GENFIT
TOWARDS BETTER MEDICINE

ACLF Day

NOVEMBER 11, 2023 - Boston, U.S.
DECEMBER 12, 2023 - Paris, FRANCE

Corporate Presentation

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In addition, even if the Company's results, performance, financial condition and liquidity, and the development of the industry in which it operates are consistent with such forward-looking statements, they may not be predictive of results or developments in future periods. These forward-looking statements speak only as of the date of publication of this document. Other than as required by applicable law, the Company does not undertake any obligation to update or revise any forward-looking information or statements, whether as a result of new information, future events or otherwise.

Towards a new GENFIT

Pascal PRIGENT, CEO

- ACLF disease state
- GENFIT's approach to ACLF
- ACLF market opportunity
- Highlights on newsflow

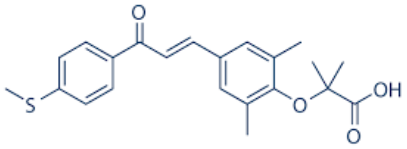
Towards a new GENFIT

Inception & early years

1999

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

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



Clinical development in chronic liver diseases

Today

Development of **elafibranor in NASH/MASH**[1] up to Phase 3 included

Positive 52-week ELATIVE Phase 3 trial evaluating **elafibranor in PBC**

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.)

Pivoting to rare and life-threatening liver diseases with high unmet needs

2023

A **diversified pipeline** in **ACLF** (5 programs) and **other life-threatening diseases** (2 programs)

- Acute on Chronic Liver Failure (ACLF)
  - **VS-01 (Phase 2 initiated)**
  - **NTZ (Phase 2 under preparation)**
  - **SRT-015** *(preclinical)*
  - **CLM-O22** *(preclinical)*
  - **VS-02-HE** *(preclinical)*
- Other life-threatening liver diseases
  - **GNS561 (Phase 2 initiated)**
  - **VS-01-HAC** *(preclinical)*

Potential future milestone payments and royalties from PBC[2] to partially fund pipeline development

- **Cash position:** $94M as of Sept 30, 2023
- Eligible for up to **$360 million** in milestone payments and tiered double-digit royalties under Ipsen agreement[2]

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1: NASH now called MASH, standing for **metabolic dysfunction-associated steatohepatitis**

2: https://ir.genfit.com/news-releases/news-release-details/genfit-ipsen-and-genfit-enter-exclusive-licensing-agreement

2024 Outlook Following Acceptance of Elafibranor Filings in PBC in U.S./EU

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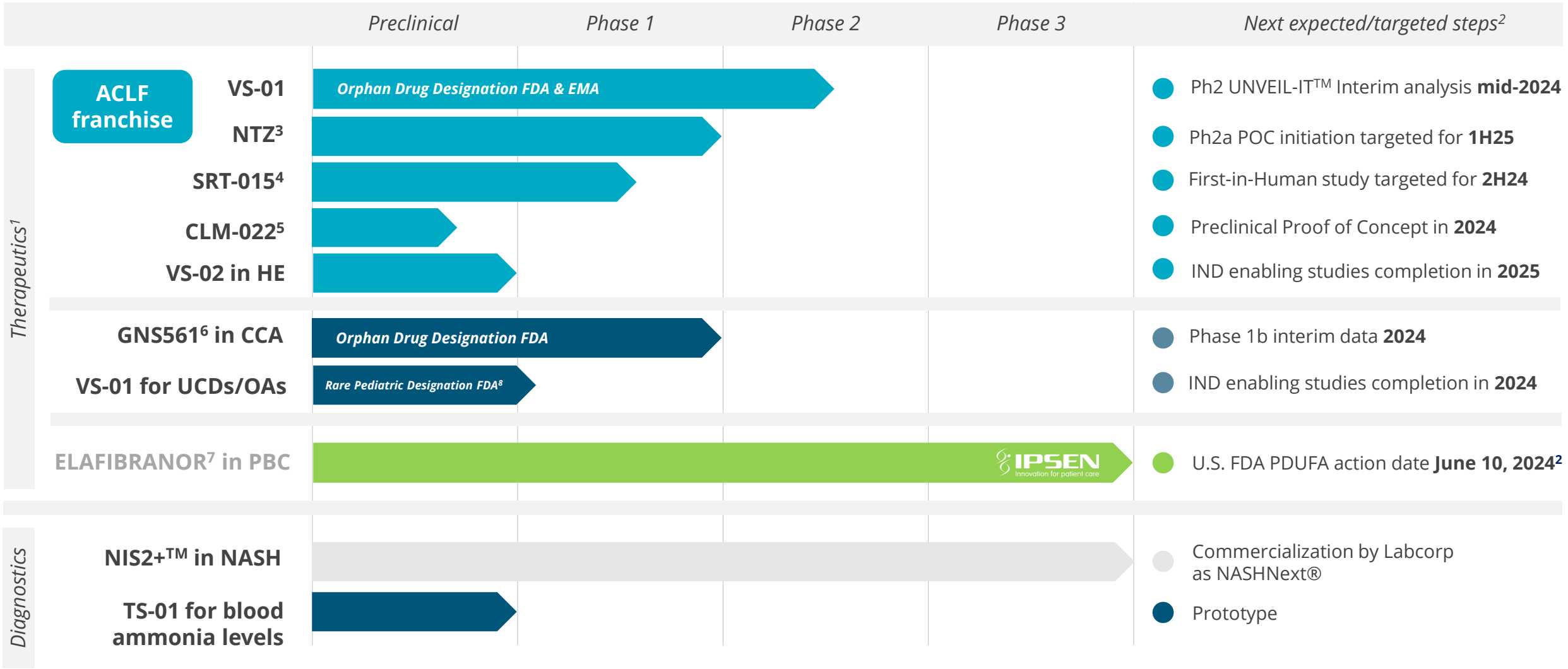
PRESS RELEASE

GENFIT Updates 2024 Outlook Following Acceptance of Elafibranor Filings in Primary Biliary Cholangitis (PBC)

- US Food and Drug Administration (FDA) has granted Priority Review for New Drug Application (NDA) for elafibranor in PBC, and European Medicine Agency (EMA) has also validated the Marketing Authorization Application (MAA) for elafibranor.
- Acceptance triggers a first milestone payment. Further milestones are expected upon US and European launches which could now happen in 2Q24 in the US (FDA PDUFA[1] action date: June 10, 2024) and 2H24 in Europe. These milestones total approximately 89M€.
- Launches in the US and Europe will also make GENFIT eligible for royalty payments.
- Revenues will fund the development of GENFIT's pipeline, now mainly focused on Acute On-Chronic Liver Failure (ACLF) with 5 differentiated assets.

- Regulatory filings U.S. and Europe
  - **<6 months** after topline data
- Expected launch of elafibranor in the U.S.
  - **Priority Review** granted by U.S. FDA
  - FDA PDUFA set to **June 10, 2024**
- Financial implications for GENFIT
  - Expected milestones of approx. **89M€ by the end of 2024**
- PBC market
  - **$1.5bn by 2030** *(source Ipsen Capital Market Day December 7, 2023)*
- Global annual peak sales of elafibranor
  - **Expected to exceed >500M$** *(source Ipsen Capital Market Day December 7, 2023)*

Pipeline



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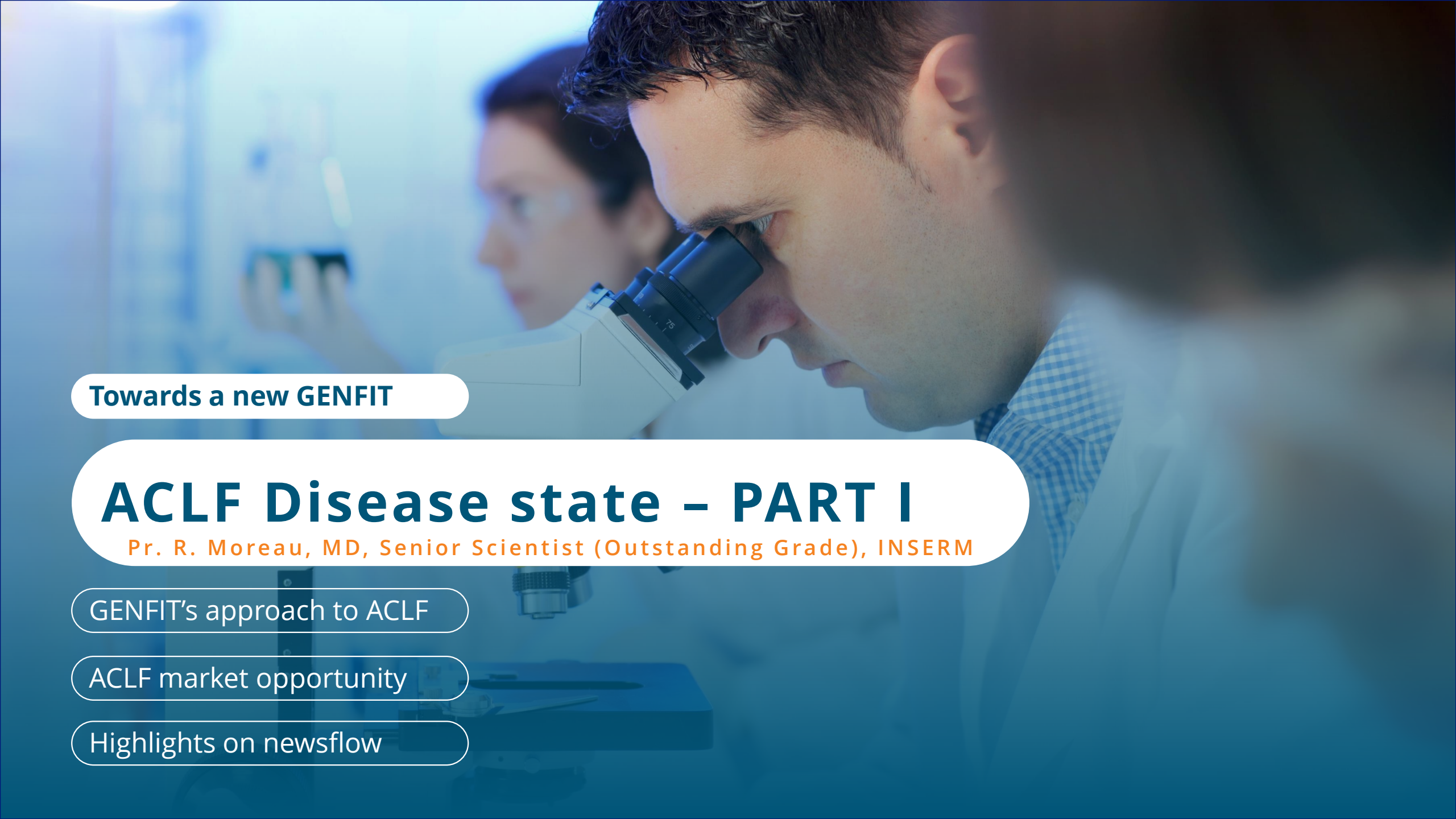
1. All drugs under development are investigational compounds that have not been reviewed nor been approved by a regulatory authority in targeted indications
2. https://ir.genfit.com/news-releases/news-release-details/ipsen-confirms-us-fda-grants-priority-review-new-drug
3. Repositioned molecule (Nitazoxanide)
4. In-licensed from Seal Rock Therapeutics
5. In-licensed from Celloram
6. In-licensed from Genoscience Pharma
7. Out-licensed to Terns Pharmaceuticals and Ipsen Pharmaceuticals
8. Potentially eligible for priority review voucher upon approval by the FDA



Towards a new GENFIT

ACLF Disease state – PART I

Pr. R. Moreau, MD, Senior Scientist (Outstanding Grade), INSERM

- GENFIT's approach to ACLF
- ACLF market opportunity
- Highlights on newsflow

Professeur Richard Moreau, Founding Member of EF-CLIF and Worldwide Leader in ACLF

RICHARD MOREAU

Senior Scientist, Directeur de Recherche de Classe Exceptionnelle (DRCE) à l'INSERM (French NIH)

FRANCE

City: Paris

Institution: UMR_S 1149, Centre de Recherche sur l'Inflammation CRI

Contact: richard.moreau@inserm.fr

BIOGRAPHY OF RICHARD MOREAU

Dr. Richard Moreau, Senior Scientist, Vice-Chairman of the Center for Research on Inflammation, INSERM, Paris Diderot University and Cnrs, Paris, France

Dr. Richard Moreau is: 1) Senior Scientist (Outstanding Grade) at the French NIH (INSERM); 2) Vice-Chairman of the Centre of Research on Inflammation (CRI, Paris, France), endorsed by the French NIH (INSERM), Paris Diderot University, and Cnrs; 3) Consultant in Hepatology at the Liver Unit at Beaujon Hospital, Assistance Publique Hôpitaux de Paris, Clichy, France; 4) Adjunct Professor at the Institute of Liver and Biliary Sciences (ILBS), New Delhi, India; 5) Advisor for Hepatology at the INSERM' Institute "Pathophysiology, Metabolism, Nutrition"; 6) Deputy Director of the Grifols Chair for Translational Research at the European Foundation for the Study of Chronic Liver Failure (EF Clif), Barcelona, Spain.

His main research interest is pathophysiology and treatment of complications of cirrhosis, in particular acute-on-chronic liver failure (ACLF). He was responsible for the fact that France was the first country in the world to approve terlipressin as a first-line treatment for hepatorenal syndrome. Because of his interest for end-stage liver disease. In 2009, he was among founding members of the EASL-Chronic Liver Failure (CLIF) Consortium which includes now 90 European Centers and is dedicated to develop research on cirrhosis. He was PI of the first study (called CANONIC study) performed under the umbrella of the EASL-CLIF Consortium; this study was the first to provide an evidence-based definition for ACLF.

He is now Senior Editor of Journal of Hepatology (2015-19). He has been Associate Editor for Journal of Hepatology (2010-14) and Liver International (2007-9).

His scientific production consists of 318 Peer-Reviewed publications (PubMed, November 2017), of which 222 Original Articles, 96 Review Articles or Editorials; his h-index is of 63; his SIGAPS score (French score) is 4497.

He was Editor of 1 book and 34 book chapters

He gave 242 Invited lectures (70% outside France), 300 communications in International meetings.

ACLF Day

December 12, 2023

Acute-on-Chronic Liver Failure (ACLF)

Richard Moreau, MD, FAASLD,[1,2,3]

[1]European Foundation for the Study of Chronic Liver Failure (EF CLIF), Barcelona, Spain;

[2]Centre de Recherche sur l'Inflammation (CRI), INSERM, Université Paris Cité, CNRS, Paris, France;

[3]Service d'hépatologie, Hôpital Beaujon, APHP, Cichy, France.

Outline

- Cirrhosis & ACLF
- Defining ACLF
- Pathophysiology
- Medical management
- Liver transplantation
- Unmet needs

Cirrhosis

- **11th most common cause of death**
  - 2 million deaths worldwide/year (~4% of deaths worldwide)
- **2 billion consume alcohol**
  - At risk for alcohol-associated cirrhosis
- **2 billion overweight/obese**
  - At risk for metabolic-associated cirrhosis

Asrani et al. J Hepatol 2019;70:151-71. Devarbhavi et al. J Hepatol 2023;79:516-37.

Characteristics of Cirrhosis

- **Chronic liver disease**
- **Compensated for years**
- **Decompensated: ascites, gastrointestinal hemorrhage, hepatic encephalopathy**
  - Recent onset defines acute decompensation
- **Acute decompensation: often leads to nonelective hospital admission**
- **ACLF: cause of death in acute decompensation.**

Characteristics of ACLF

- **Men ~55 yr**
- **Seen among patients nonelectively admitted for acutely decompensated cirrhosis**
- **Defined by impaired function of major organ systems & intense systemic inflammation**
- **Associated with high short-term mortality (by 28 & 90 days)**
- **Engages health-care system resources (ICU, liver transplantation)**

ACLF Burden in Europe

- **Under evaluation (commissioned by Journal of Hepatology)**
- **Currently estimated to ~150,000 cases/yr (projection from German data).**

Evidence-Based Knowledge Produced by EF CLIF

- **Studies in patients nonelectively admitted for acute decompensation:**
  - CANONIC: 1343 European patients
  - PREDICT: 1273 European patients
  - ACLARA: 1274 LATAM patients

Moreau et al. Gastroenterology 2013;144:1426-37. Trebicka et al. J Hepatol 2020;73:842-54. Farias, Curto Vilalta, et al. Gastroenterology 2023;165:696-16.

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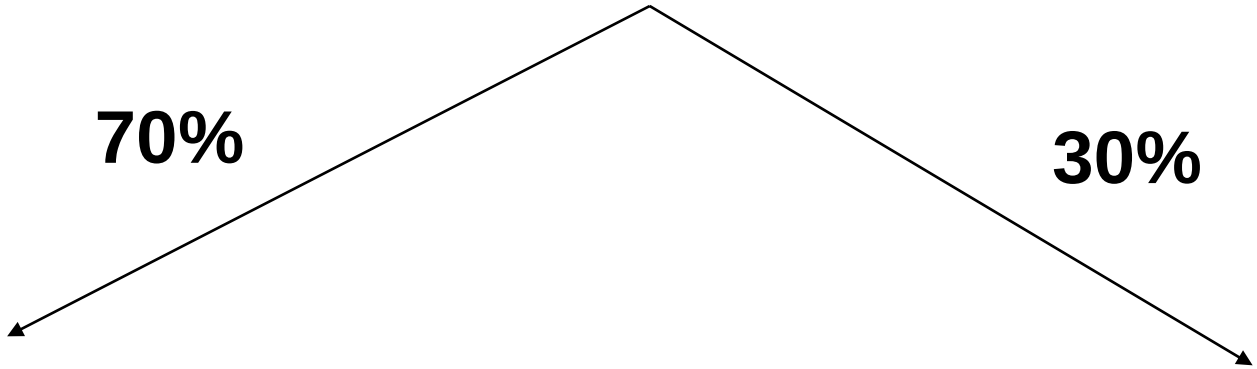
Diagnostic Criteria & Prevalence of Organ System Failures (CANONIC Study)

Organ system	Diagnostic criteria*	Prevalence (%)
Liver	Bilirubin ≥12 mg/dL	15.4
Kidney	Creatinine ≥2 mg/dL or RRT	12.6
Coagulation	INR ≥2.5	7.8
Brain	Grade 3 or 4 HE	7.4
Circulation	Use of vasopressor	4.8
Respiration	SpO2/FiO2 ≤214	2.4

*According to CLIF-C OF score. Moreau et al. Gastroenterology 2013;144:1426-37.

The CANONIC Study Defined ACLF

1343 patients nonelectively admitted for acutely decompensated cirrhosis (*new ascites, encephalopathy, infection, GI hemorrhage*)



Absence of ACLF
- **Low-grade systemic inflammation**
- **No organ failure**
- **Low 28-day mortality**

Presence of ACLF
- **High-grade systemic inflammation**
- **Organ failures (ACLF-1, ACLF-2, ACLF-3)**
- **High 28-day mortality (ACLF-3>ACLF-2>ACLF-1)**

Moreau et al. Gastroenterology 2013;144:1426-37.

Triggers of Inflammation & ACLF (PREDICT Study)

Trigger	Prevalence
Type:	
Bacterial infection	44%
Alcohol-related hepatitis	44%
GI hemorrhage with shock	6%
Toxic encephalopathy	6%
Number:	
1	46%
≥ 2	25%
0	29%

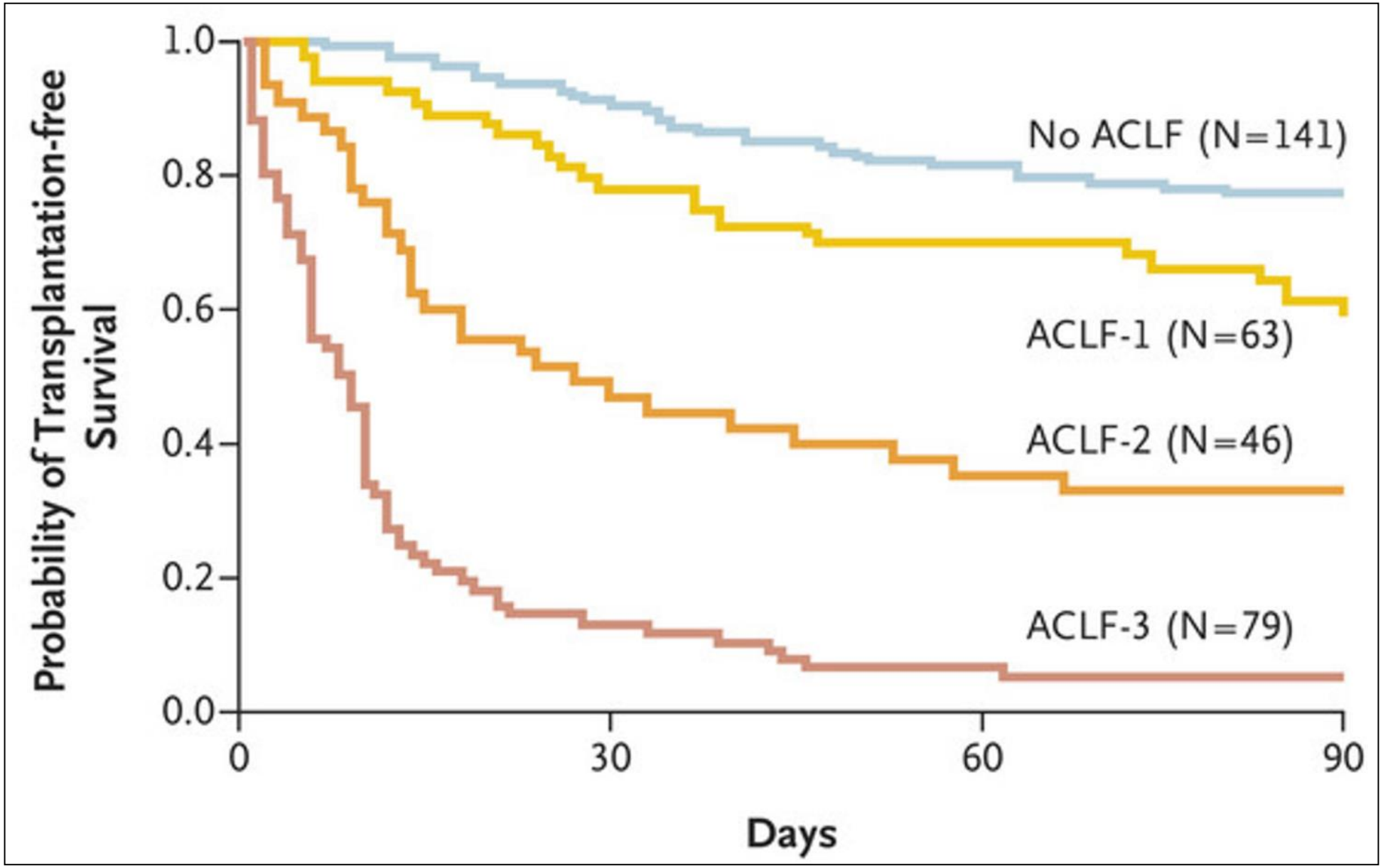
Trebicka, Fernandez, et al. J Hepatol 2021:74;1097-108.

