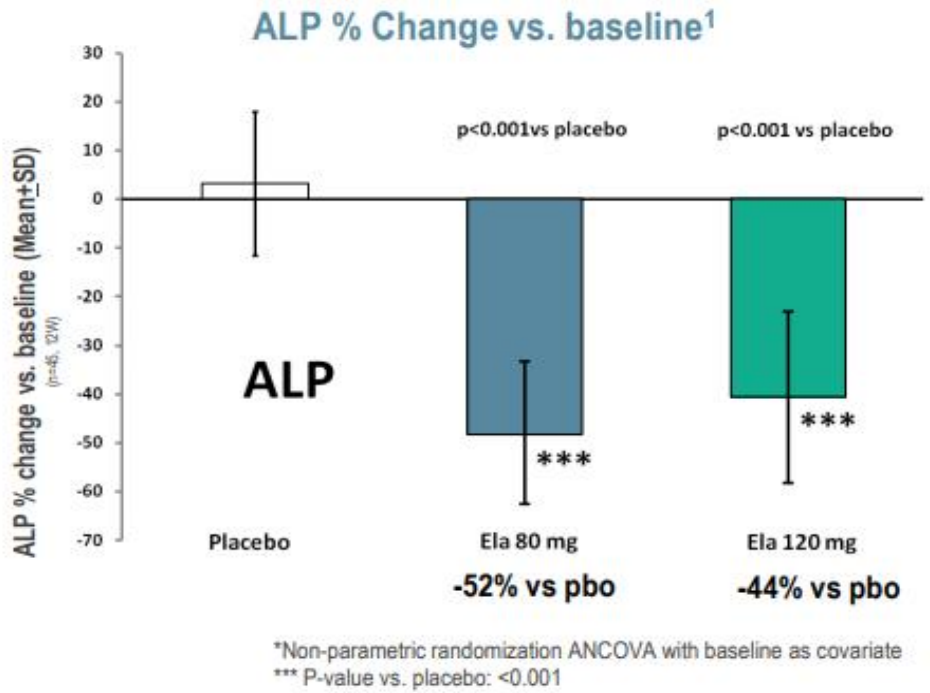
1. Itching. **UDCA**: ursodeoxycholic acid; **1L**: first line.

Elafibranor as a potential treatment for PBC

Clinical development – Phase II

Statistically significant treatment effects in both 80mg and 120mg doses on the primary endpoint (confirmed in mITT* set) of serum ALP change from baseline





mITT: modified intention to treat; **ALP**: alkaline phosphatase. Note:* mITT (all subjects with 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 = placebo (N=15), elafibranor 80mg (N=14), elafibranor 120mg (N=15).

References:1. Schattenberg et al. J. of Hepatol. 2021;Vol. 74, Issue 6:1344-1354.

Elafibranor as a potential treatment for PBC

Clinical development – ELATIVE Phase III trial in PBC

Placebo: N=50

Elafibranor (PPAR α/δ agonist) 80mg: N=100

Design

A randomized 2:1, double blind, placebo-controlled, global trial followed by an open-label long term extension

Evaluation

Evaluating the efficacy and safety of elafibranor 80mg in patients with PBC with an inadequate response or intolerance to UDCA