Clinical Course of ACLF Within the 1st Week

Initial Grade	ACLF Grade at Day 7			
	0	1	2	3
	% patients			
ACLF-1	55	24	8	12
ACLF-2	35	15	25	25
ACLF-3	16	4	12	68

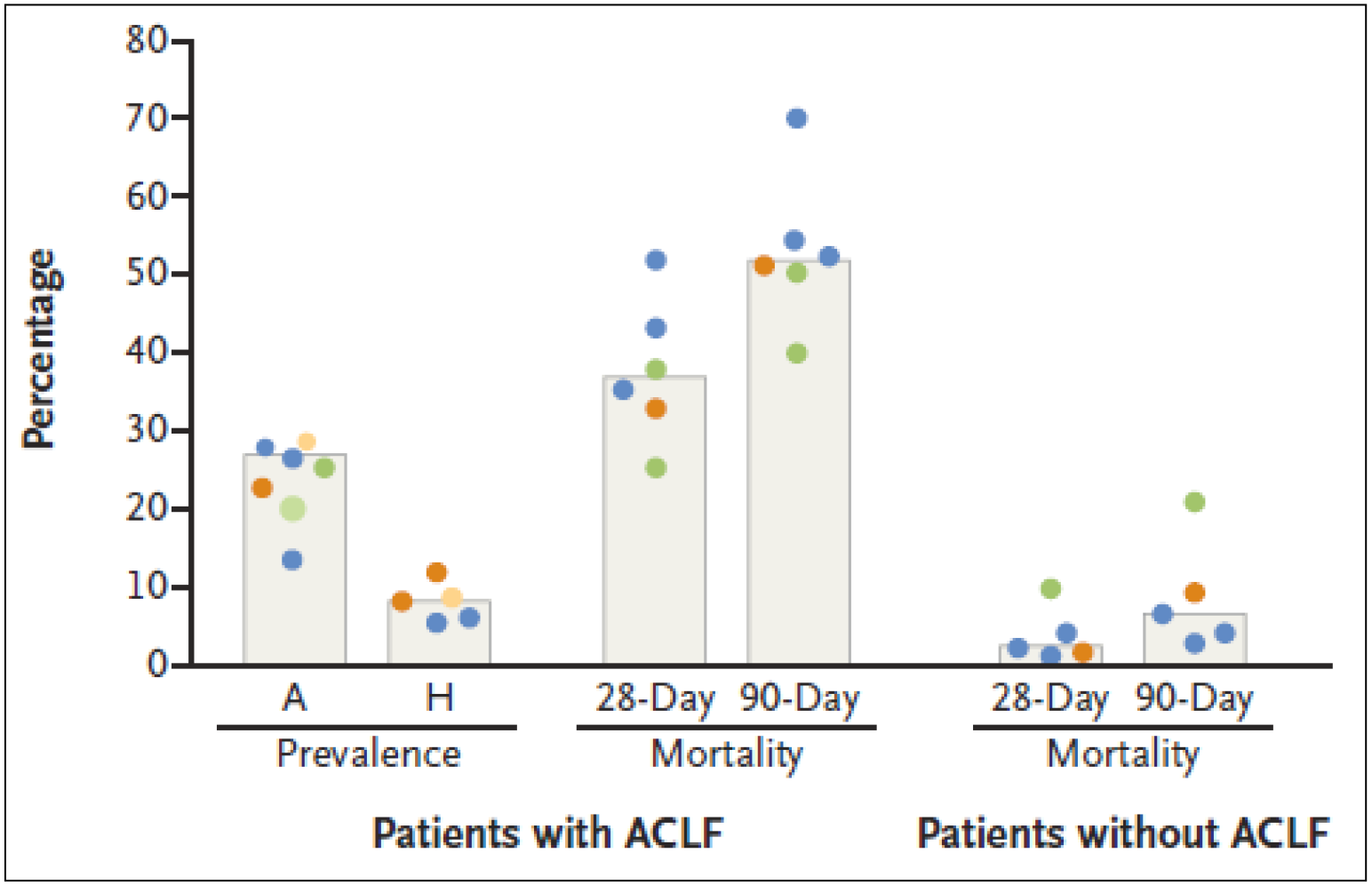
Gustot, Fernàndez, et al. Hepatology 2015;62:243-52.

90-Day Transplantation-Free Survival According to Status at Day 7 Among 329 Patients Had ACLF on Admission



Arroyo, Moreau, Jalan. N Engl J Med 2020;382:2137-45.

ACLF is a Global Disorder



Europe USA Asia Latin America

Arroyo, Moreau, Jalan. N Engl J Med 2020;382:2137-45.

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- **Pathophysiology**
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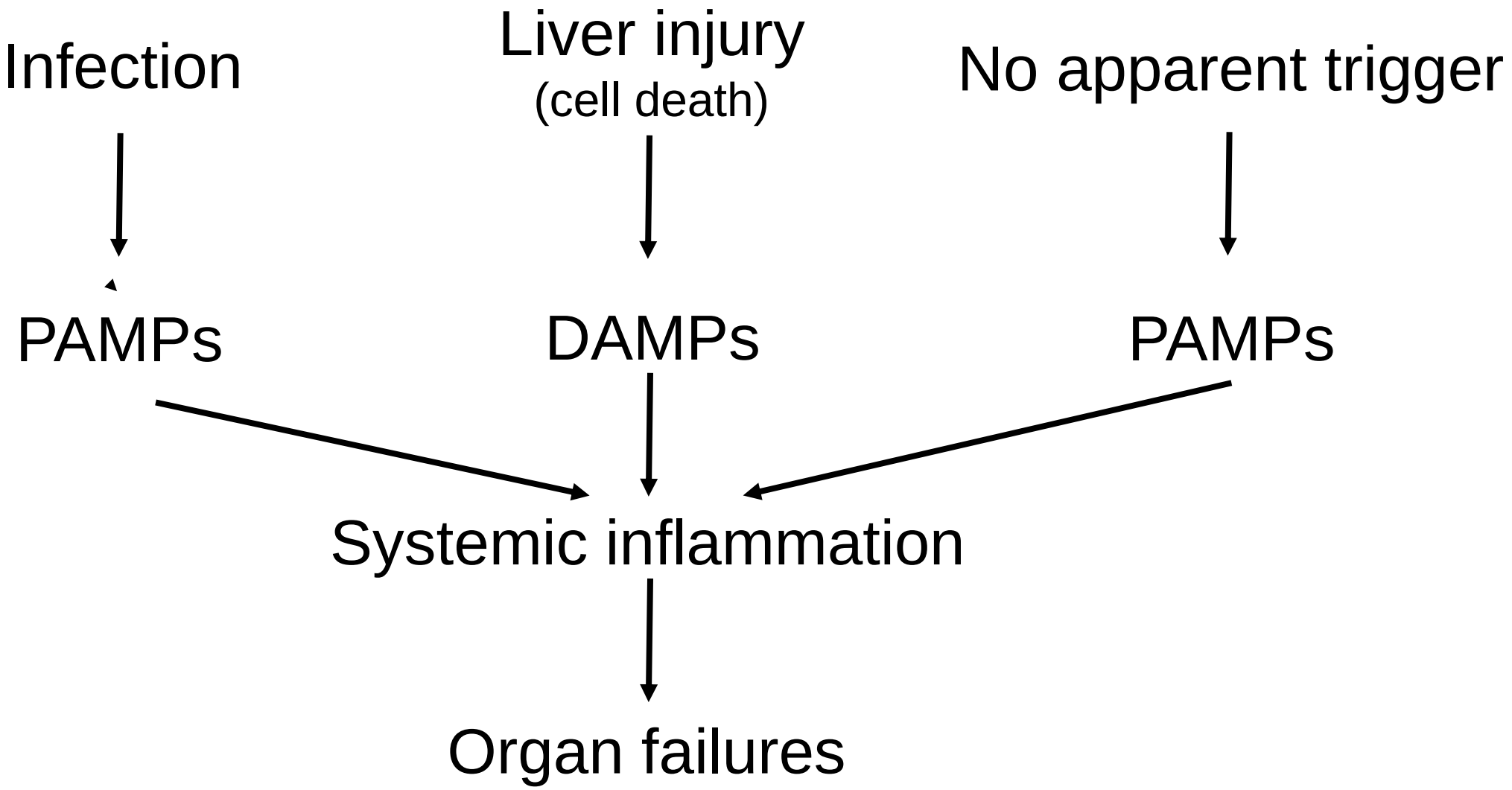
Inducers of Inflammation

- **Pathogen-associated molecular patterns (PAMPs) = bacterial byproducts immediately recognized by immune system; induce inflammation**

- **Damage-associated molecular patterns (DAMPs) = intracellular molecules released by dying cells; immediately recognized by immune system; induce inflammation**

Inducers of Inflammation According to Triggers



Arroyo, Moreau, Jalan. N Engl J Med 2020;382:2137-45.

Impaired Gut Barrier in Decompensated Cirrhosis

- **Changes in gut microbiome (↑ pathobionts = “bad” bacteria)**
- **↑ Intestinal permeability to bacteria and/or bacterial PAMPs**
- **Translocation of bacteria and/or bacterial PAMPs to blood flowing to the liver**
- **↓ Function of the “hepatic filter”; bacteria and/or bacterial PAMPs reach systemic circulation**
- **Bacteria can cause infection & inflammation; isolated bacterial PAMPs can cause inflammation.**

Bajaj, Kamath, Reddy. N Engl J Med 2021;384:2317-30.

Outline

- Cirrhosis & ACLF
- Defining ACLF
- Pathophysiology
- **Medical management**
- Liver transplantation
- Unmet needs

Key Points

- **Main principle: Diagnose acute precipitants & treat them urgently**
- **Provide supportive therapy in ICU**
- **Objective: Bridge to early liver transplantation**
- **No “pathophysiology-based” therapy available.**

Arroyo, Moreau, Jalan. N Engl J Med 2020;382:2137-45. EASL CPG. J Hepatol 2023;79:461-91.

Supportive Therapy

- **Cardiovascular: vasoconstrictors.**
- **Respiratory: mechanical ventilation.**
- **Brain: protective intubation if necessary; lactulose; albumin dialysis (MARS) if lactulose failure.**
- **Liver: 2 negative RCTs of extracorporeal MARS.**

Arroyo, Moreau, Jalan. N Engl J Med 2020;382:2137-45. EASL CPG. J Hepatol 2023;79:461-91.

Other Interventions

- **Granulocyte colony-stimulating factor**
  - **No efficacy**
- **Plasma exchange**
  - **Trial recruiting**
- **Cell therapy**
  - **Under evaluation**

EASL CPG. J Hepatol 2023;79:461-91.

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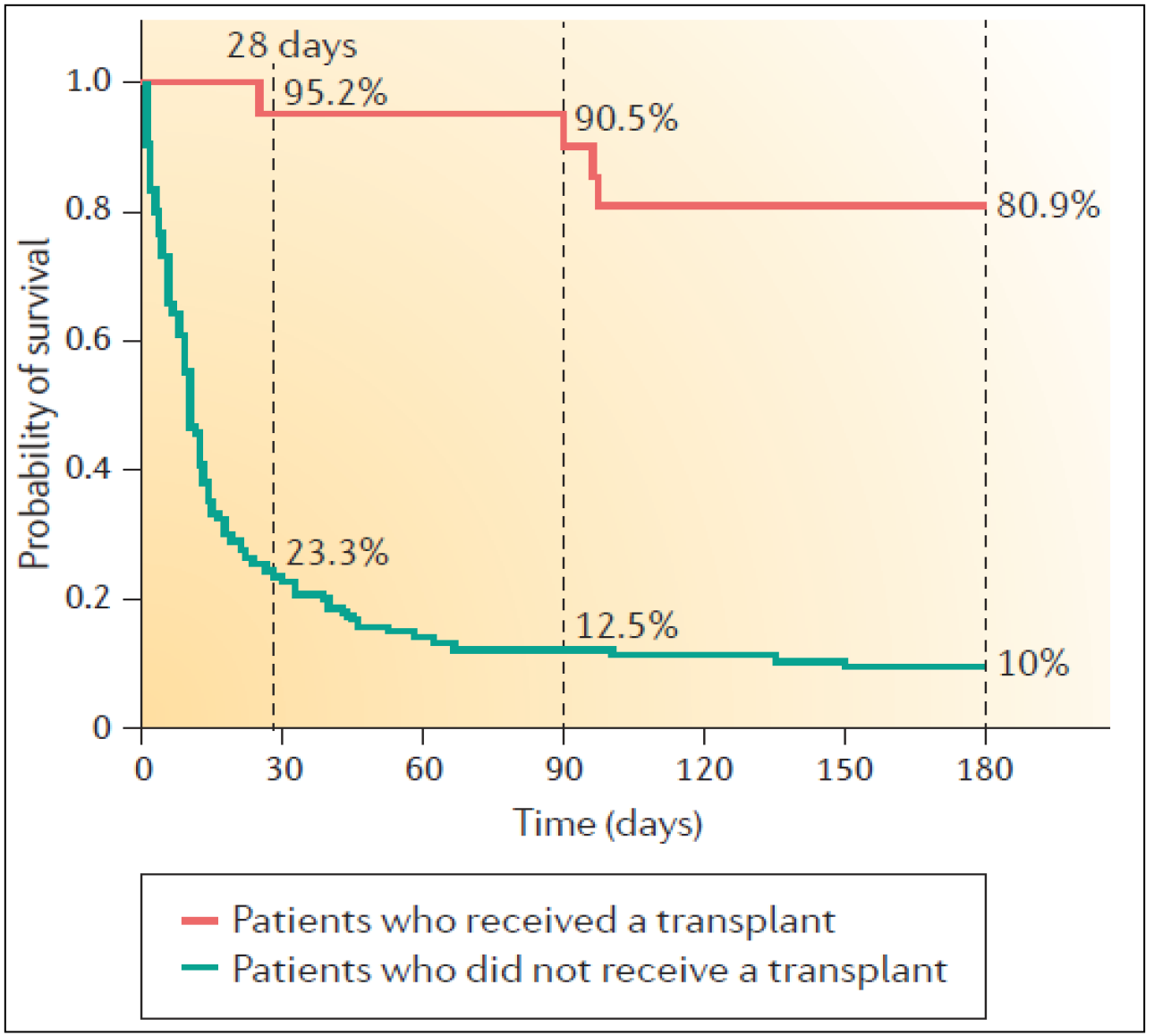
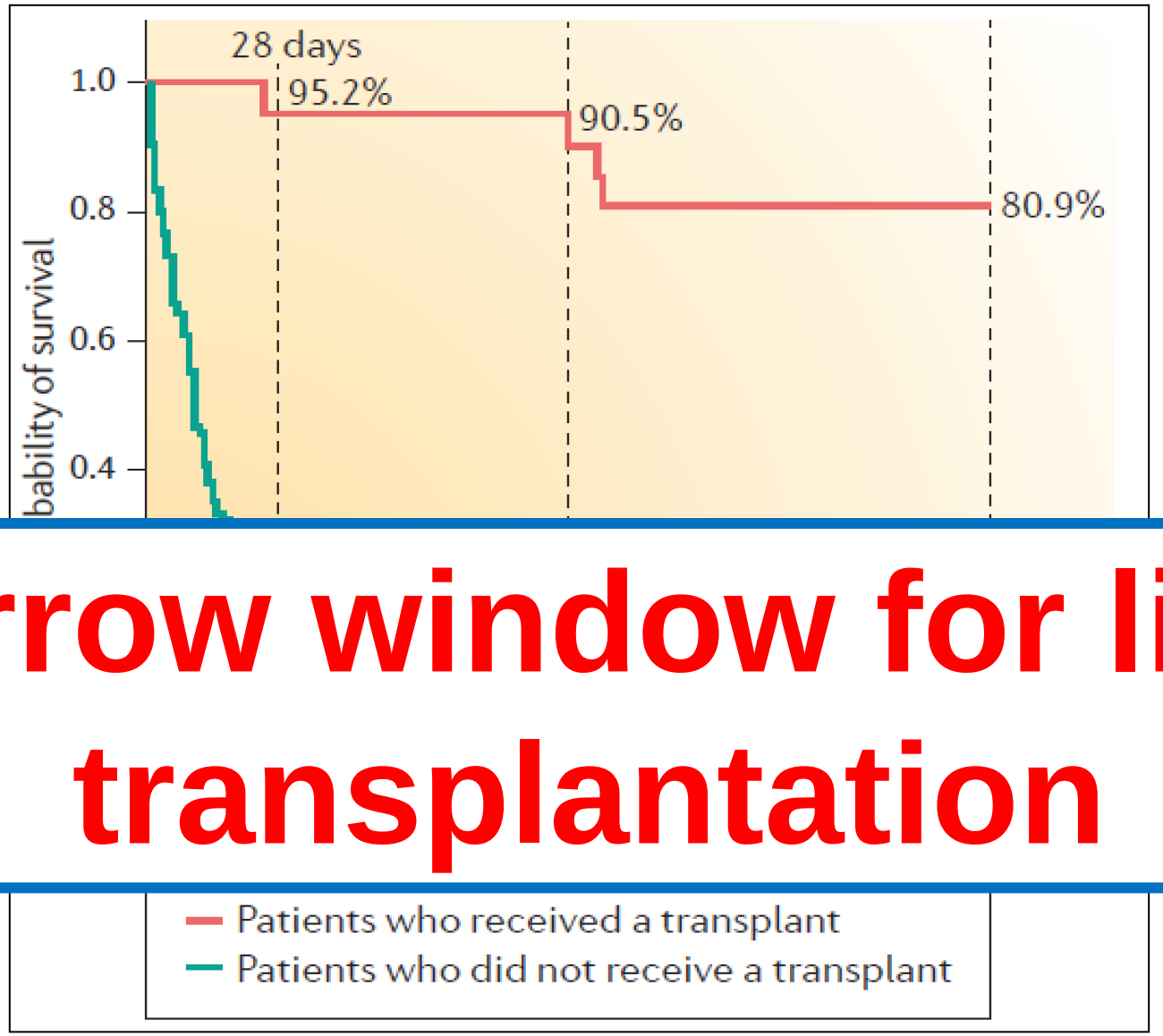
Survival Among Patients with ACLF-2, -3 who Did or Did not Receive Early (<28 days) Liver Transplant



Gustot, Fernandez, et al.
Hepatology 2015;62:243-52.

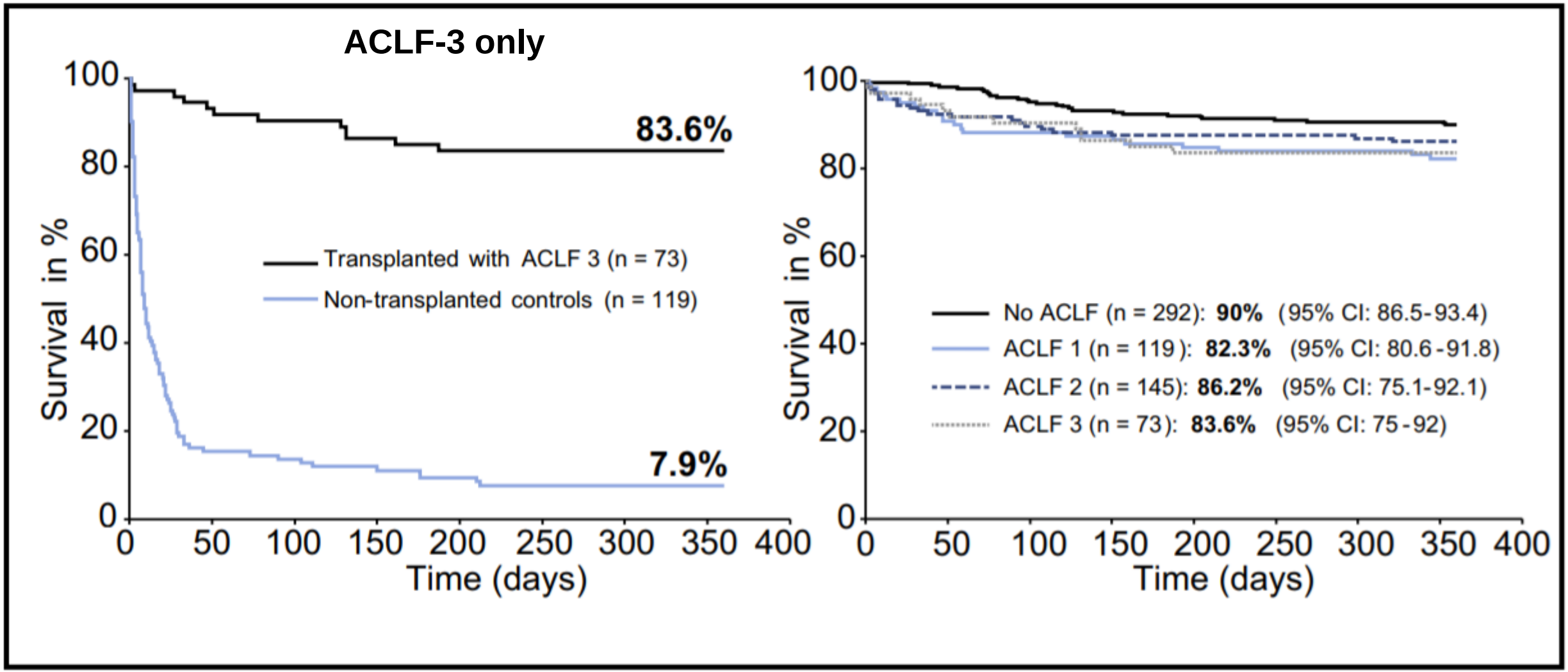
Survival Among Patients with ACLF-2, -3 who Did or Did not Receive Early (<28 days) Liver Transplant



Narrow window for liver transplantation

Gustot, Fernandez, et al.
Hepatology 2015;62:243-52.

Liver Transplantation in Patients with ACLF



Artru et al. J Hepatol 2017; 67:708-15.

Outline

- Cirrhosis & ACLF
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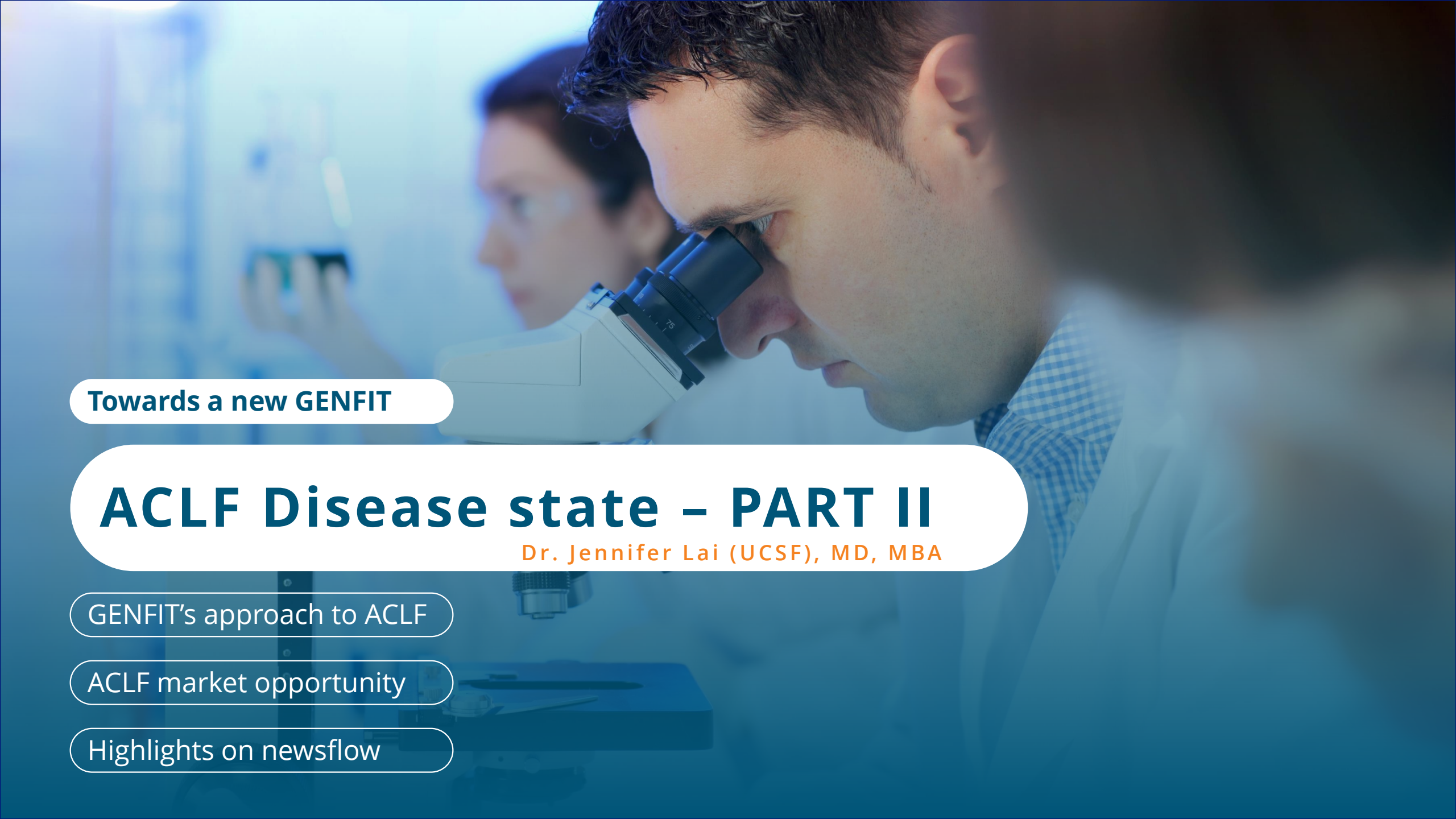
- Pathophysiology
- Medical management
- Liver transplantation
- **Unmet needs**

Targeting Bacterial/PAMP Translocation

- **Current approaches are based on antibiotics**
- **Restricted to few patients**
- **Major issues with antibiotic use (emergence of multidrug-resistant bacteria)**
- **Alternative approaches: unmet need.**

Conclusions

- **ACLF is the most severe form of acutely decompensated cirrhosis**
- **Bacterial/PAMP translocation & systemic inflammation are key pathogenic mechanisms**
- **There is no “pathophysiology-based” therapy currently available**
- **Liver transplantation is effective but limited due to narrow time, organ shortage, poor access in high-level care.**



Towards a new GENFIT

ACLF Disease state – PART II

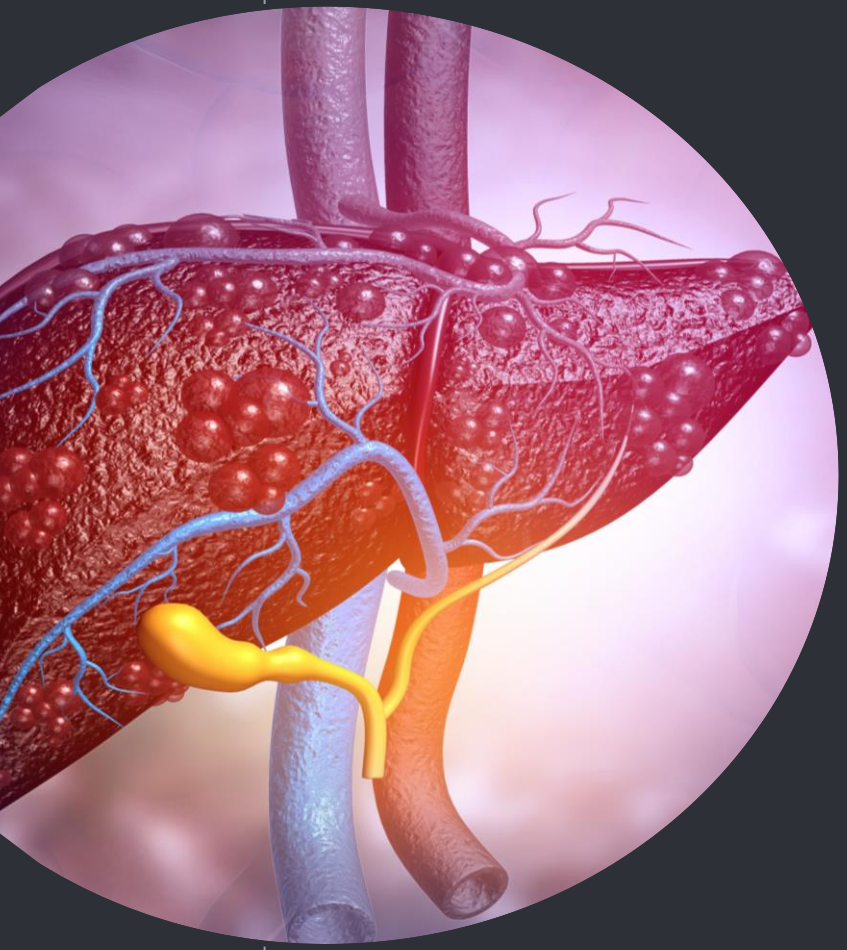
Dr. Jennifer Lai (UCSF), MD, MBA

- GENFIT's approach to ACLF
- ACLF market opportunity
- Highlights on newsflow

Acute-on-Chronic Liver Failure (ACLF)

Jennifer C. Lai, MD, MBA
Transplant Hepatologist
Endowed Professor of Liver Health & Transplantation
University of California, San Francisco (UCSF)

Acute-on-Chronic Liver Failure : Defined



…a potentially reversible condition in patients with chronic liver disease with or without cirrhosis that is associated with potential for multiple organ failure and high mortality within 3 months in the absence of treatment…

Bajaj J, *et al*. Am J Gastro 2022.