Primary Endpoint

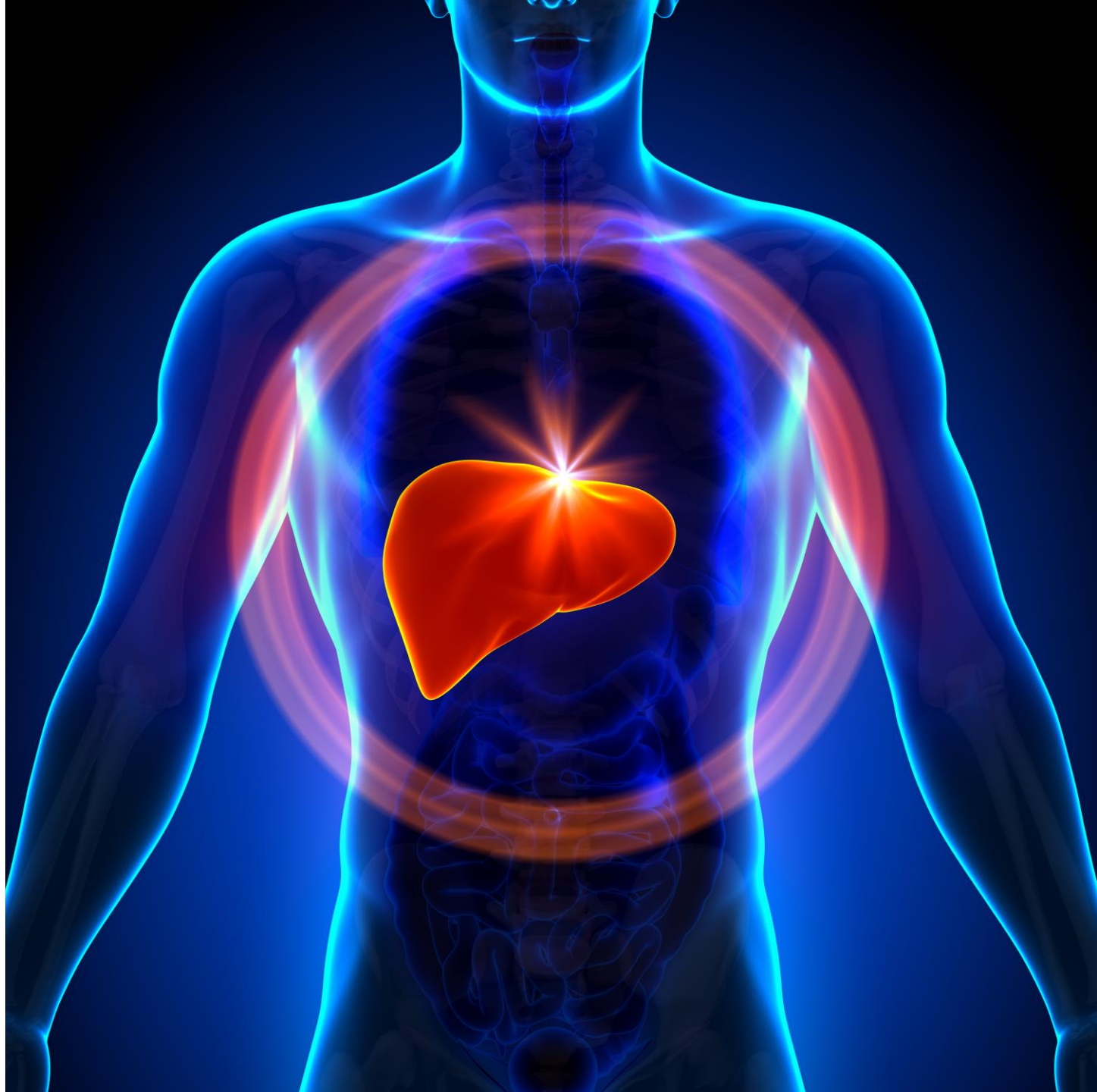
Response to treatment defined as ALP < 1.67 x ULN and Total Bilirubin ≤ ULN and ALP decrease ≥ 15 percent

Data anticipated in 2023
A pathway to Accelerated Approval

ULN: upper limit normal. NCT04526665.