“ There is no direct therapeutic for ACLF.

SCOPE OF THE UNDERLYING PROBLEM :

Chronic liver disease & cirrhosis

Chronic Liver Disease & Cirrhosis

11th most common cause of death

2 million deaths worldwide (~4% of deaths worldwide)

2 billion consume alcohol

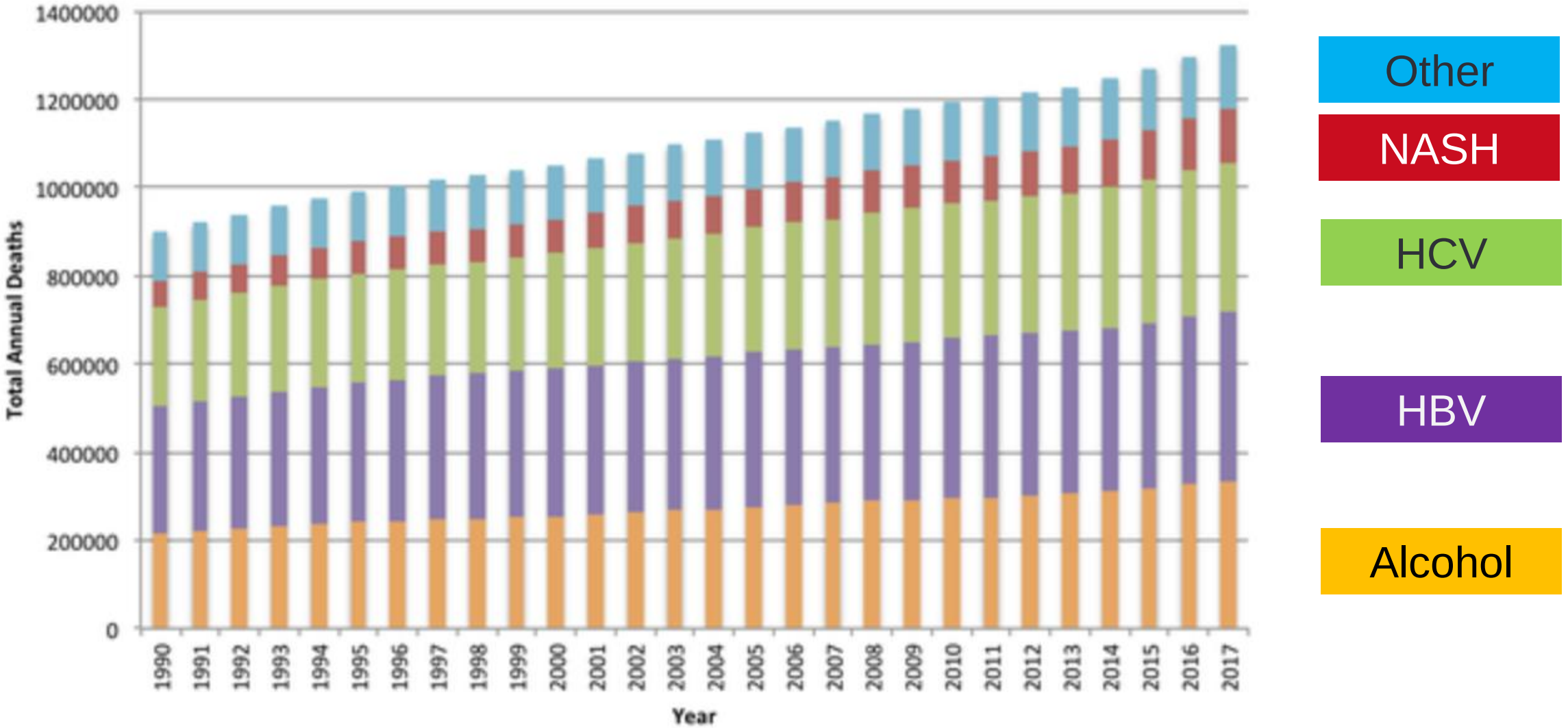
At risk for alcohol-associated liver disease / cirrhosis

2 billion overweight/obese

At risk for non-alcoholic fatty liver disease / cirrhosis

Asrani S, *et al*. J Hep 2019.

Deaths by liver disease etiology : RISING



Cheemerla S, *et al*. Clin Liv Dis 2021. https://vizhub.healthdata.org/gbd-results/

Economic burden of chronic conditions in the U.S. : Cirrhosis and ACLF much higher!

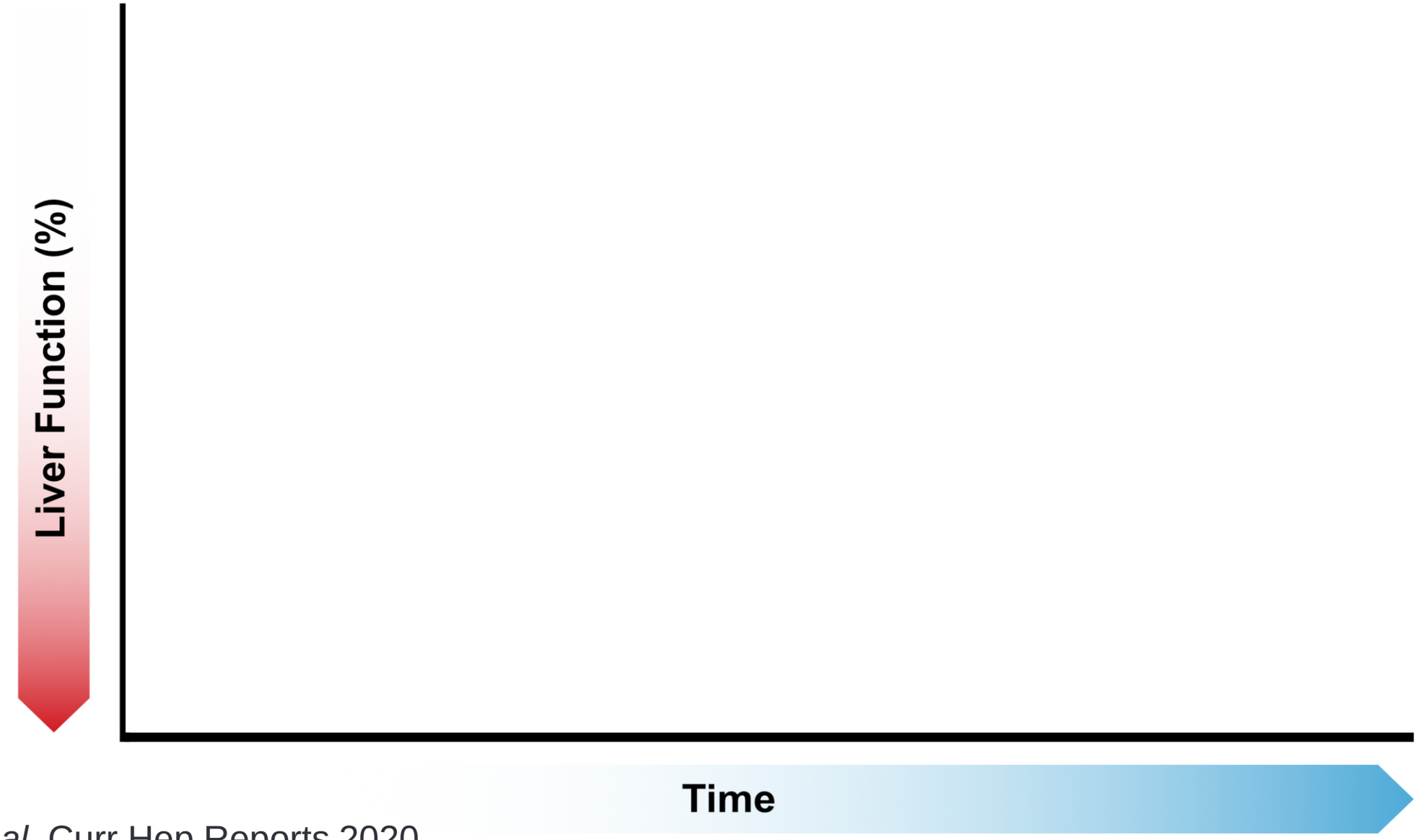
Chronic disease	Length of hospital stay	Inpatient mortality	Mean cost per hospitalization
Pneumonia	5 days	3.3%	$7,581
Congestive heart failure	5 days	3.0%	$8,315
Cerebrovascular disease	6 days	4.7%	$8,117

Allen A, *et al*. Hepatol 2016.

THE PATIENT :

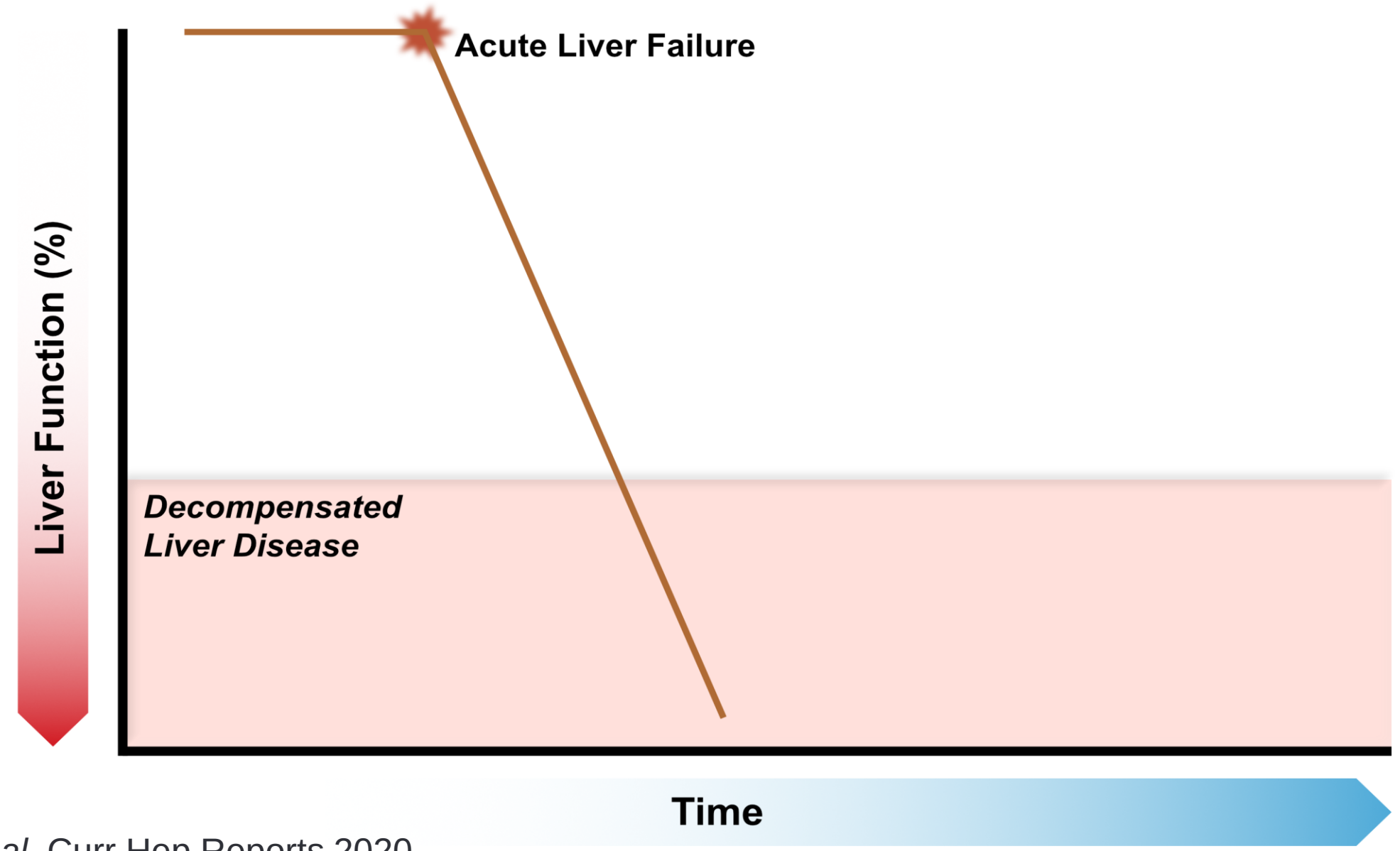
Clinical Course & Features

Trajectories of liver function in 3 common liver states



Mahmud N, *et al*. Curr Hep Reports 2020.

Trajectories of liver function in 3 common liver states



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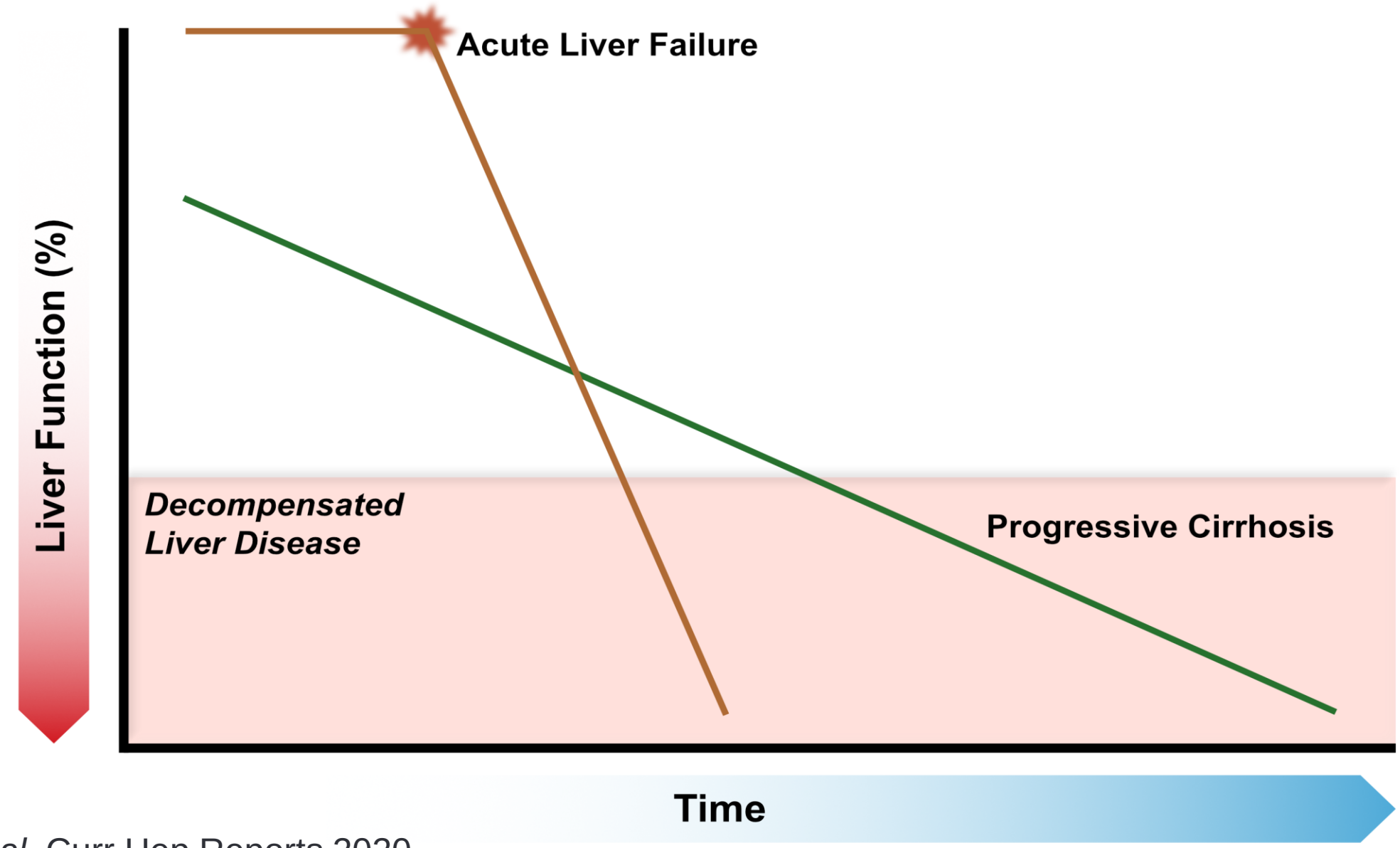

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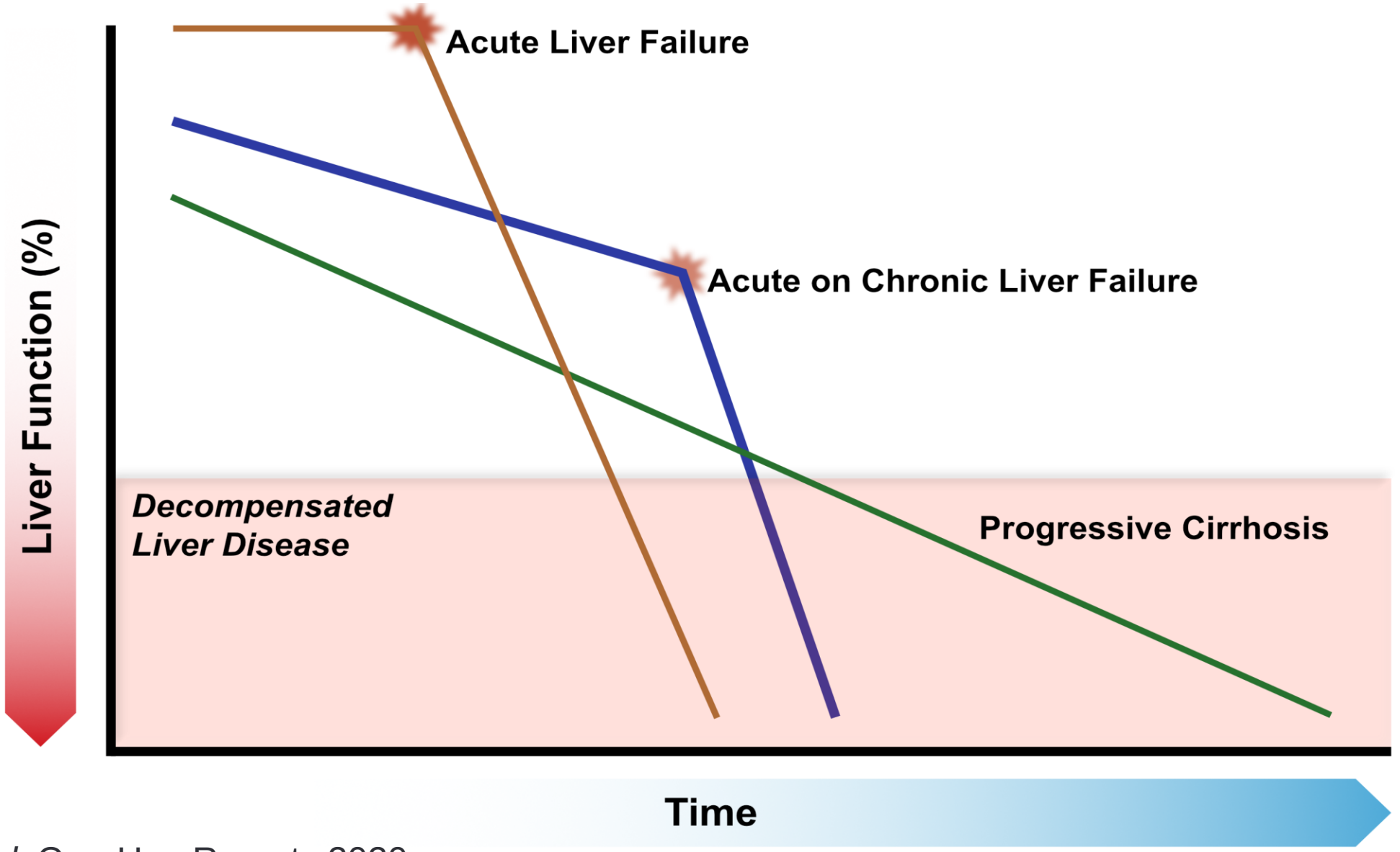


Mahmud N, *et al*. Curr Hep Reports 2020.

Clinical characteristics (U.S. cohort)

	n=1,031
Age (years)	57 (11)
Men	66%
Liver disease etiology	
Alcohol only	31%
HCV only	21%
Alcohol + HCV	15%
NASH	17%
Other	15%

Reason for admission	n=1,031
Bacterial infection	25%
GI bleed	16%
Hepatic enceph.	17%
Renal dysfxn	12%
Alcohol related	4%
Electrolytes abnl	3%
Other	23%

Wong F, *et al*. Liver Transpl 2022.

Role of prior hepatic decompensation

	n=417
No prior event	26%
<3 months prior	16%
3-12 prior	17%
>12 months prior	41%

Moreau R, *et al*. Gastroenterol 2013.

Percent with *extra-hepatic* organ failure on admission

RENAL

50%

NEUROLOGIC

22%

CIRCULATORY

23%

RESPIRATORY

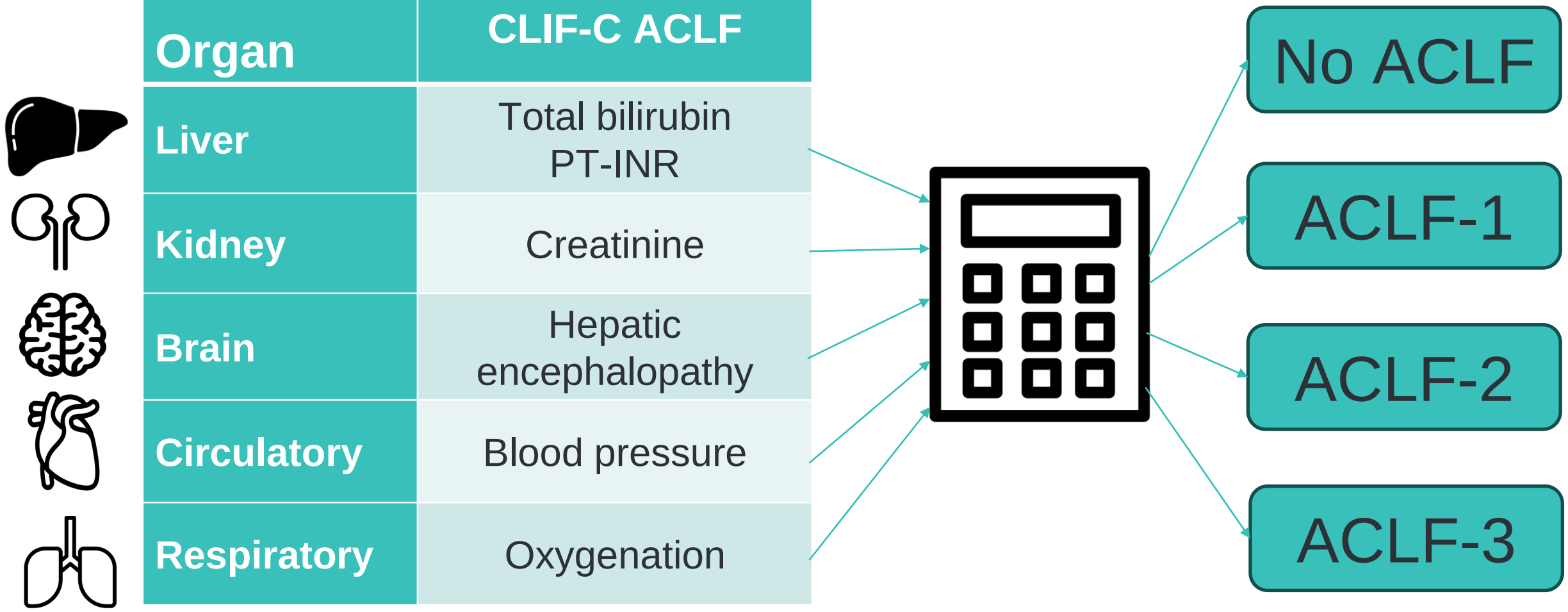
13%

Arroyo V, *et al*. J Hepatol 2015.

ACLF Scoring System

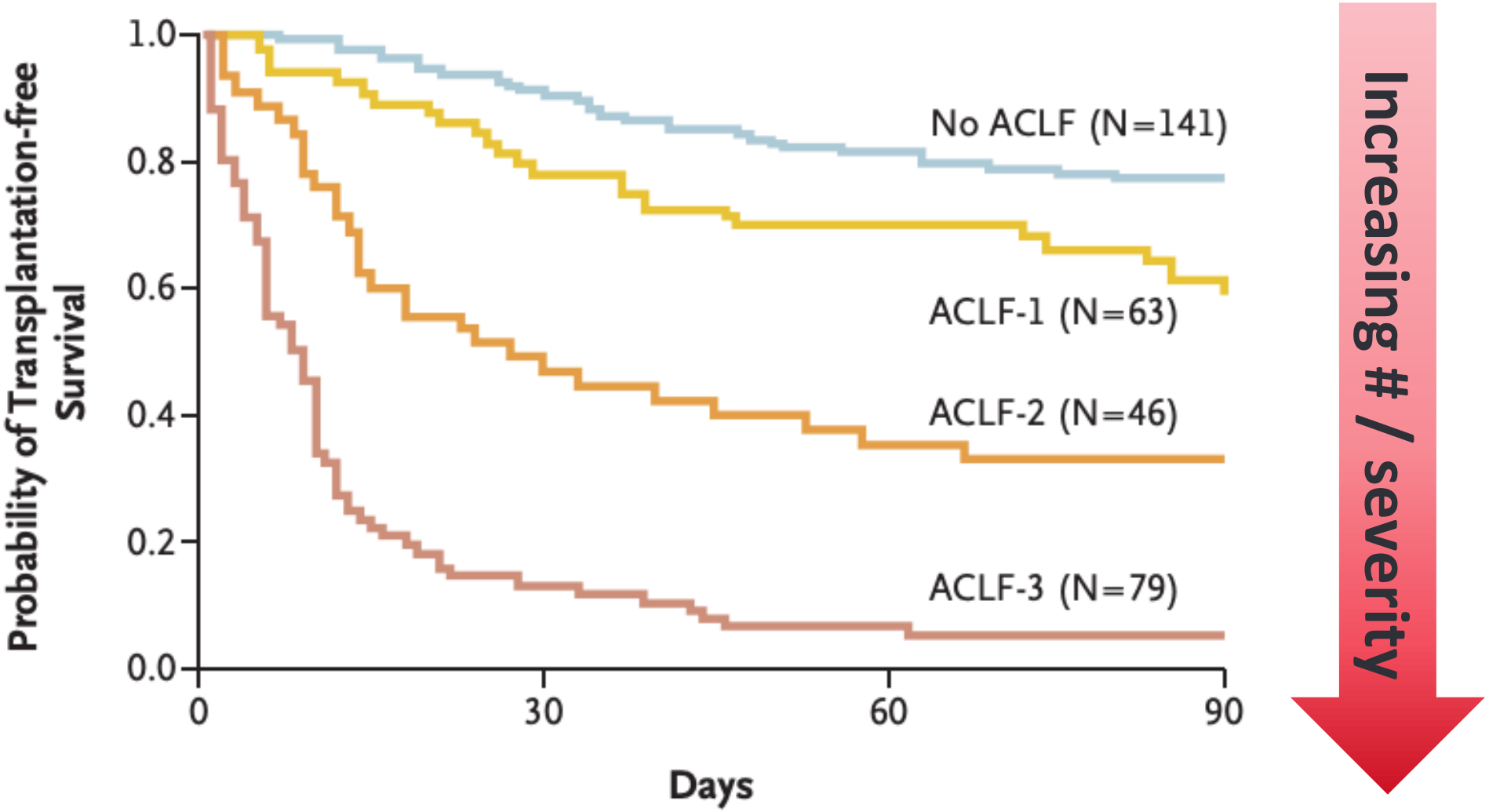
Chronic Liver Failure Consortium (CLIF-C) ACLF

Organ	CLIF-C ACLF
Liver	Total bilirubin PT-INR
Kidney	Creatinine
Brain	Hepatic encephalopathy
Circulatory	Blood pressure
Respiratory	Oxygenation



*CLIF-C ACLF = 10 x [0.33 x CLIF-Organ Failures + 0.04 x Age + 0.63 x ln(WBC)-2]

Probability of survival by ACLF severity



The greater the number/severity of organ failures, the greater the risk of death.

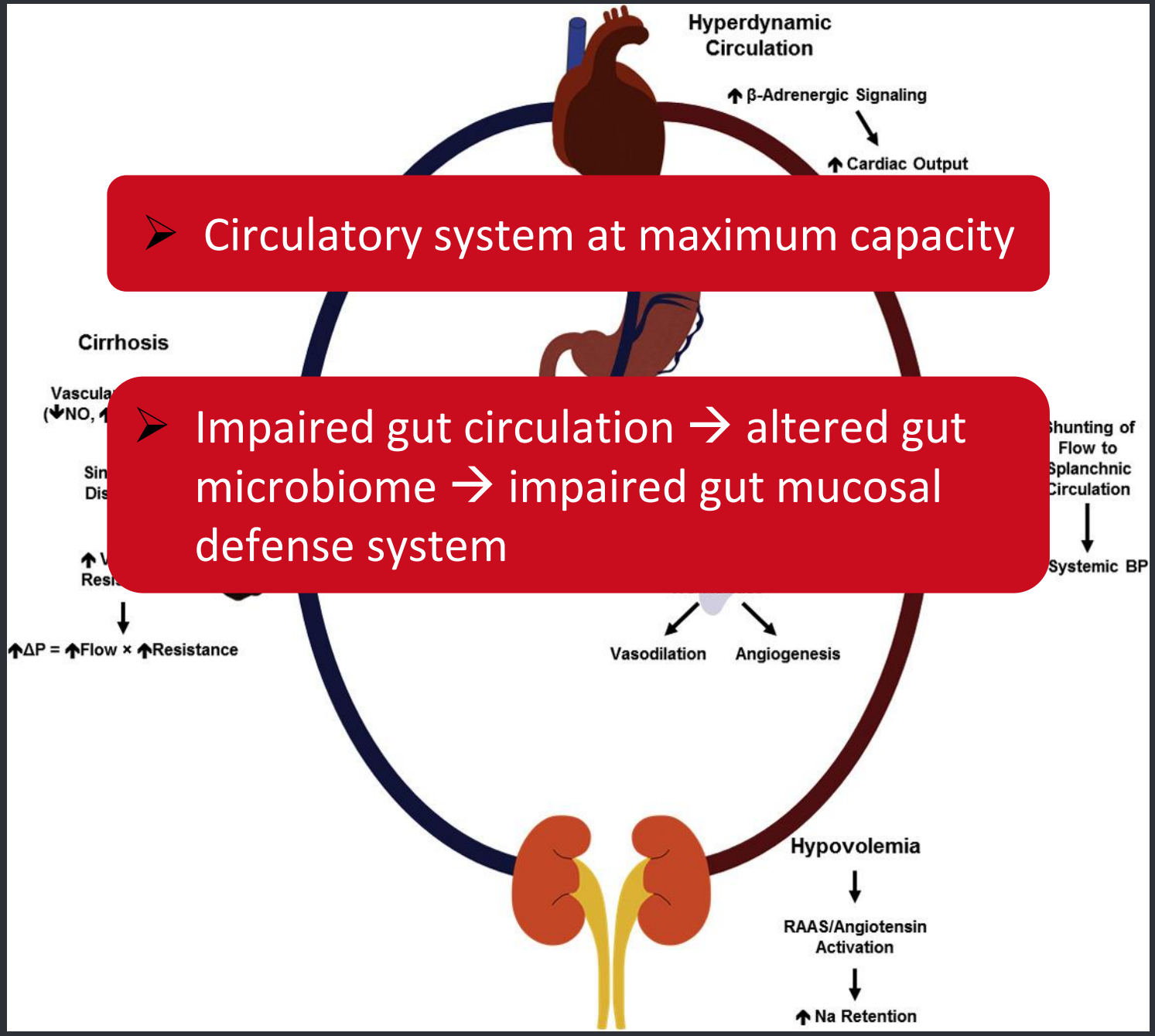
Gustot T, *et al*. Hepatol 2015. Arroyo V, *et al*. NEJM 2020.

PATHOGENESIS :

Leading hypotheses and supporting data

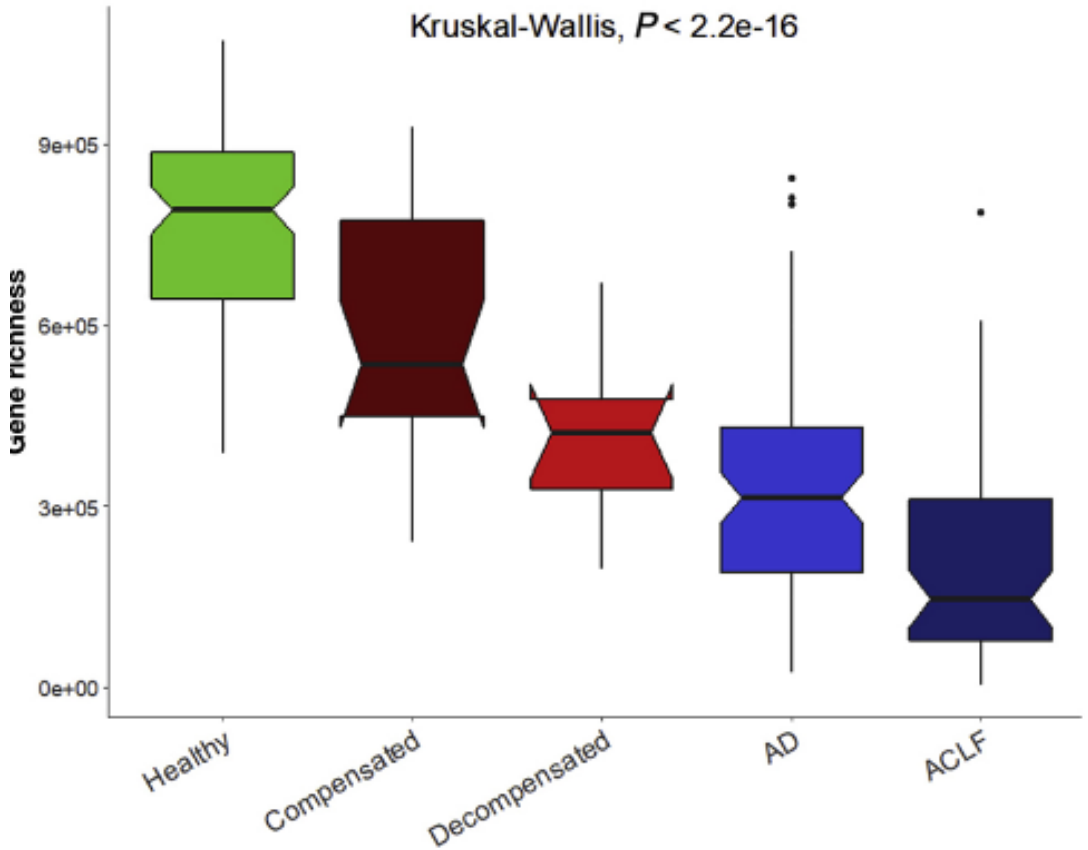
The underlying condition

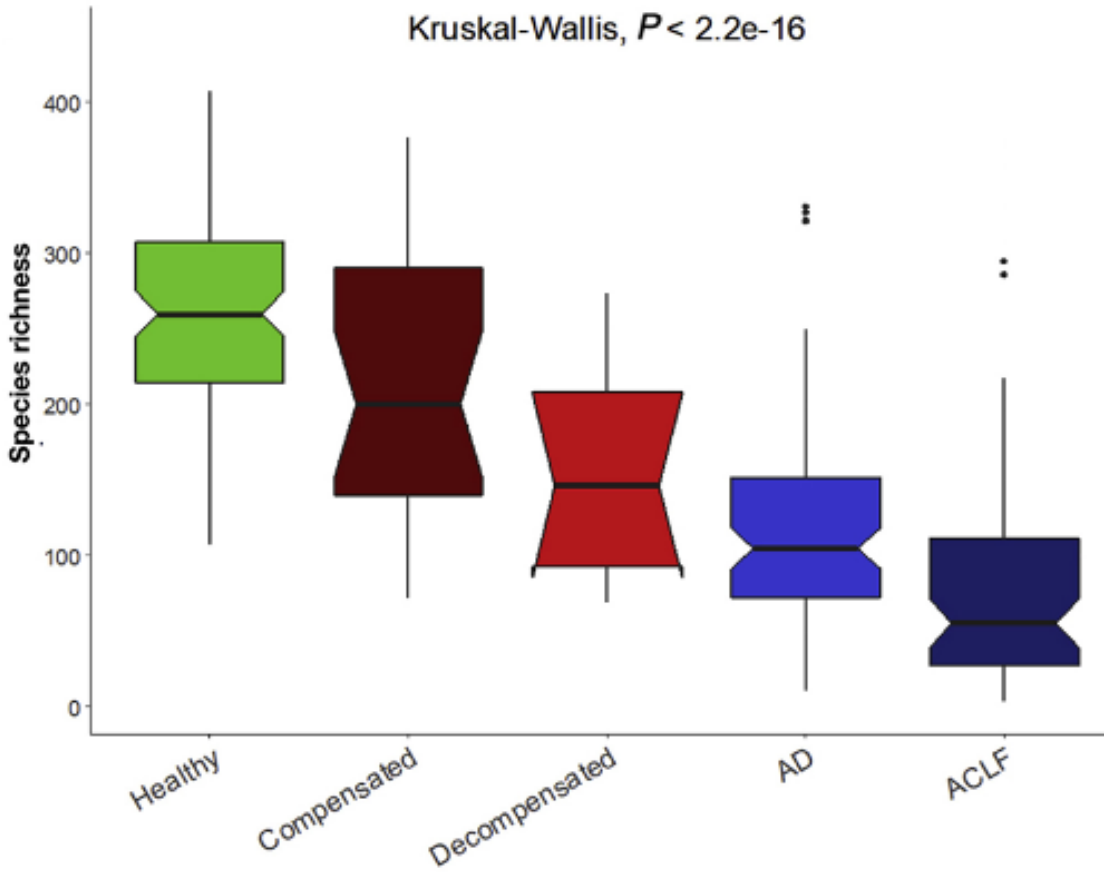
Portal hypertension 101



Simonetto DA, *et al*. Mayo Clinic Proc 2019.

Greater severity of liver disease is associated with less diverse microbiome



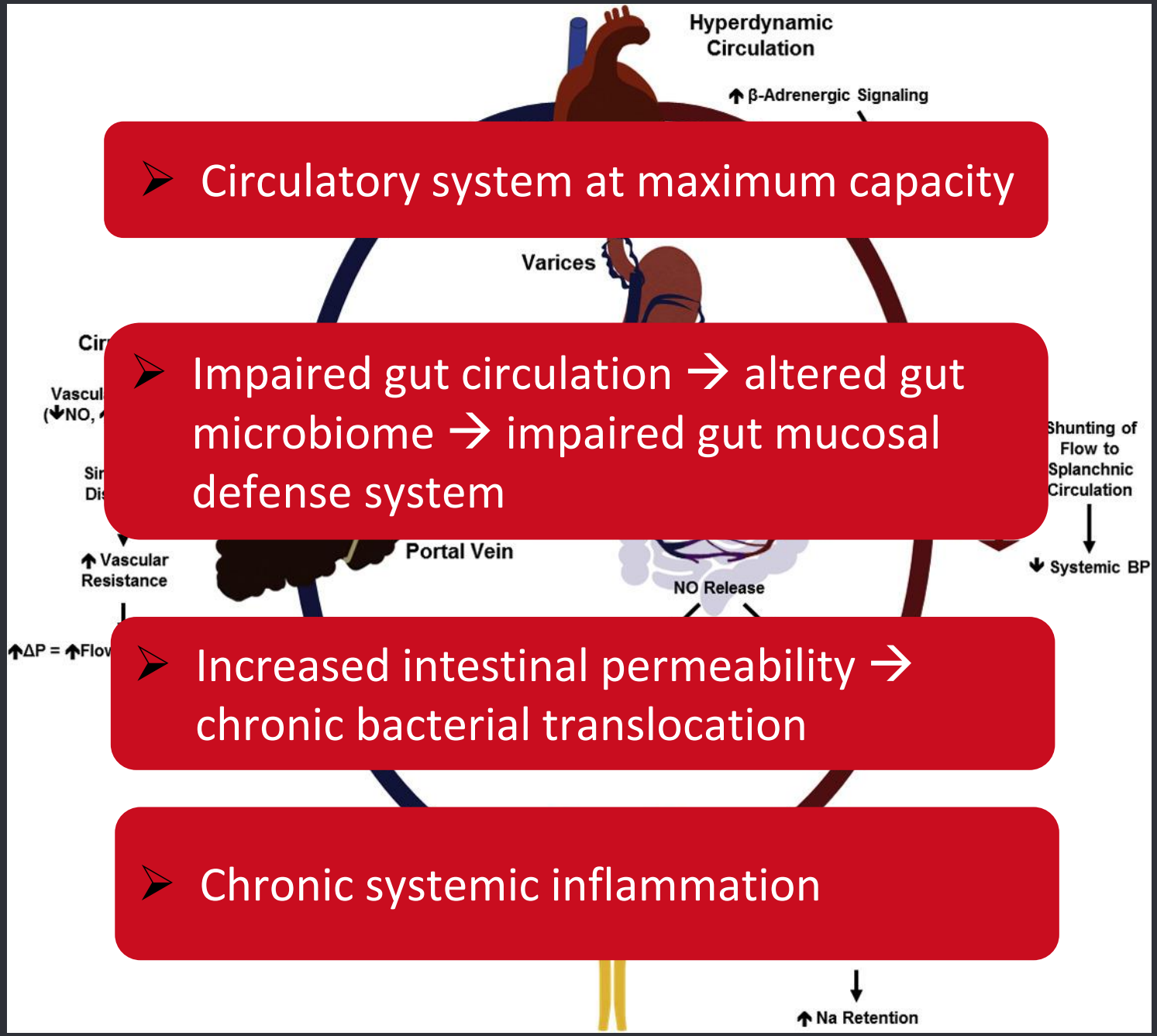


Is there a role for gut microbiota manipulation to improve ACLF outcomes?

Sole C, *et al*. Gastroenterol 2021.

The underlying condition

Portal hypertension 101

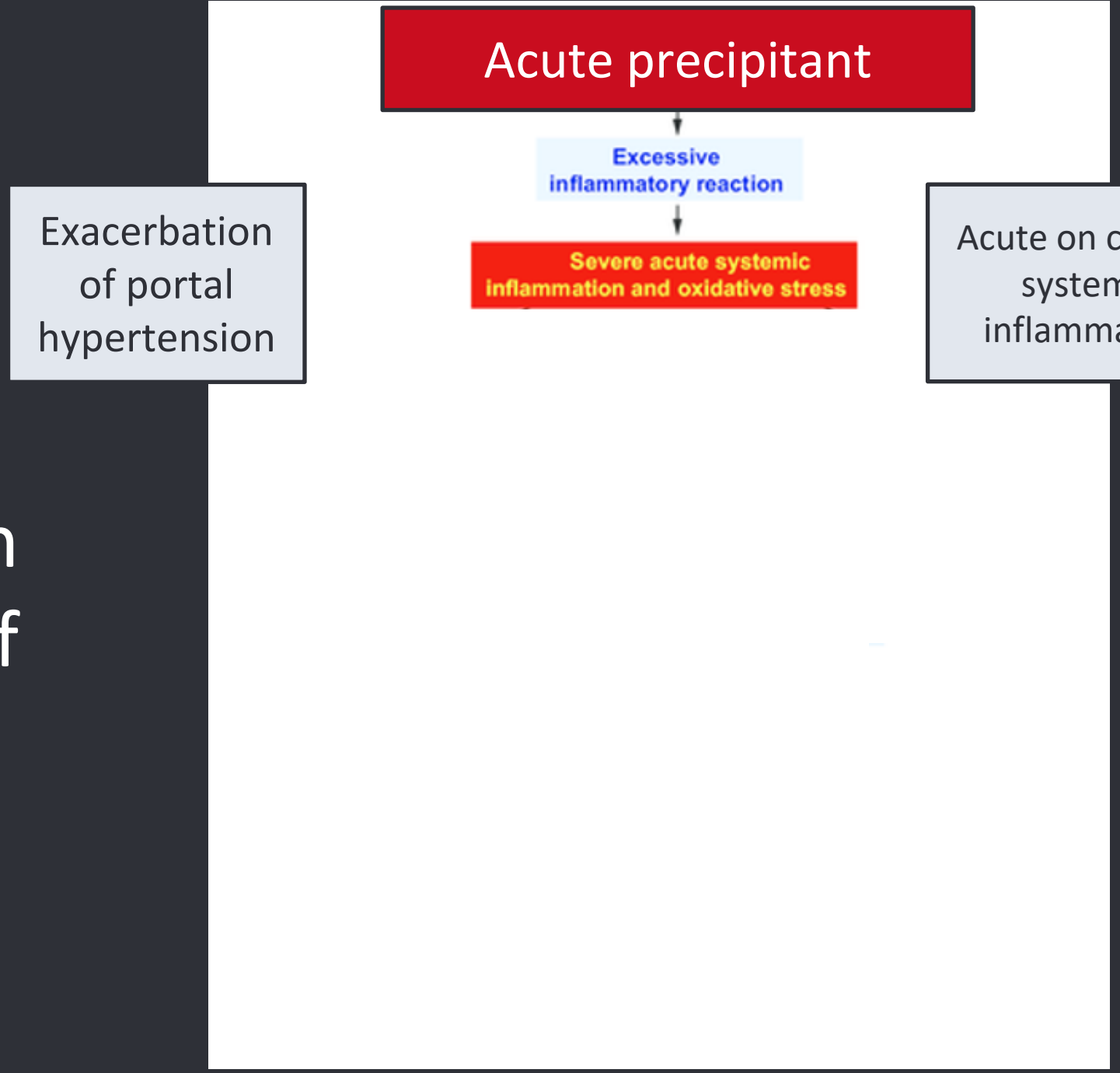


- Circulatory system at maximum capacity
- Impaired gut circulation → altered gut microbiome → impaired gut mucosal defense system
- Increased intestinal permeability → chronic bacterial translocation
- Chronic systemic inflammation

Simonetto DA, *et al*. Mayo Clinic Proc 2019.