Financials

Aymeric Le Chatelier



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Financials

Transaction aligned to strategy

Commitment to invest in R&D supported by SG&A efficiencies

Lower SG&A costs
as a % of total sales
- driven by focus & optimization

Higher R&D costs
as a % of total sales
- driven by external-innovation strategy

€3bn cumulative firepower for pipeline expansion by 2024

Excludes the sale of any assets

Based on net debt below
2.0x EBITDA

Financials

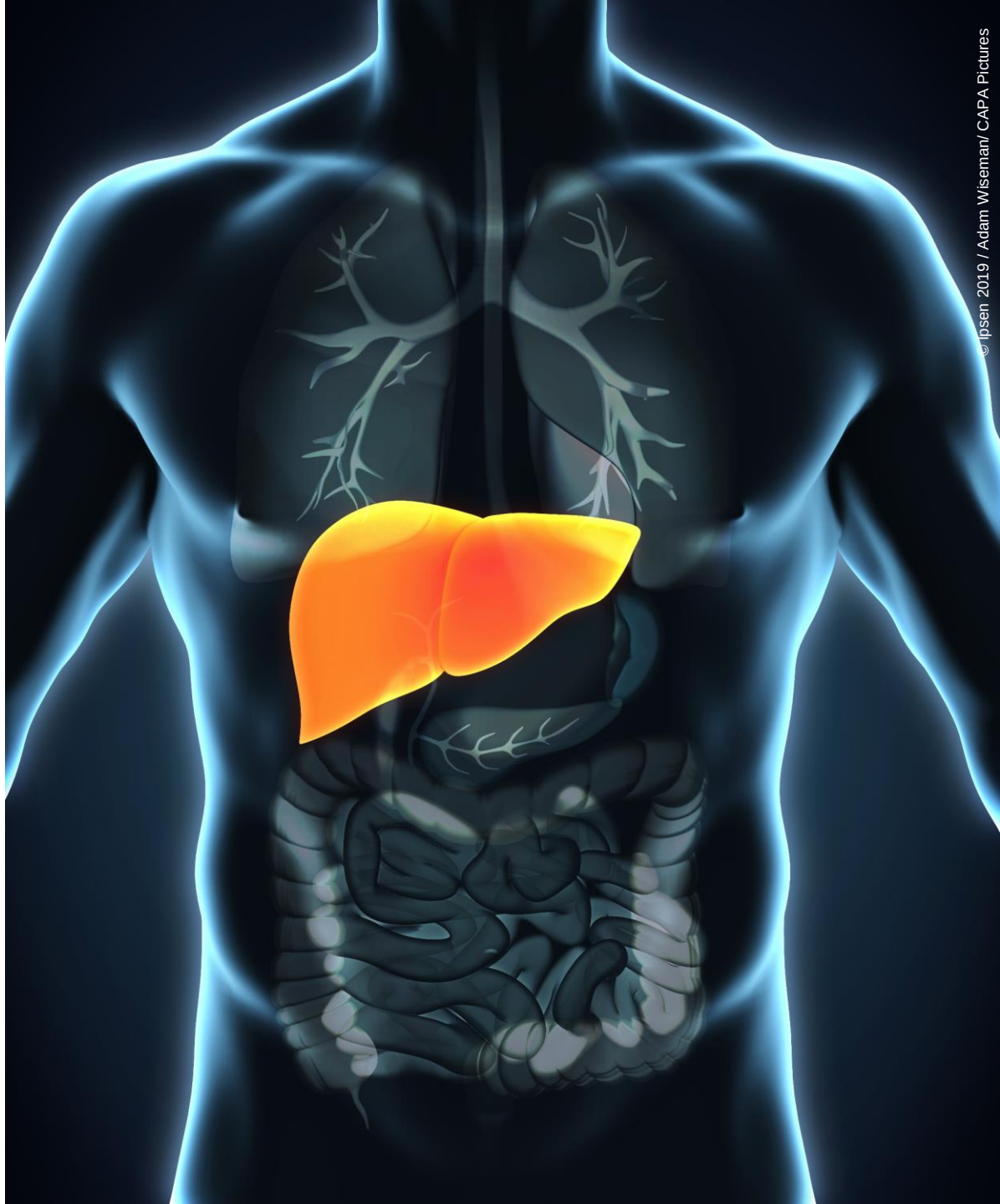
Transaction aligned to strategy

Upfront payment of €120m	Anticipated **peak sales** of around €500m
Regulatory, commercial, and sales-based **milestone payments**: up to around €360m	Expected **dilution** over the near term from R&D and pre-launch expenses
Double-digit **royalties** of up to 20%	No material impact on funding available for **further transactions**
Equity investment of €28m representing an 8% shareholding of GENFIT	