The acute insult

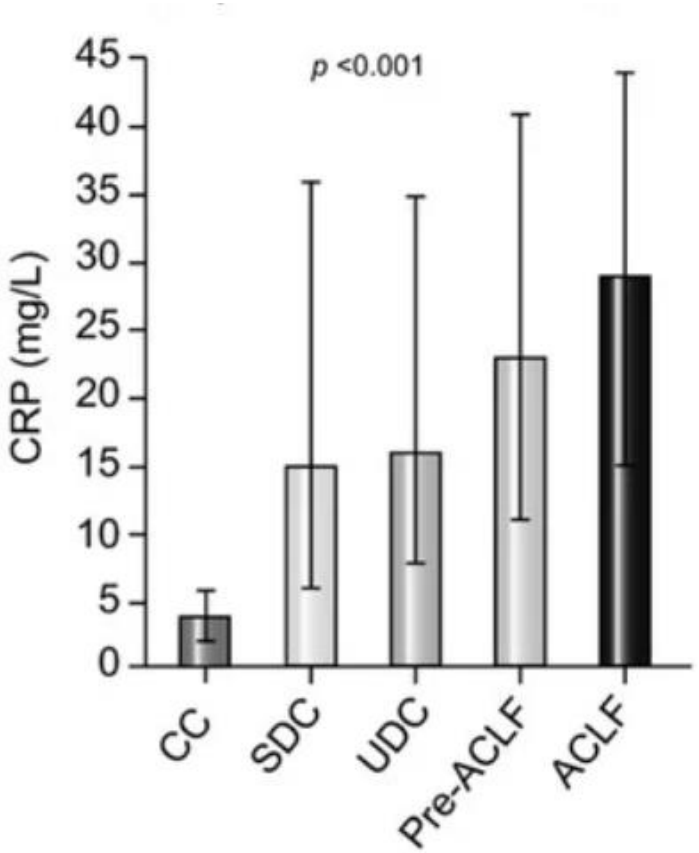
- Systemic inflammation hypothesis of ACLF

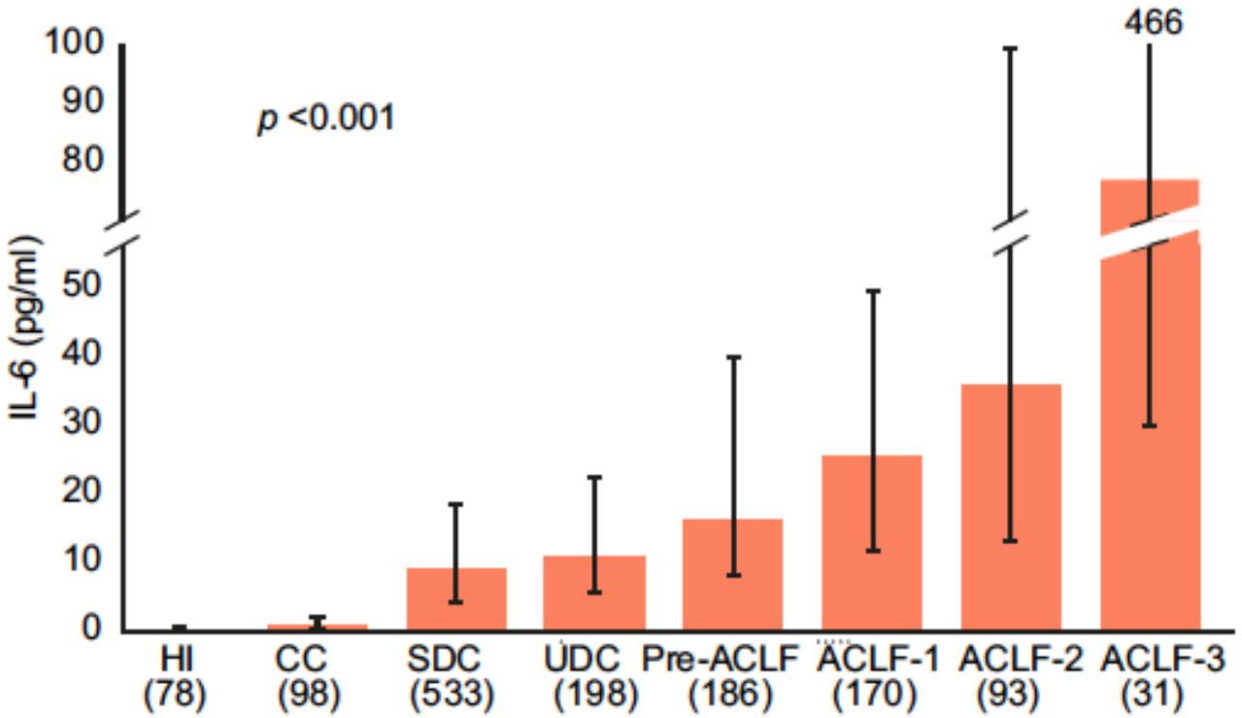


Arroyo V, *et al*. J Hep 2021.
Fig adapted from Arroyo V, *et al*. J Hepatol 2014.

Systemic inflammatory markers and risk of ACLF

Escalating risk as systemic inflammatory markers increase

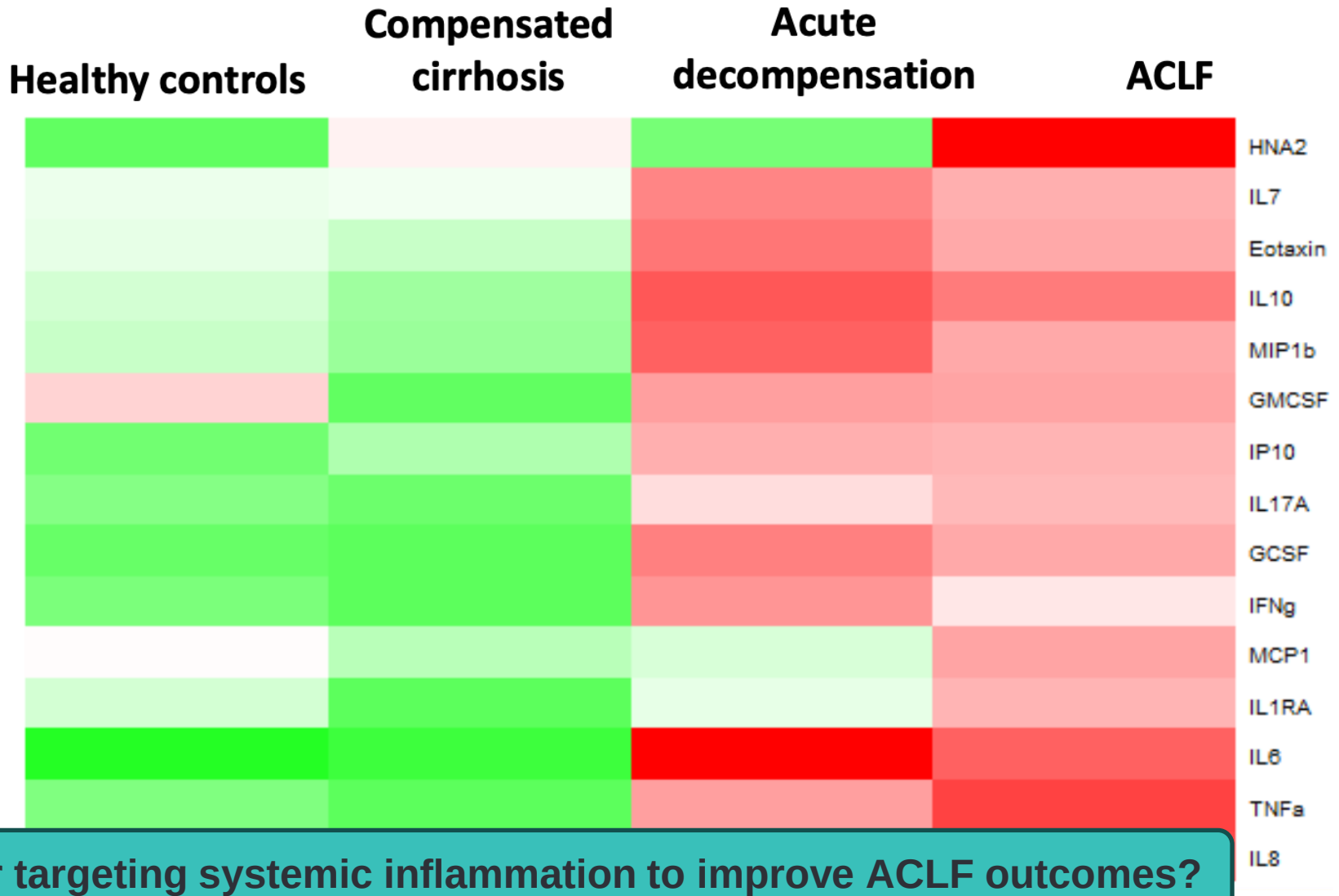




Kimman M, Trebicka J. J Pers Med 2023.

Arroyo V, *et al*. J Hep 2021.

Systemic inflammatory markers are elevated



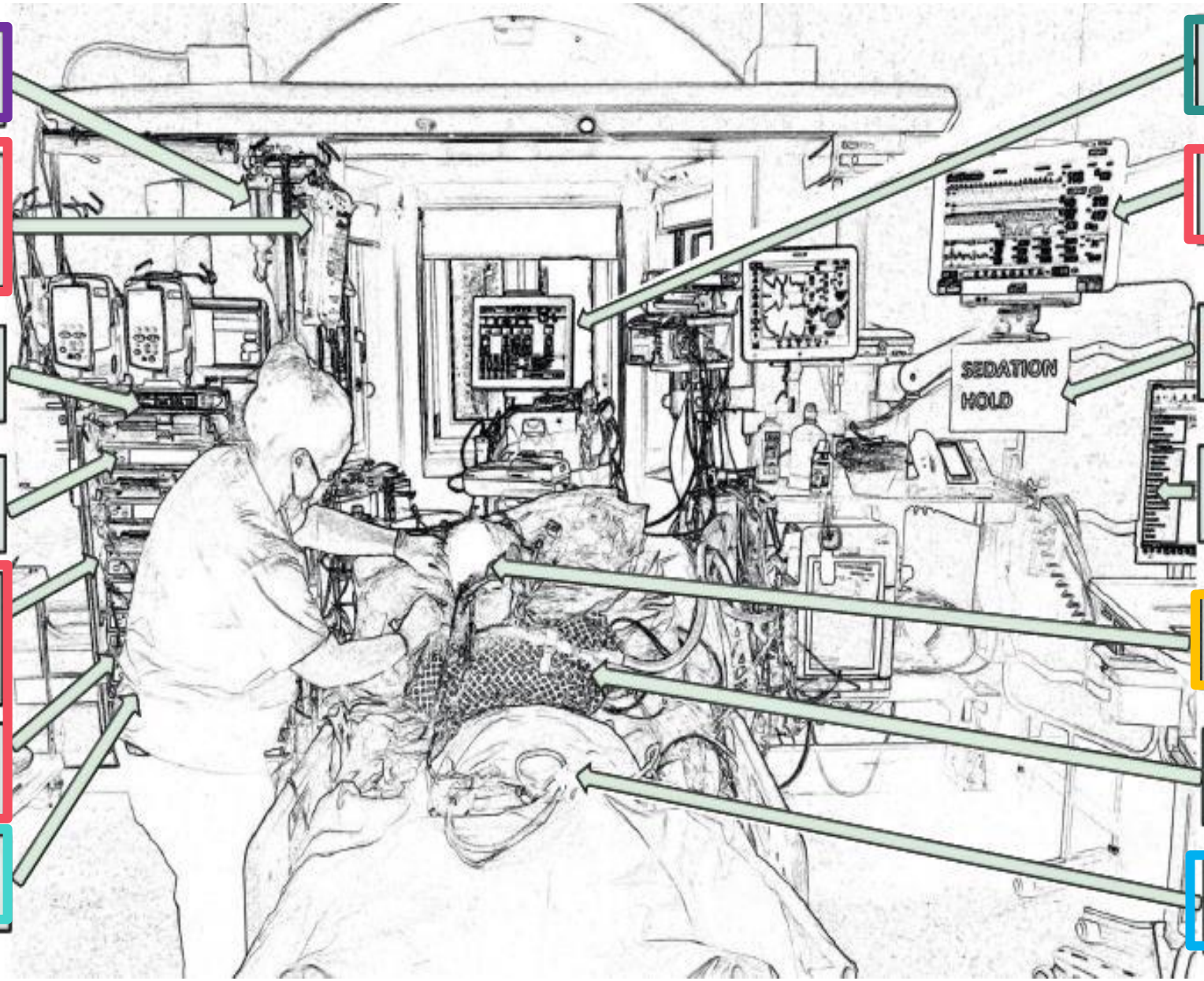
Is there a role for targeting systemic inflammation to improve ACLF outcomes?

Trebicka J, *et al*. Front Immunol 2019.

AT THE BEDSIDE :

Management

“ There is no direct therapeutic for ACLF.



Enteral nutrition via nasogastric tube

Monitored circulating volume expansion with intravenous fluids

Insulin infusion for glycaemic stability

Electrolyte infusion for metabolic stability

Noradrenalin/ terlipressin for cardiovascular support

Hydrocortisone for adrenal insufficiency

Nursing staff experienced in liver care

Continuous haemofiltration for acute kidney injury

Haemodynamic monitoring fo cardiovascular stability

Encephalopathy: minimal use of sedation

Serial illness severity assessment

Encephalopathy: intubation for airway protection

Ascitic decompression for tense ascites

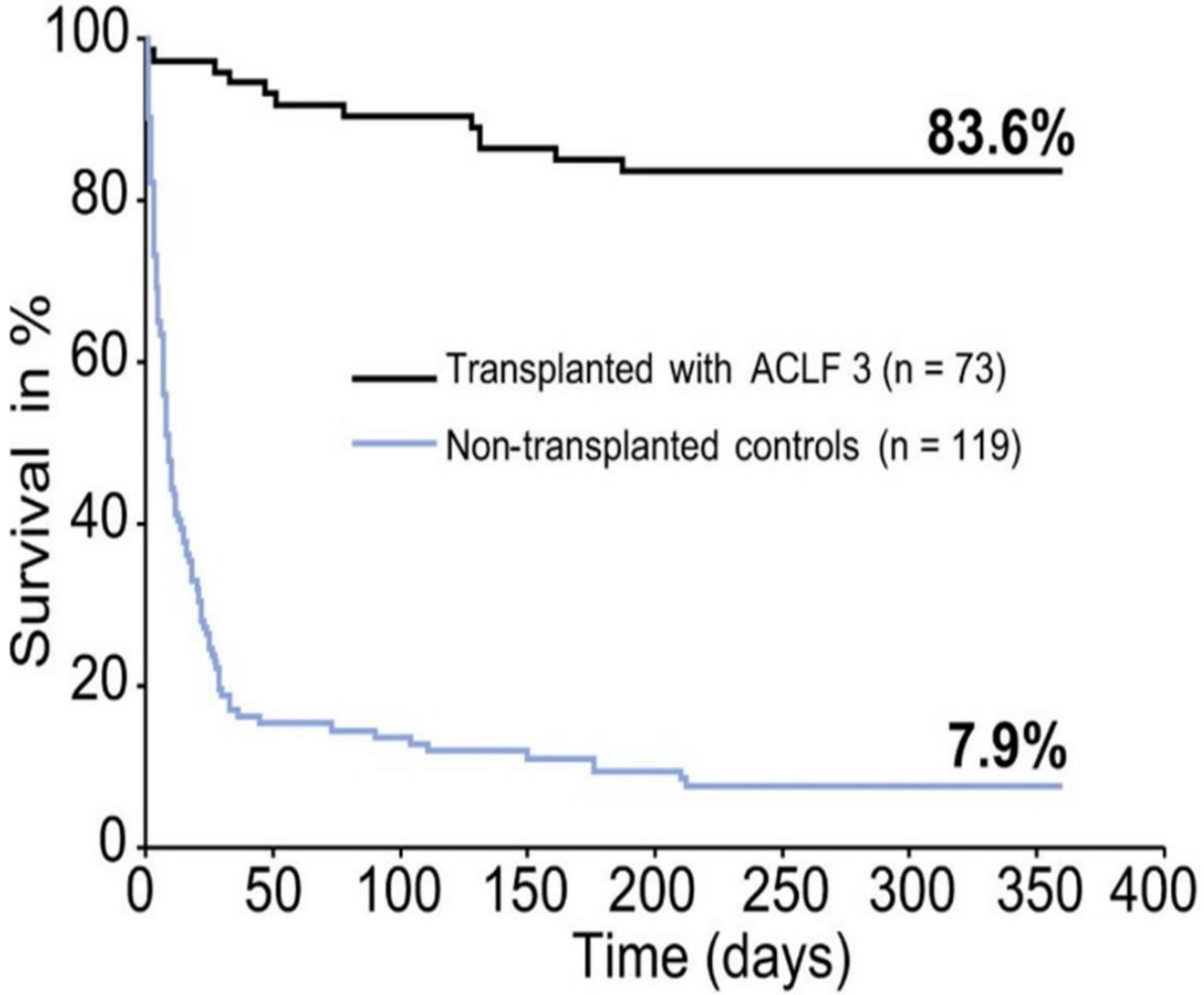
Microbial cultures to guide antibiotic selection

Bernal W, *et al*. J Hepatol 2021.

GOAL OF TREATMENT : BUY TIME

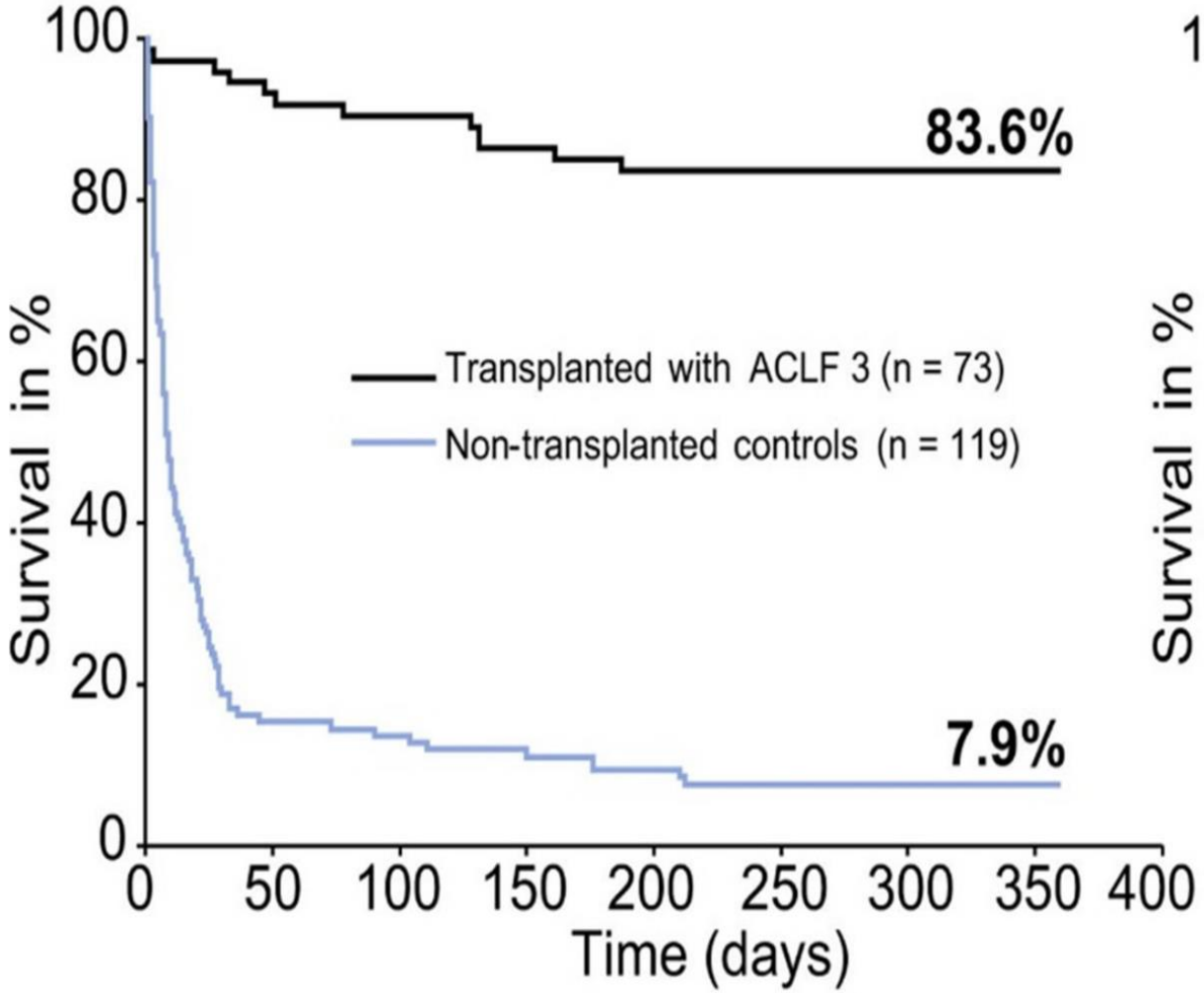
- Allow the precipitant to resolve
- To allow families to say goodbye
- To prepare for liver transplant

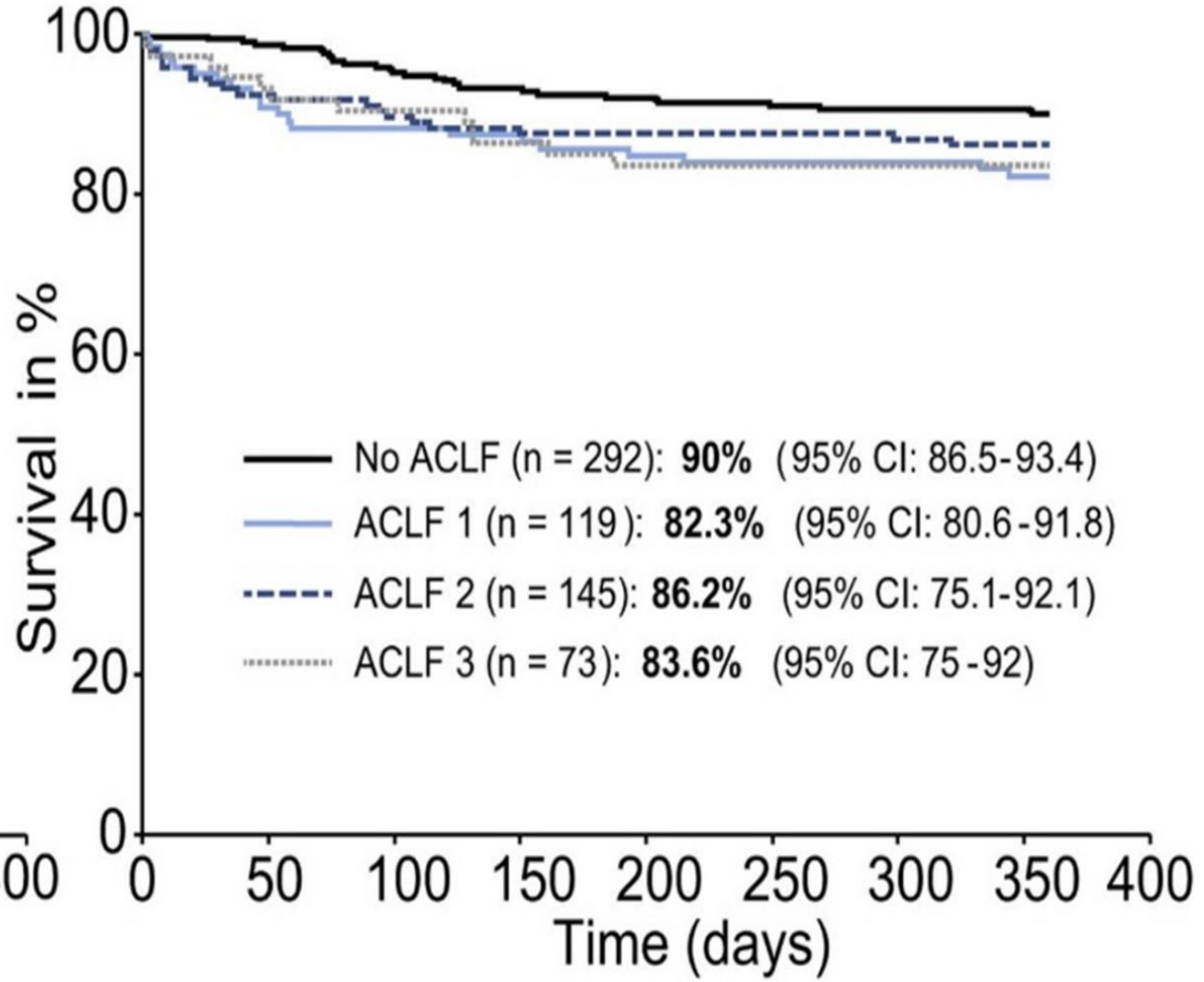
Survival is better with transplant than without



Gustot, *et* al. Hepatol 2015. Artru F, *et al*. J Hep 2017.