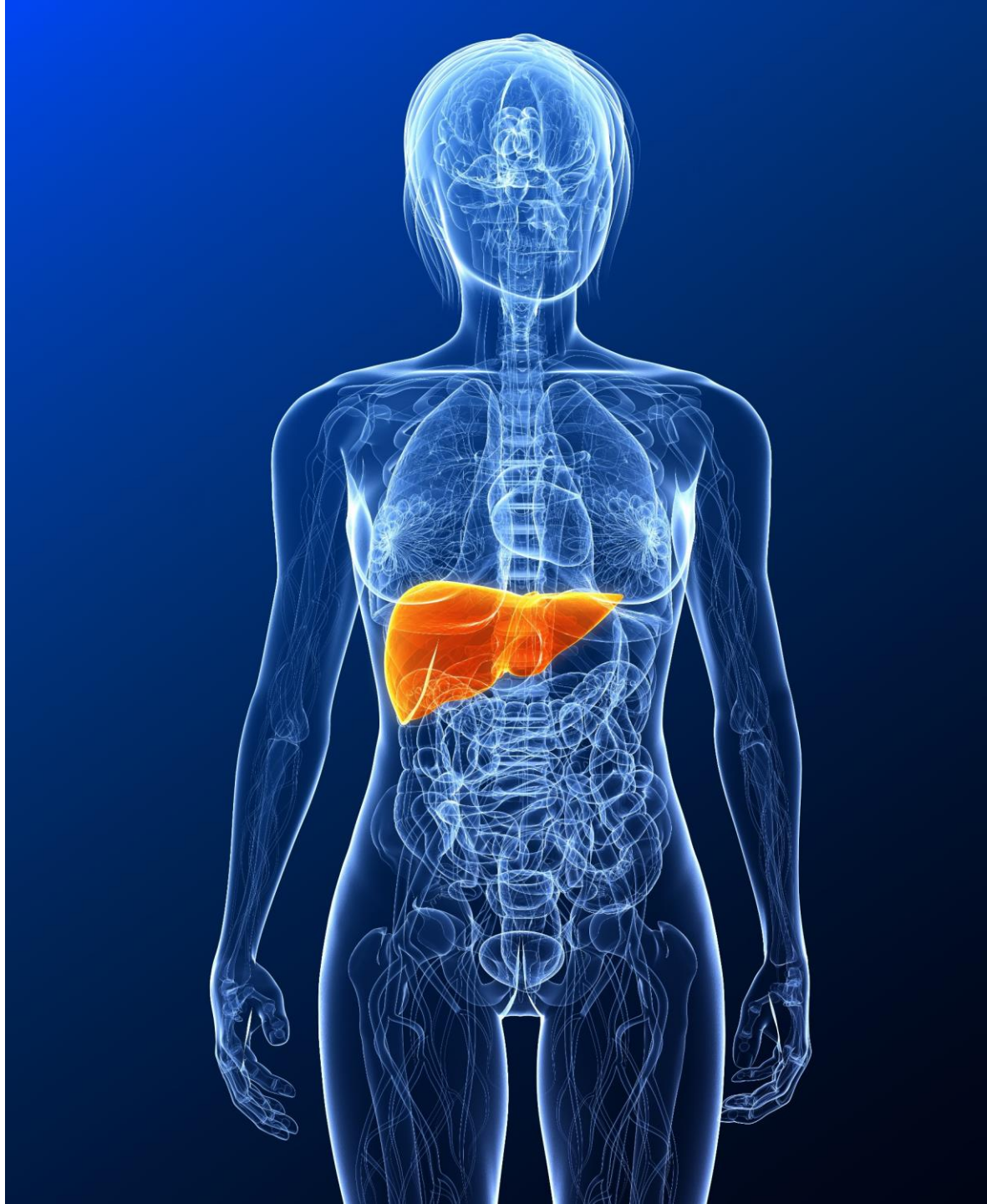
In line with medium-term outlook and strategic focus on building the pipeline through external innovation

Conclusion

David Loew



Questions



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THANK YOU

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