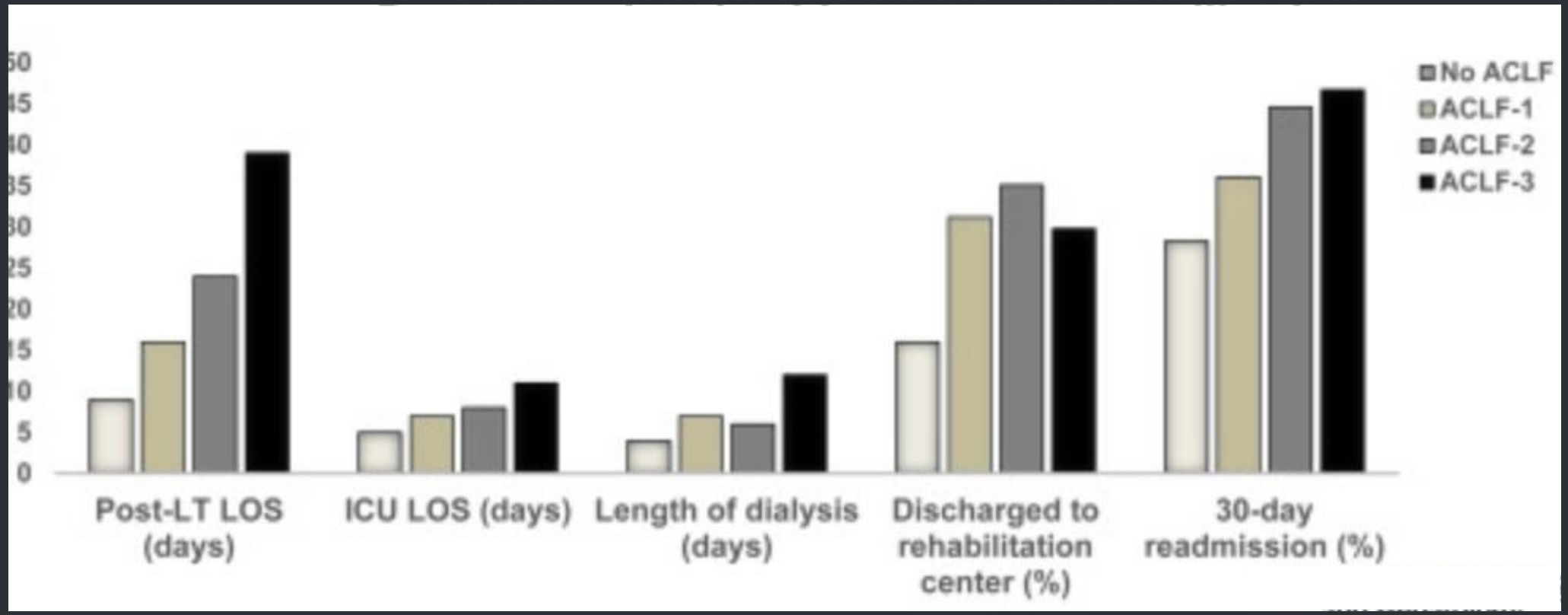
Transplant survival is acceptable in all ACLF grades





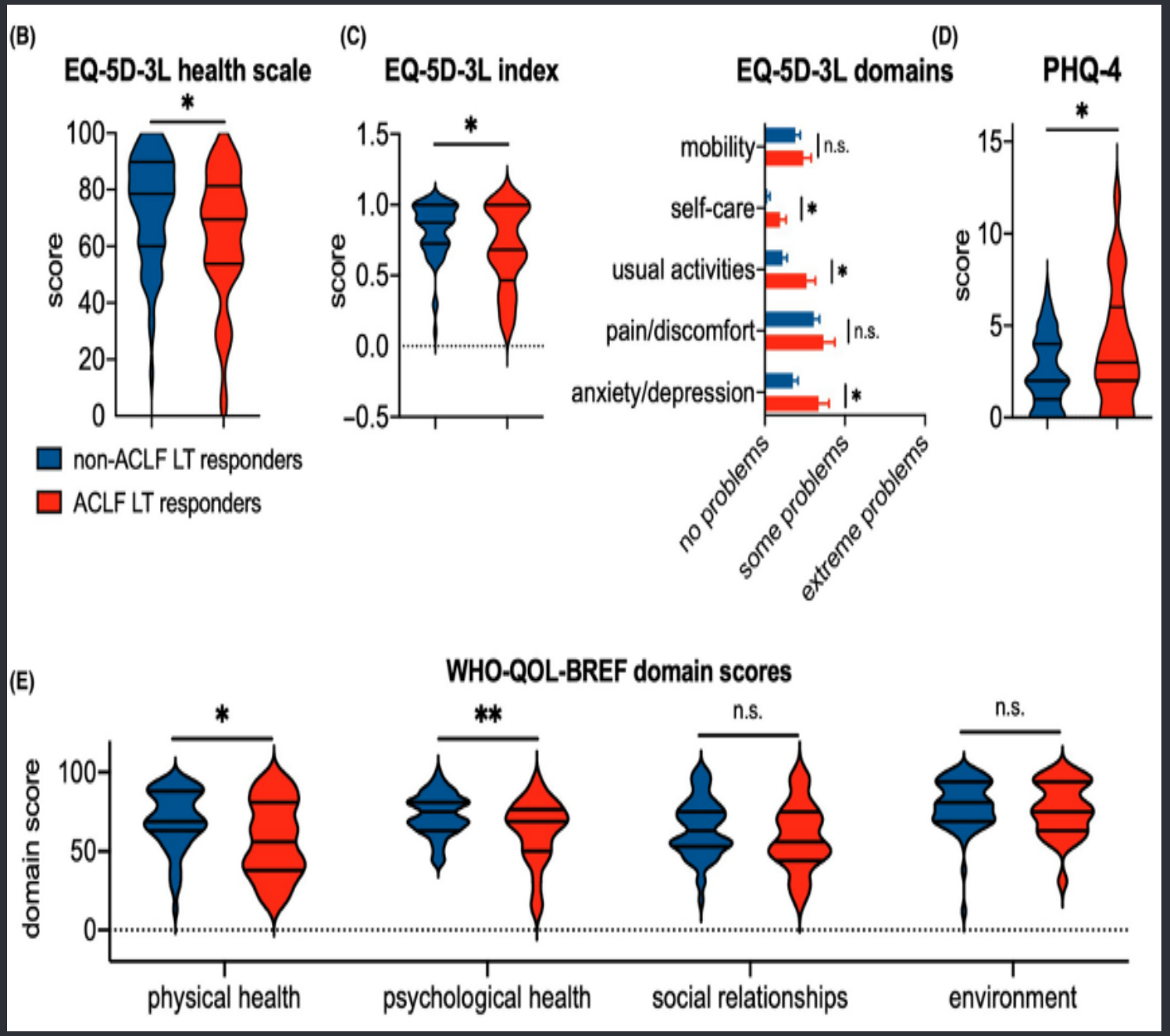
Gustot, *et* al. Hepatol 2015. Artru F, *et al*. J Hep 2017.

Post-transplant healthcare utilization increases by stage of ACLF



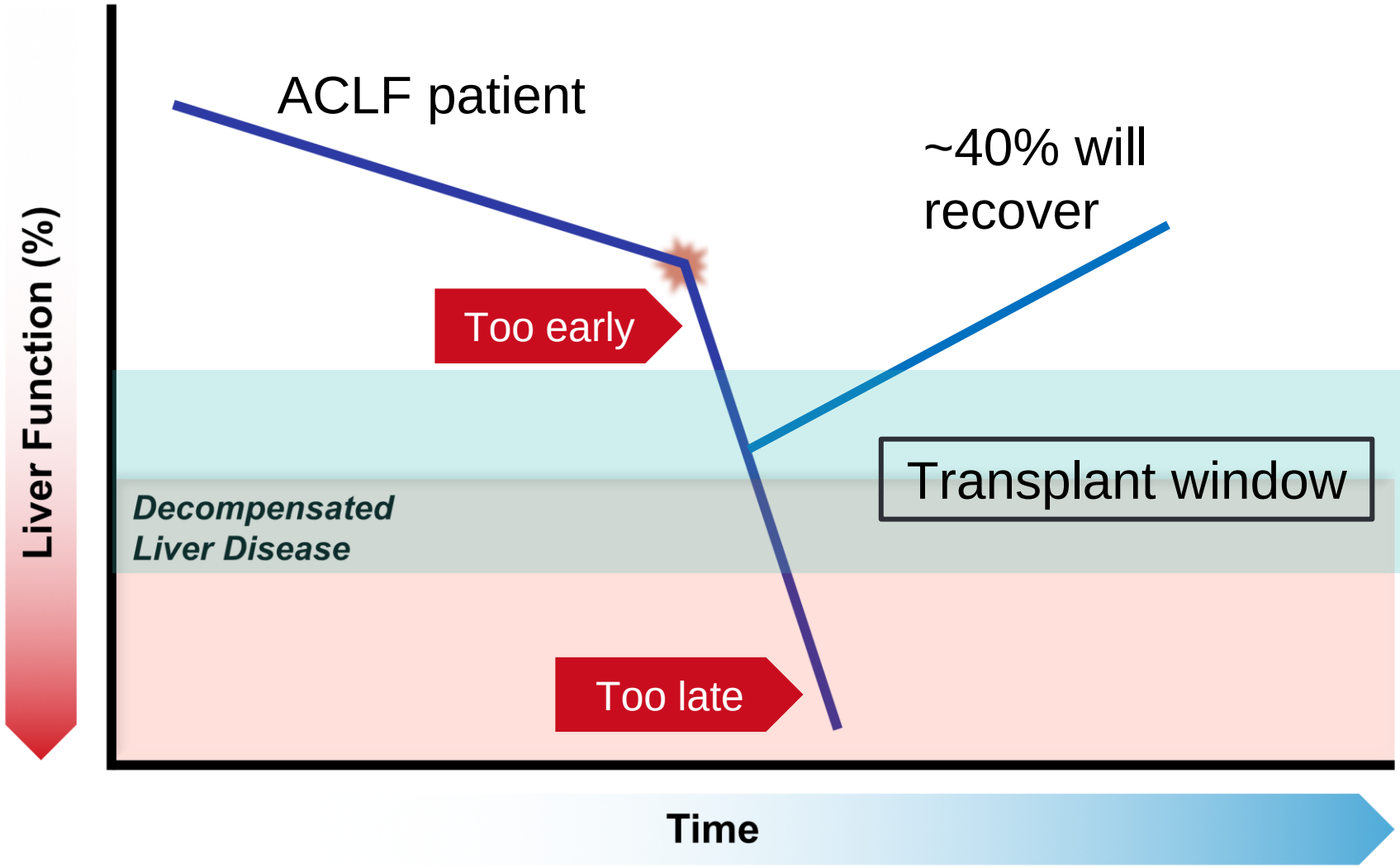
Sundaram V, *et al*. Clin Gastro Hep 2022.

Post-LT quality of life is significantly impaired



Sundaram V, *et al*. Clin Gastro Hep 2022.

Narrow window for liver transplantation



- ~4% of patients with cirrhosis are listed for liver transplant
- 1 in 4 patients listed for transplant die while waiting

Adapted from Mahmud N, *et al*. Curr Hep Reports 2020 and Gustot T, *et al*. J Hepatol 2018. Atiemo *et al*. AJT 2017.

Interventions other than liver transplantation :
Statements from the ACG ACLF guidelines

- Artificial liver support systems

  "whether they provide any clinical benefit is unclear"

- Plasma exchange

  "its effect in ACLF is unknown"

- Granulocyte colony stimulating factor

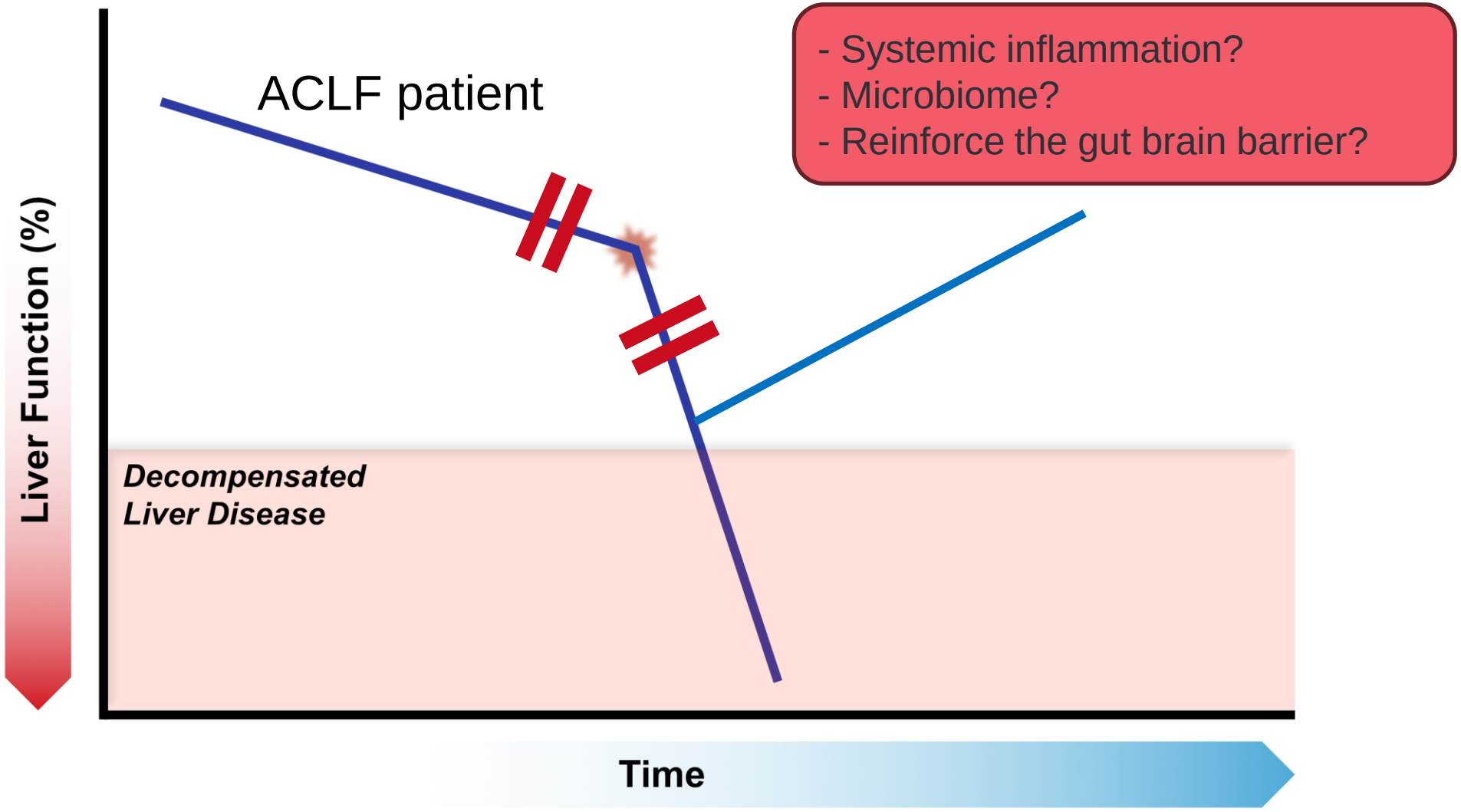
  "we suggest against the use of G-CSF"

- Stem cell therapy

  "evidence to support its use is currently insufficient"

Bajaj J, *et al*. Am J Gastro 2022.

The Opportunity



Adapted from Mahmud N, *et al*. Curr Hep Reports 2020 and Gustot T, *et al*. J Hepatol 2018.

Key Points : ACLF (Disease state)

- ACLF is a highly lethal, resource-intensive condition that occurs in patients with chronic liver disease.
- Portal hypertension, altered microbiome, and systemic inflammation drive ACLF.
- There is no direct therapeutic for ACLF.
  - Liver transplantation, while effective, is limited due to narrow timing, low availability of organs, and poor access to high-level care.

Towards a new GENFIT

ACLF disease state

GENFIT's approach to ACLF

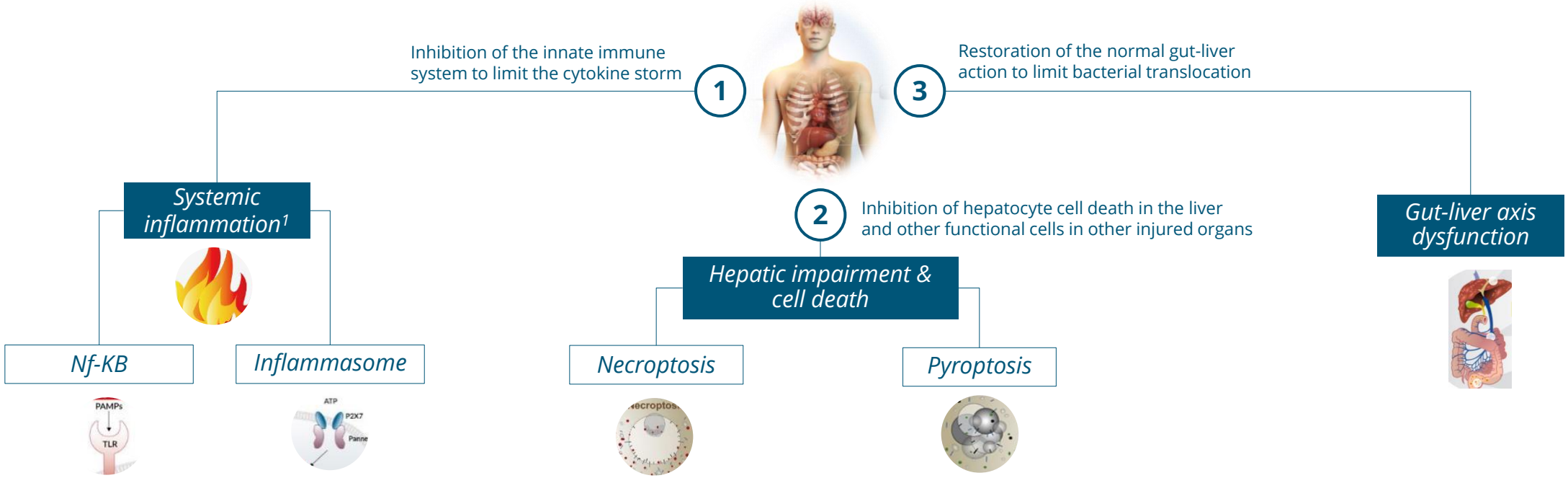
Dean Hum, CSO – Meriam Kabbaj, CTO – Dr. Carol Addy, CMO

ACLF market opportunity

Highlights on newsflow

Building a targeted portfolio to address the unmet need that exists with current (not approved) Standard of Care in ACLF

Specific selection of strategic assets: based on pathophysiology[1] of ACLF, as defined by liver experts and consortiums such as EF-CLIF (European Foundation for the study of Chronic Liver Failure), to address most relevant pathways



ACLF patient management[1] (no drug approved)

1. Treating acute precipitants
-Antimicrobial therapy
-Corticosteroids for alcoholic hepatitis
-Acute variceal haemorrhage

2. Organ support
-Intravenous fluids
-Renal replacement therapy
-Extracorporeal liver support
-Liver transplantation

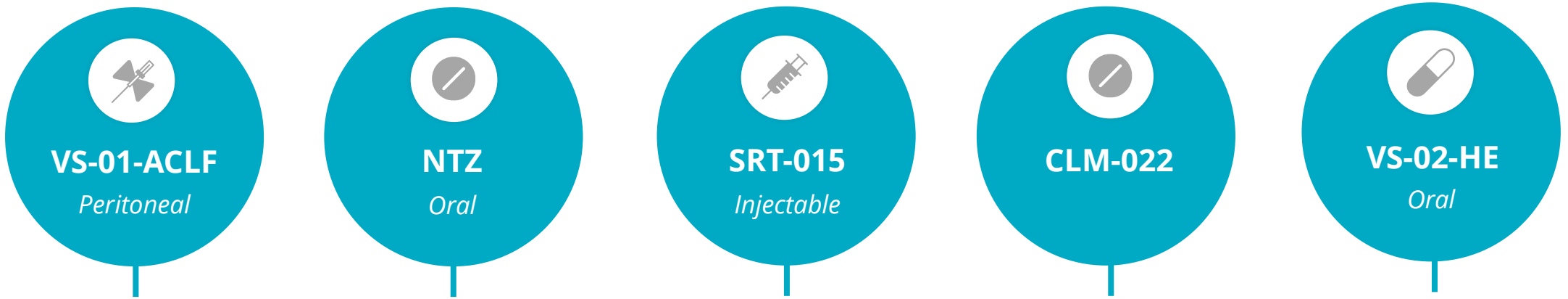
Benefits of a diversified pipeline targeting complementary/relevant pathways

- Explore more options for **patients**
- Provides **multiple opportunities** for success
- Allows exploration of potential synergies in **combinations**
- Offers possibility to apply key learnings across all programs, to **accelerate execution**

1: JHEP, Moreau, 2021 (https://www.jhep-reports.eu/article/S2589-5559(20)30110-5/pdf) / Critical Care, Moreau& Li, 2023 (https://ccforum.biomedcentral.com/articles/10.1186/s13054-023-04540-4)

5 assets with complementary mechanisms of action targeting key pathways

We are developing a **diversified pipeline**
to better address the **complexities of ACLF** and improve **treatment outcomes**



Liposomal-based technology

To drain out **ammonia** and **ACLF toxins** from the blood

Anti-inflammatory and anti-bacterial

To reduce **systemic inflammation** and impede **PAMPs release** and **bacterial translocation**

[New formulation under development for dosing flexibility]

ASK1 inhibitor

To inhibit cell death **apoptosis**, **inflammation (liver-centricity)**, and **fibrosis**

NLRP3 inflammasome inhibitor

To inhibit **inflammation (systemic)**, and **cell death** (pyroptosis)

Urease inhibitor

To reduce **hyperammonemia**, stabilize blood ammonia and **prevent HE**

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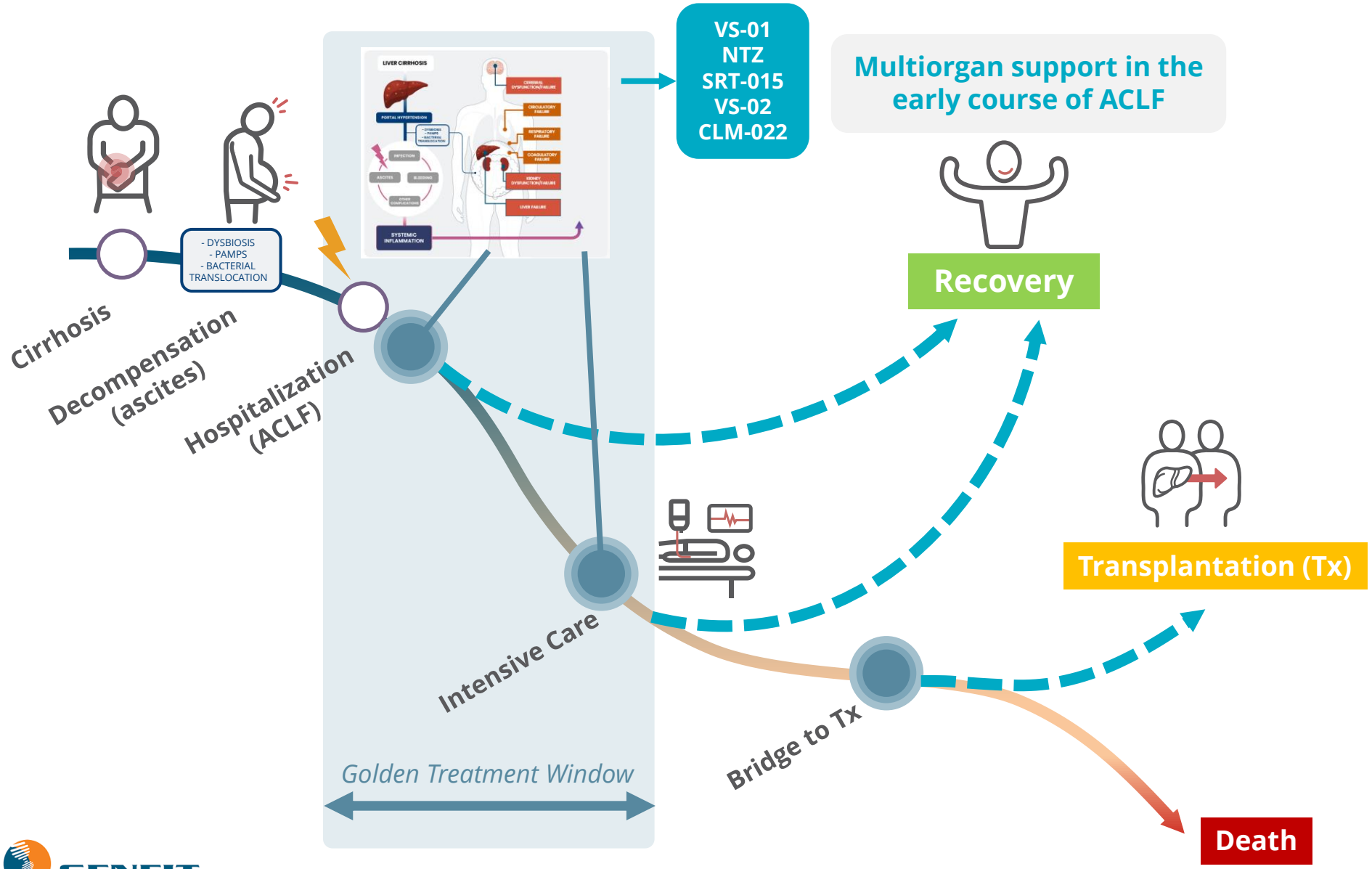
Patient Journey & Window of Opportunity for Treatment



TREATMENT GOALS

- **Resolve** ACLF
- Improve **survival**
- Chance of liver **transplant** increased
- **Healthcare** costs reduced

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VS-01

Clinical Stage Program in ACLF

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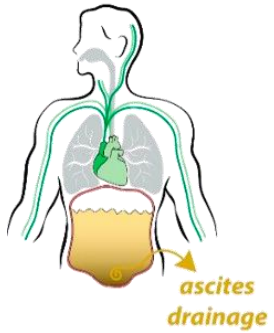
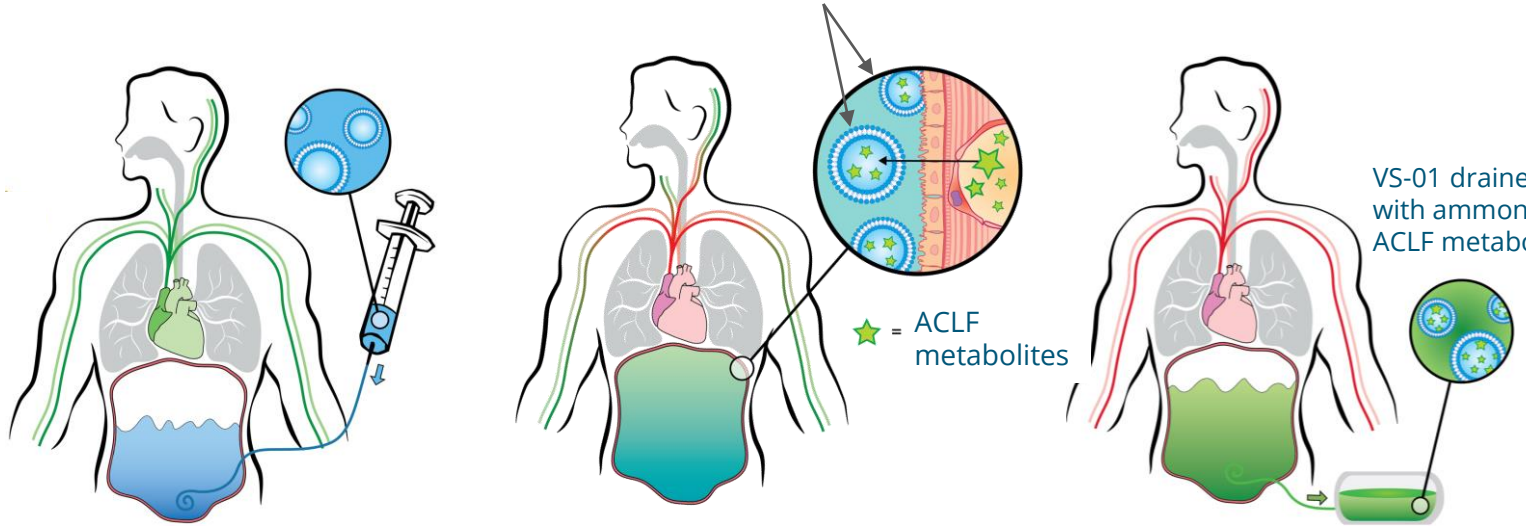
Extraction of Metabolites to Reduce Mortality

Standard of care
Ascites drainage



VS-01

VS-01 scavenging liposomes



Harnesses the intraperitoneal route of administration following paracentesis

VS-01 in brief

High unmet medical need in ACLF with **no approved treatment and 112'000 cases**[1]

Targets **first-line treatment for ACLF** to **reverse** the disease

Delivered via **in-place peritoneal access** catheter

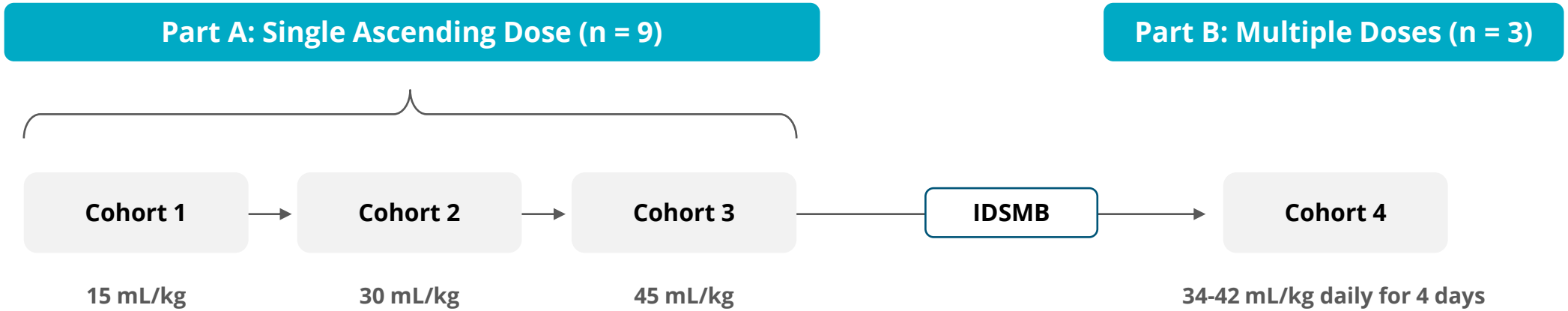
Targets multiorgan support: brain, liver, and kidney

Early ACLF treatment may reduce

- Length of hospital/ ICU stay
- Acute need of transplantation
- Re-hospitalization
- Healthcare and hospital costs

1. Prevalence US+EU5 of patients with ascites and candidates for VS-01 Source: third-party US Market Research, December 2021

First in Human Study



DETAILS

- Study population (n=12):
  - Decompensated liver cirrhosis with
    - Ascites
    - Covert hepatic encephalopathy (minimal HE & HE 1)
- Principal investigator: Prof Dr Jonel Trebicka
- Clinical site:

UNIVERSITÄTS KLINIKUM FRANKFURT GOETHE-UNIVERSITÄT

OUTCOME

- ✓ Generally **safe** and **well tolerated**
- ✓ Promising **preliminary efficacy results**
- ✓ Confirmed **ease of *i.p.* administration**
- ✓ Data selected for **Clinical Hepatology Debrief** at AASLD 2021

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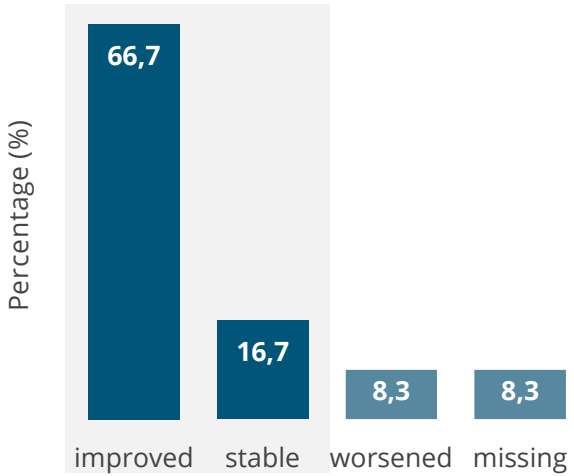
SOC, standard of care | IDSMB, Independent Data and Safety Monitoring Board | HE, hepatic encephalopathy

Phase 1b Preliminary Efficacy Results on Liver & Brain Function

IMPACT ON OVERALL LIVER DISEASE SEVERITY

e.g., assessed by Child-Pugh Score (CPS)

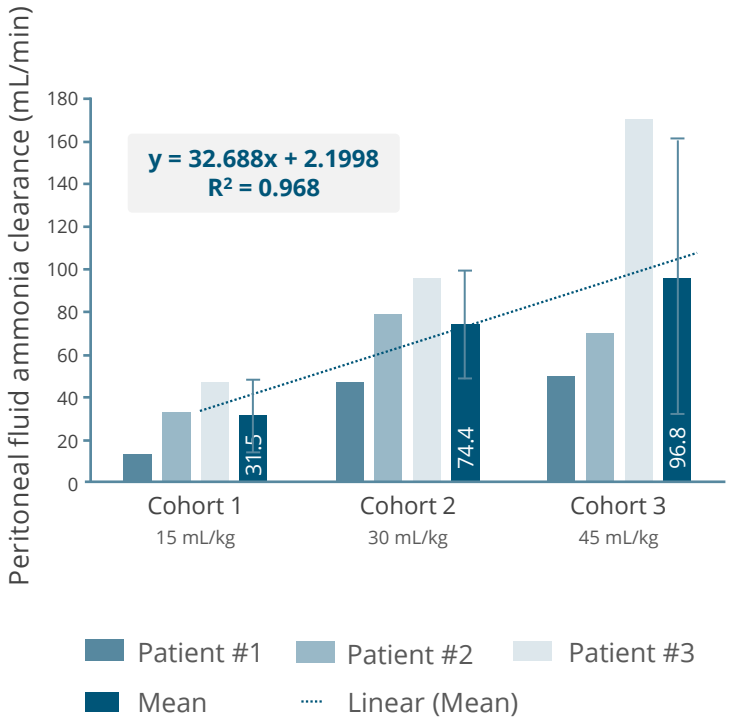
Improved or stable disease: 83.4%



NO PATIENTS PROGRESSED TO ACLF

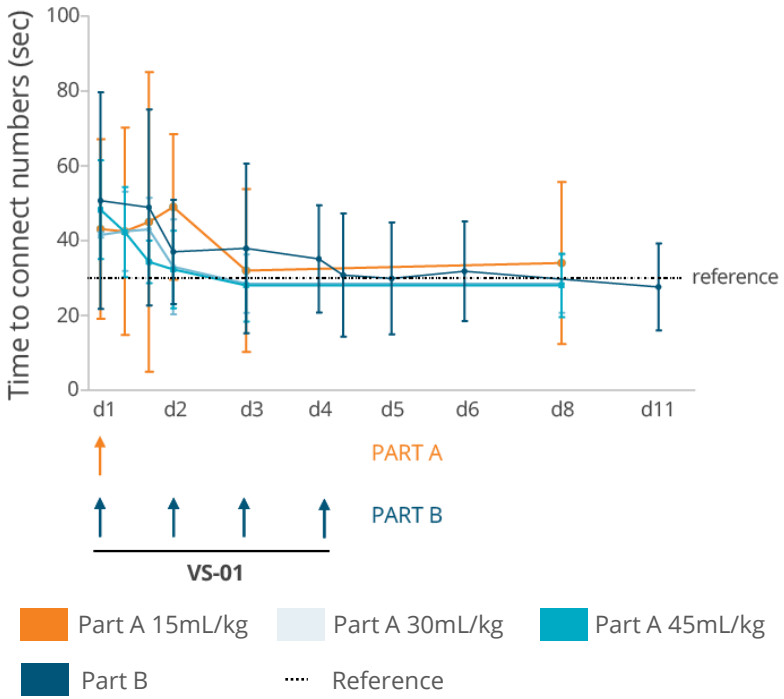
DOSE-DEPENDENT AMMONIA REMOVAL FROM THE BODY

Ammonia clearance increased with VS-01 dosage in peritoneal fluid



IMPROVEMENT IN PSYCHOMETRIC TESTS FOR HE

e.g., number connection test was performed faster



Uschner FE et al., Oral presentation at AASLD 2021, Abstract # 208

UNVEIL-IT™ Phase 2 Proof-of-Concept Trial

Phase 2a Proof Of Concept Study of VS-01 in **Patients with Acute-on-Chronic Liver Failure**

OPEN-LABEL | 1:1 RANDOMIZED | CONTROLLED | MULTI-CENTER GLOBAL STUDY | INTERIM ANALYSIS* TARGETED 1H2024

Patient Population

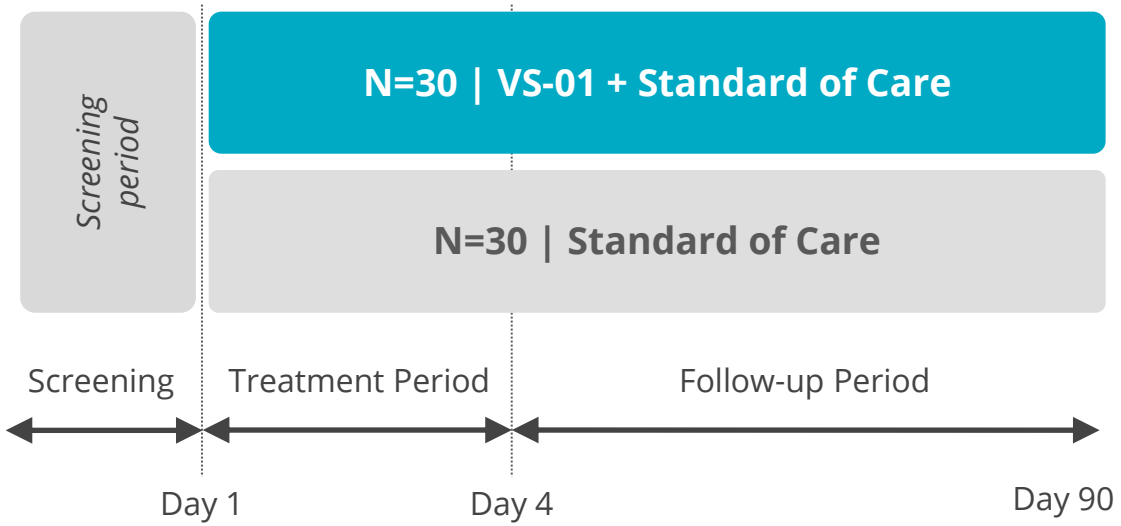
Adult patients with Acute-on-Chronic Liver Failure (ACLF) **grade 1 and 2** and **ascites**

Number of Patients

~60

Number of Sites

50 (EU/US)



Primary Objective

Efficacy measured by CLIF-C ACLF score at Day 7**

Secondary Objectives

90 day - mortality
28 day - mortality
Time to death
ACLF grade change
Transplant-free survival
Safety and tolerability

*Interim analysis for the purpose of unblinded sample size re-estimation
** www.efclif.com

NTZ

Clinical Stage Program in ACLF

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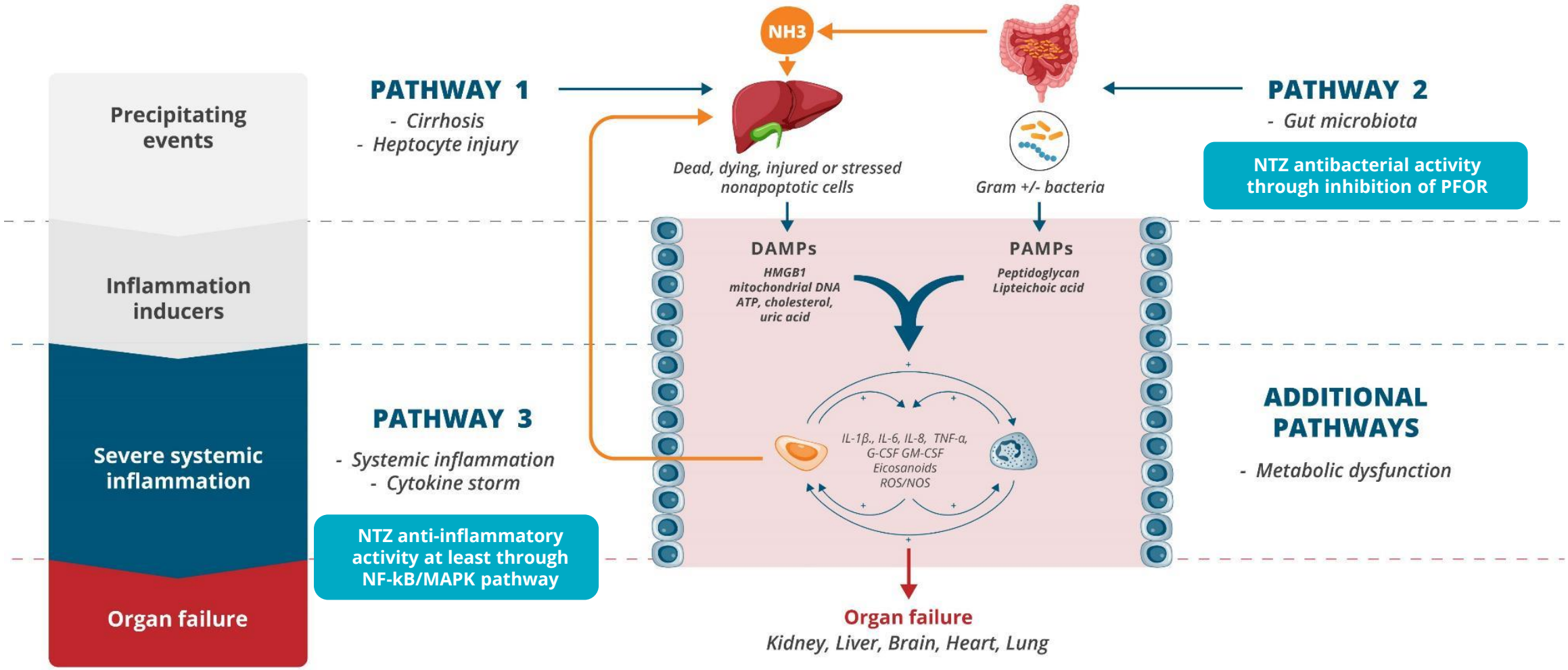
NTZ (Nitazoxanide) is a repositioned molecule

NTZ Impacts Multiple Pathways



Activity in Disease Models Support ACLF Clinical Development

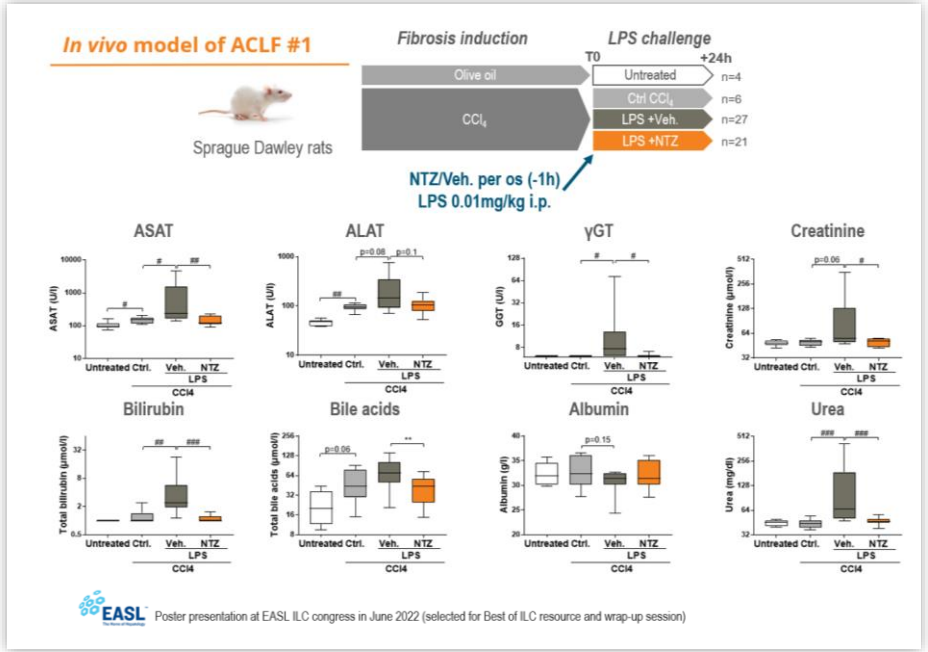
Reduces LPS-induced inflammation in healthy rats*

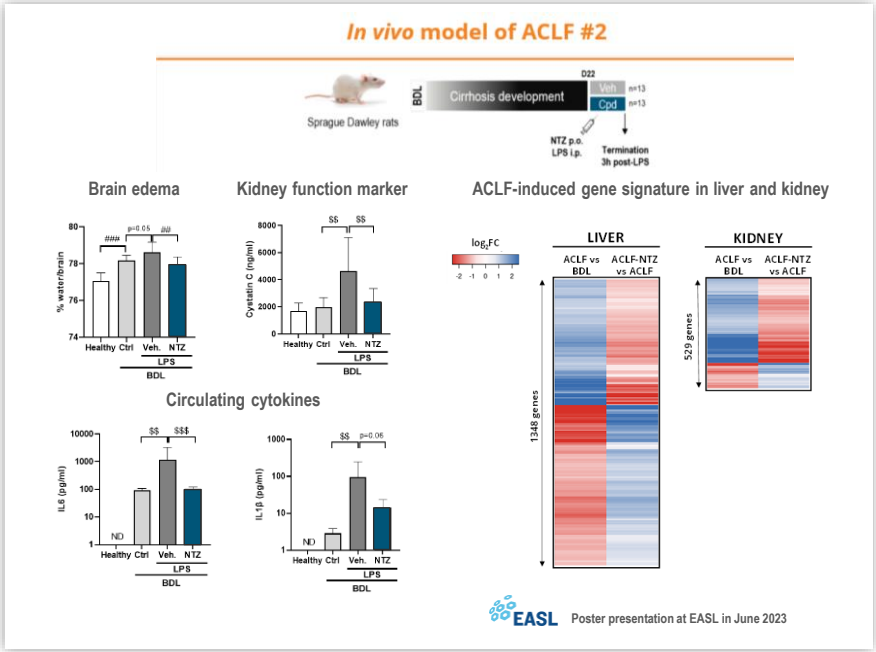
Beneficial effects on liver function markers (bil, alb) in models of cirrhosis*

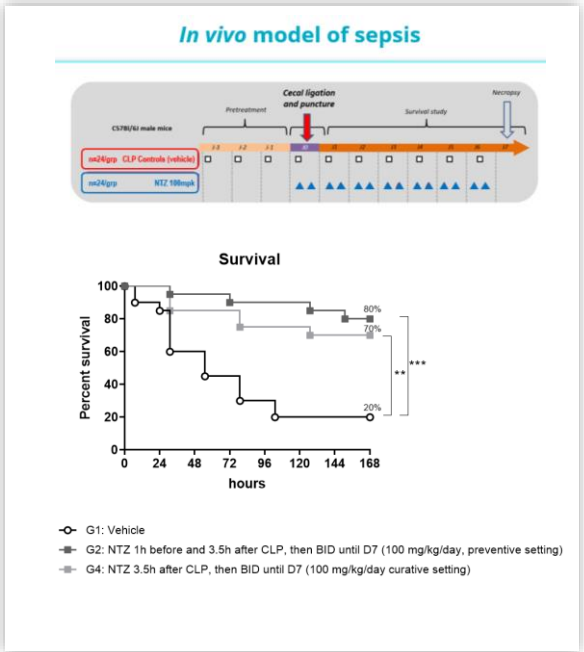
Alleviates liver and renal damages in a model of ACLF (CCL4+LPS)

Reduces brain edema, inflammation markers and reverses the ACLF-induced gene signature in a model of ACLF (BDL+LPS)

Improves survival in treatment models of **Sepsis** (CLP)







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EASL CONGRESS

* Poster presentation at the ILC 2022 (London) – EASL
Selected for The Best of ILC

Completed Ph1 studies in subjects with hepatic impairment (HI) and renal impairment (RI)

An Open-label, Phase 1, Multiple-dose Study to Evaluate the **Pharmacokinetics and Safety of NTZ 500 mg twice daily for 7 days in Adult Subjects with Moderate & Severe Hepatic Impairment** and Adult Healthy Control Subjects

Design

- Moderate to Severe HI subjects vs healthy subjects
- 6-8 Subjects in each group
- Treatment period 7 days
- PK, safety, pharmacodynamics

Healthy control subjects (n=8)

Moderate hepatic impairment (n=8)

Severe hepatic impairment (n=8)

An Open-label, Phase 1, Multiple-dose Study to Evaluate the **Pharmacokinetics and Safety of NTZ 500 mg twice daily for 7 days in Adult Subjects with Mild, Moderate & Severe Renal Impairment** and Adult Healthy Control Subjects

Design

- Mild, Moderate and Severe RI subjects vs healthy subjects
- 8-10 Subjects in each group
- Treatment period 7 days
- PK and safety

Healthy control subjects (n=7-8)

Mild renal impairment (n=7-8)

Moderate renal impairment (n=7-8)

Severe renal impairment (n=7-8)

Development of a New Formulation, ahead of a Phase 1b/2a Proof-of-concept Targeted to Start in 1H25

New formulation under development

To permit **greater dosing flexibility** and ultimately better serve the ACLF patients:

- This population is known to have **impaired/organs failure**, and this new formulation will also permit to optimize safety and drug exposure in this patient population.
- Optimization of the future potential of NTZ, taking into account specific needs of the targeted patients.

Objectives of the POC

Phase 1b

- To evaluate safety and tolerability of NTZ across a range of doses in patients with ACLF
- To evaluate NTZ dose response relationship in patients with ACLF
- To select the optimal NTZ dose for evaluation in Phase 2a

Phase 2a

- To evaluate clinical outcomes in patients with ACLF following administration of NTZ
- To evaluate safety and tolerability of NTZ in patients with ACLF
- To evaluate NTZ PK/PD relationships in patients with ACLF

Patient Population: Patients with **ACLF1** or **ACLF2**

SRT-015

Preclinical stage program in ACLF

GENFIT
TOWARDS BETTER MEDICINE

SRT-015 has been in-licensed from Seal Rock Therapeutics

An Injectable Formulation of ASK1 Inhibitor

SRT-015 in brief

ASK1 inhibitor
in-licensed from Seal Rock Therapeutics
in **acute liver diseases**

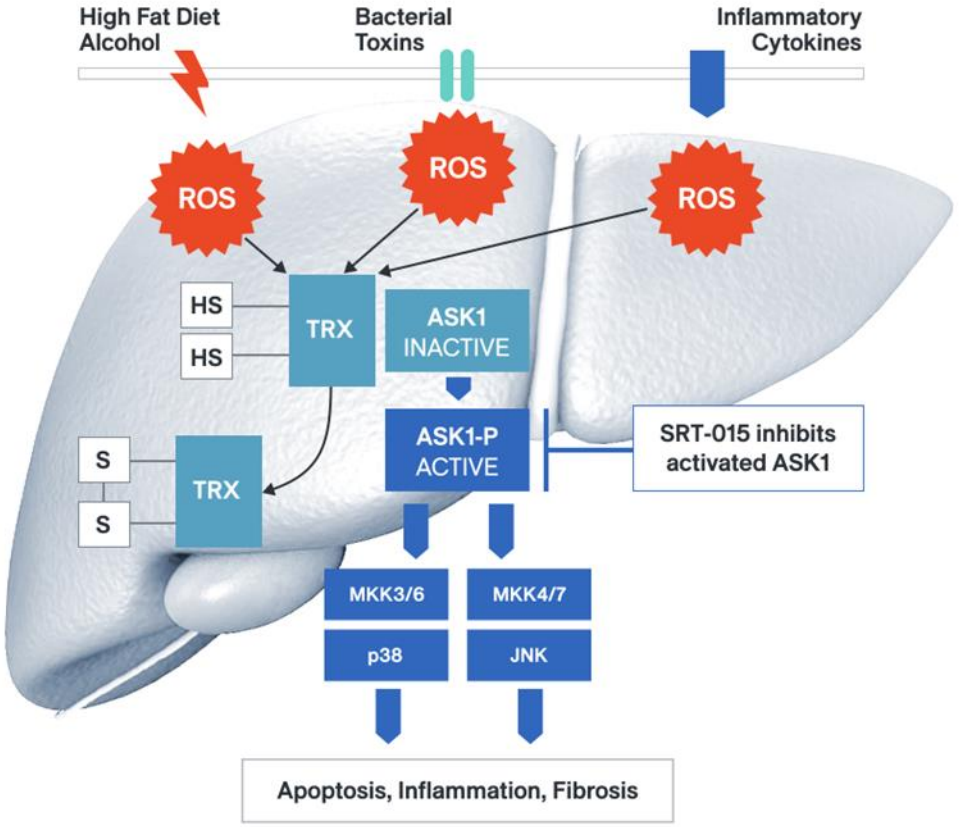
Injectable formulation

Targets inhibition of **cellular apoptosis**, **inflammation** and **fibrosis**

Scientific rationale

ASK1 inhibition has shown **several potentially beneficial effects** that may be relevant in ACLF

- **Blocking LPS** (lipopolysaccharide) associated hyperinflammatory response
- **Reducing the ROS** (Reactive Oxygen Species)-related immune response
- **Reducing apoptosis**
- **Reducing release of the proinflammatory cytokines**
- **Reducing fibrosis**
- **Protecting macrophage mitochondrial function**

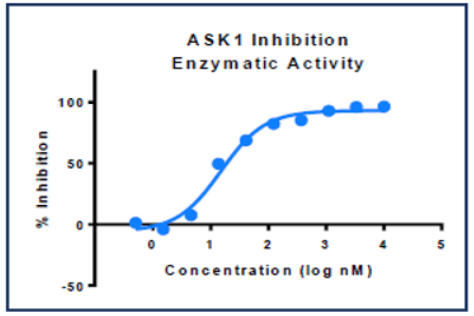


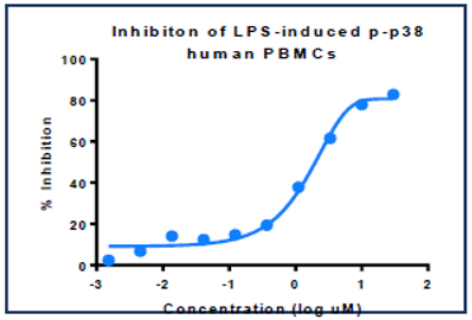
1. ASK1 inhibition: a therapeutic strategy with multi-system benefits: Journal of Molecular Medicine (2020)

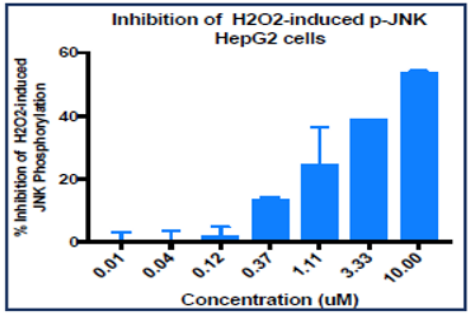
Target Engagement, MoA, Activity and Data Supporting Development in ACLF

Inhibits:

-ASK-1
-phosphorylation of p38
-phosphorylation of JNK

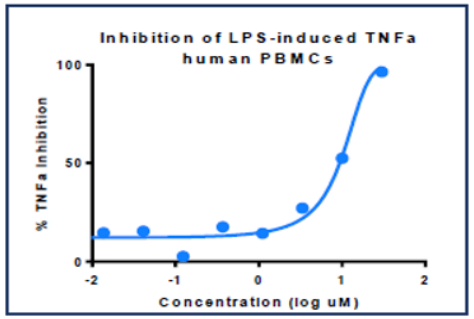


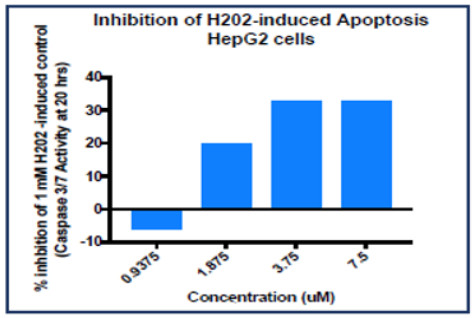


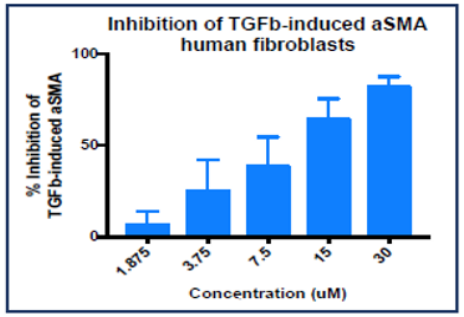


Activity:

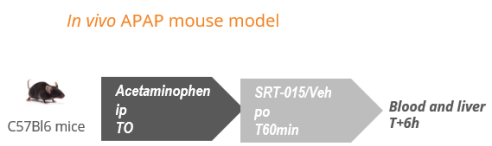
-Anti-inflammatory
-Anti-apoptotic
-Anti-fibrotic

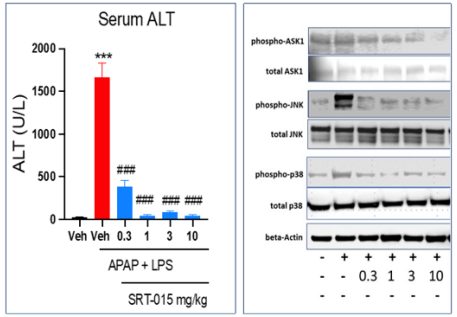




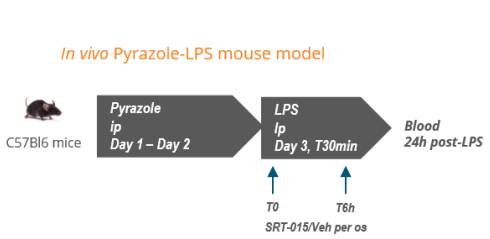


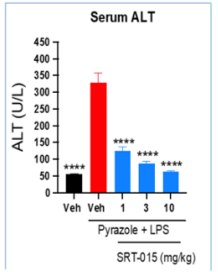
SRT-015 alleviates hepatic injury in a model of drug-induced liver injury, in association with reduction of phosphorylation of both JNK and ASK1





SRT-015 alleviates hepatic injury in a model of alcoholic hepatitis





Similar preliminary data obtained using iv administration of SRT-015

Clinical Data Support Development in Liver Diseases

Multi-organ benefits of ASK1 modulation have been observed in **several animal models and clinical trials**[1]

In **kidney diseases**
=> limits renal inflammation, apoptosis and fibrosis

In **liver diseases**
=> prevents hepatocyte death, inflammation and fibrosis

In **brain disorders**
=> ASK-1 modulation limits neurodegeneration

In **inflammatory diseases**
=> limits damaging immune responses

In **cardiopulmonary disease**
=> slows the onset of heart failure

› SRT-015 has demonstrated **efficacy in multiple preclinical models**[2] of acute and chronic liver injury

› SRT-015 phase 1 FiH trial[3] completed in healthy volunteers, achieving **therapeutically relevant exposure** with **safety and tolerability profile** supportive of ongoing clinical investigation

Upcoming milestone
First-in-Human study targeted for 2H24

1. ASK1 inhibition: a therapeutic strategy with multi-system benefits: Journal of Molecular Medicine (2020)
2. https://www.sealrocktx.com/science.html
3. NCT04887038

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CLM-022

Preclinical stage program in ACLF

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CLM-022 has been in-licensed from Celloram Inc.

Supporting Evidence and Next Steps

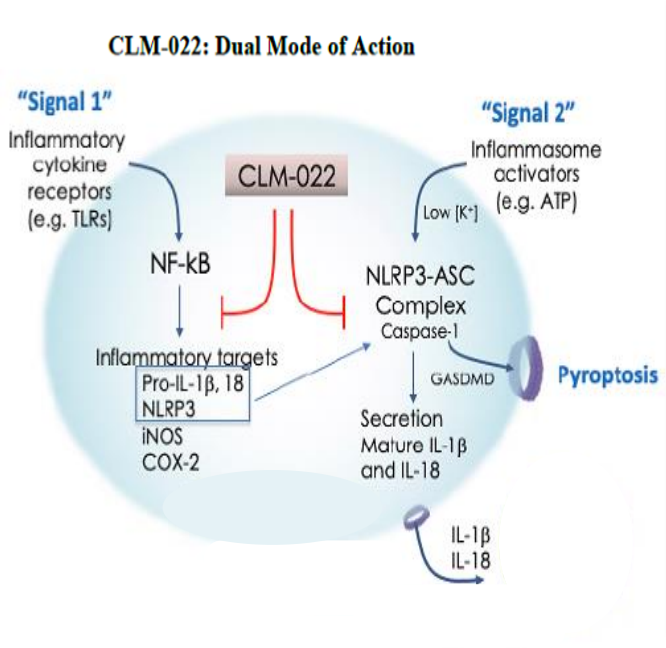
CLM-022

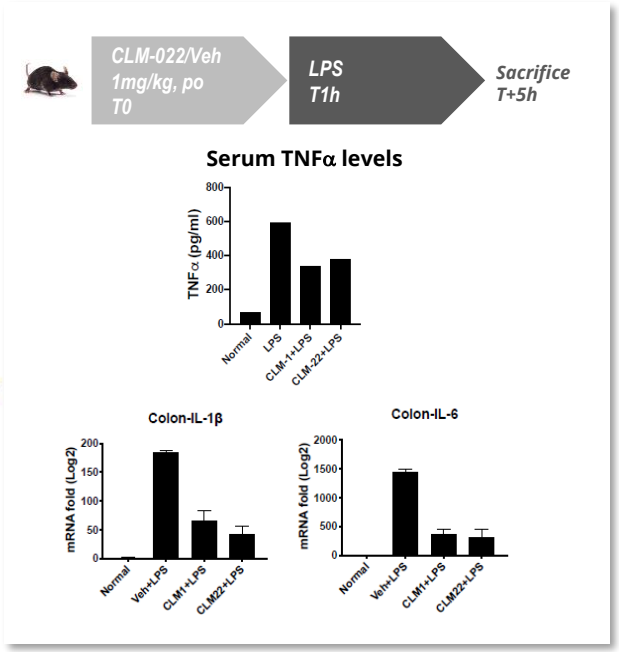
NLRP3 inflammasome inhibitor

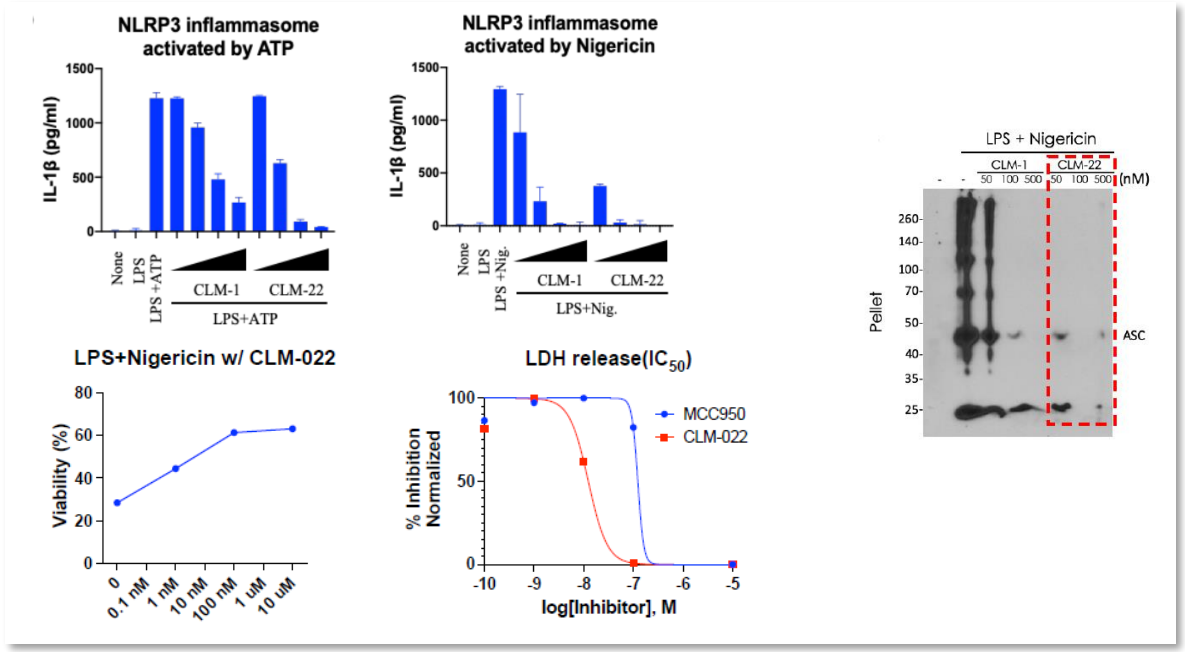
Preclinical

- Blocks NLRP3 inflammasome activated by ATP and Nigericin
- Blocks the endotoxin-induced production of inflammatory cytokines in an LPS sepsis model
- Blocks ASC speck formation at nanomolar concentrations
- Decreases IL-1β secretion by macrophages stimulated with LPS and nigericin
- Protects against nigericin-induced pyroptosis in LPS-primed macrophages
- Active *in-vivo* in rodent preclinical models of sepsis and IBD.
- Well tolerated

Preclinical Proof of Concept in 2024







VS-02-HE

Preclinical program in ACLF and its complications

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Supporting Evidence and Next Steps

About HE

- Major complications of **advanced liver disease** and **portal hypertension**[6]
- **30-40% of patients with cirrhosis** will experience at least 1 episode[5]
- **Independent risk factor of mortality** in ACLF[6]

VS-02 in ACLF-HE

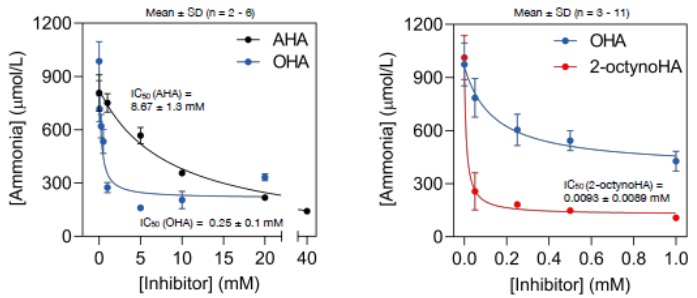
Urease inhibitor

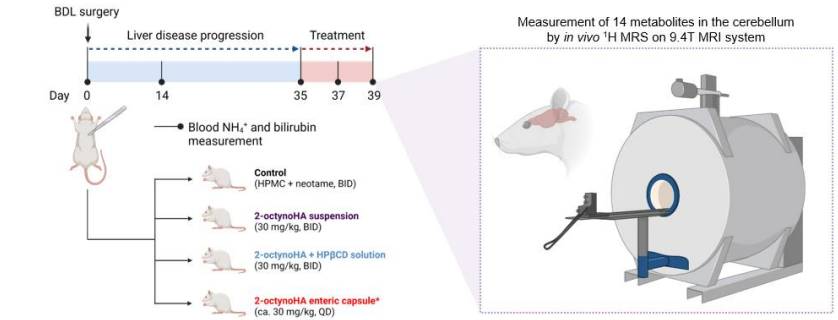
Preclinical data

- Superior urease inhibitory activity in vitro
- Cytotoxicity and mutagenicity assessment (Ames test)
- Reduces plasmatic ammonia in a model of acute liver failure in rats
- Reduces plasmatic ammonia and brain glutamine in the bile duct-ligated model in rats

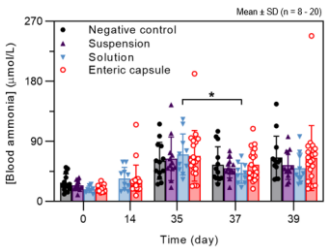
IND enabling studies completion in 2025

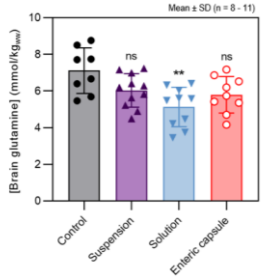
Urease inhibitory activity in the caecal content of Wistar rats





*Capsules (size 9h) were coated with 15% (w/w) Eudragit L100 solution for colonic delivery
**Solution of 2-octynoHA was prepared using HPβCD (1:1, mol/mol)





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1. Forster V. et al. Sci Transl Med 2014
2. Agostoni V. et al., Adv Funct Mater 2016
3. Giacalone G. et al., J Cont Release 2018
4. Matoori S. et al., J Cont Release 2020
5. VS-01 Phase 1b data compared to independent published studies

Towards a new GENFIT

ACLF disease state

GENFIT's approach to ACLF

ACLF market opportunity

IQVIA

Highlights on newsflow

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We conducted secondary market research / literature review to assess the commercial opportunity in ACLF

SCOPE 

ACLF disease landscape

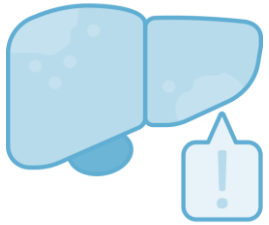
- Performed a **literature review and secondary market research** to understand:
  - Demographics and epidemiology / burden of disease with healthcare costs associated
  - Treatment algorithm
  - Competitive landscape
  - Expected future market events

ACLF addressable market estimation

- Overall ACLF market size **estimated based on epidemiology and potential price point** from secondary market research

No detailed pricing primary market research was conducted. Estimation is not a forecast – calculations represent potential overall market size based on secondary research / literature review.

ACLF is a life-threatening disease involving multiple organs failure and characterized by short term mortality



Acute on chronic liver failure

Life-threating disease characterized by **acute decompensation** of chronic **liver** disease associated with multiple **organ failures** and high short-term mortality[1]

52-57

average age at diagnosis mostly driven by onset of alcohol related cirrhosis and/or hepatitis B or D[5,6,7]

30%

Hospital readmission rate after 30 days since discharge[1]

40-50%

mortality rate at 90 days for ACLF1 & ACLF2; and up to 79% for ACLF3 [2,3]

65% of diagnosed patients are male[5,6,7]

1) Shah NJ, et al. StatPearls (2022) 2) Moreau R et. al.,Gastro, (2013); 3) Hernaez R, et al., Gut (2017); 4) IQVIA Analysis; 5) Kamath 2017; 6) Hernandez et al 2019; 7) Wong F, et al., Liver Transpl 2022; 8) Arroyo v., et al, J. Hepatol (2015)

Management of ACLF results in significant economic burden on healthcare systems, leading to a high need for innovative therapies

The burden of ACLF in numbers

52 000 $

Average cost per hospitalization **per patient** in US[1]

16 days

Average length of hospital stay[1]

(vs 7 days for cirrhotic patients)

6.4 Bn $

Estimated **annual cost burden** in US in 2021*

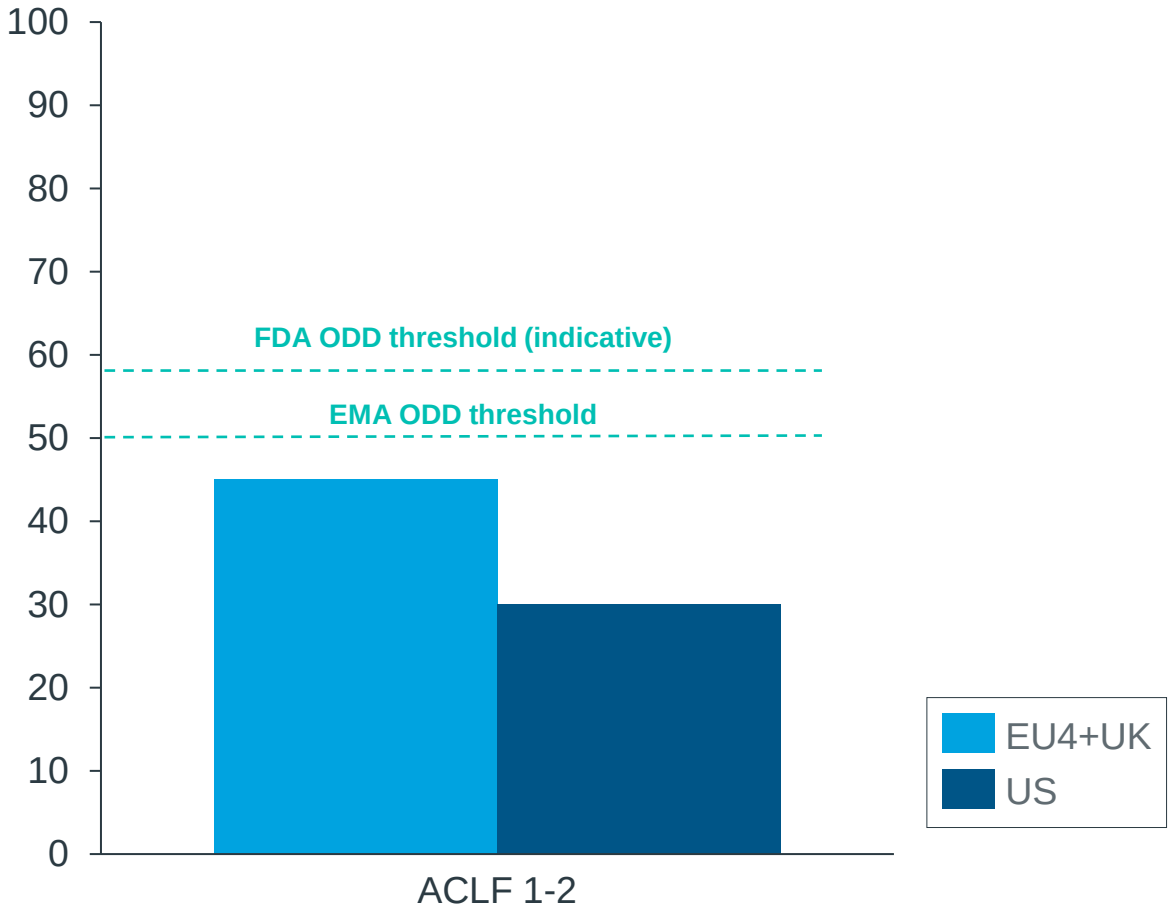
(a nearly 4-fold increase since 2011)*

*Note: Estimates based on triangulation of data from below mentioned publications and PMR interview
(Desai et al, Clin Transl Gastroenterol. (2019); Hirode et al JAMA Netw Open. (2020); Hernaez et al, J Hepatol. (2019); Mezzano et al, Gut (2022); Moreau et al, Gastroenterology. (2013))

1) Kamath 2017; 2) Hernandez et al 2019 3);
Genfit –AASLD presentation - November 2023

ACLF has low epidemiology and could be eligible to orphan designation; aging population and launch of targeted Tx can increase diagnosis rate

Estimated current prevalence (1:100,000)



Overview and future outlook

- In 2021, the **prevalence of ACLF is estimated to be ~294K** across the US, EU4 and UK[1]
  - Approx. 45-52% of ACLF patients are grade 1 and 35% are grade 2[2,3]
  - **Total addressable market (**for grade 1/2 ACLF patients) is estimated to be ~**150K in EU4 & UK and 90K in US**
- Therefore, **therapies targeting ACLF are eligible for orphan drug designation** given low prevalence and lack of therapies

***Note**: while EMA and FDA ODD thresholds capture number of patients, the estimated ACLF prevalence refers to number of episodes rather than patients, thereby leading to potential overestimation of the disease prevalence*

Notes:* Estimates based on triangulation of data from listed sources

Sources: 1. Moreau, R., et al., (2013) Supplemental Table 10; 2. Moreau, R., et al., (2013) CANONIC study Supplemental Table 10; 3.Allen MA et al., Hepatology (2016); 4. Internal Reference (PMR 2021); 5. Desai et al, Clin Transl Gastroenterol. (2019); 6. Hirode et al JAMA Netw Open. (2020); 7.Hernaez et al, J Hepatol. (2019); 8. Mezzano et al, Gut (2022); 9. Moreau et al, Gastroenterology. (2013);

Abbreviations: ACLF: Acute-on-chronic liver failure

Several analogues were selected to estimate price range of upside potential, including one-off therapies for chronic disease and drugs for acute episodes

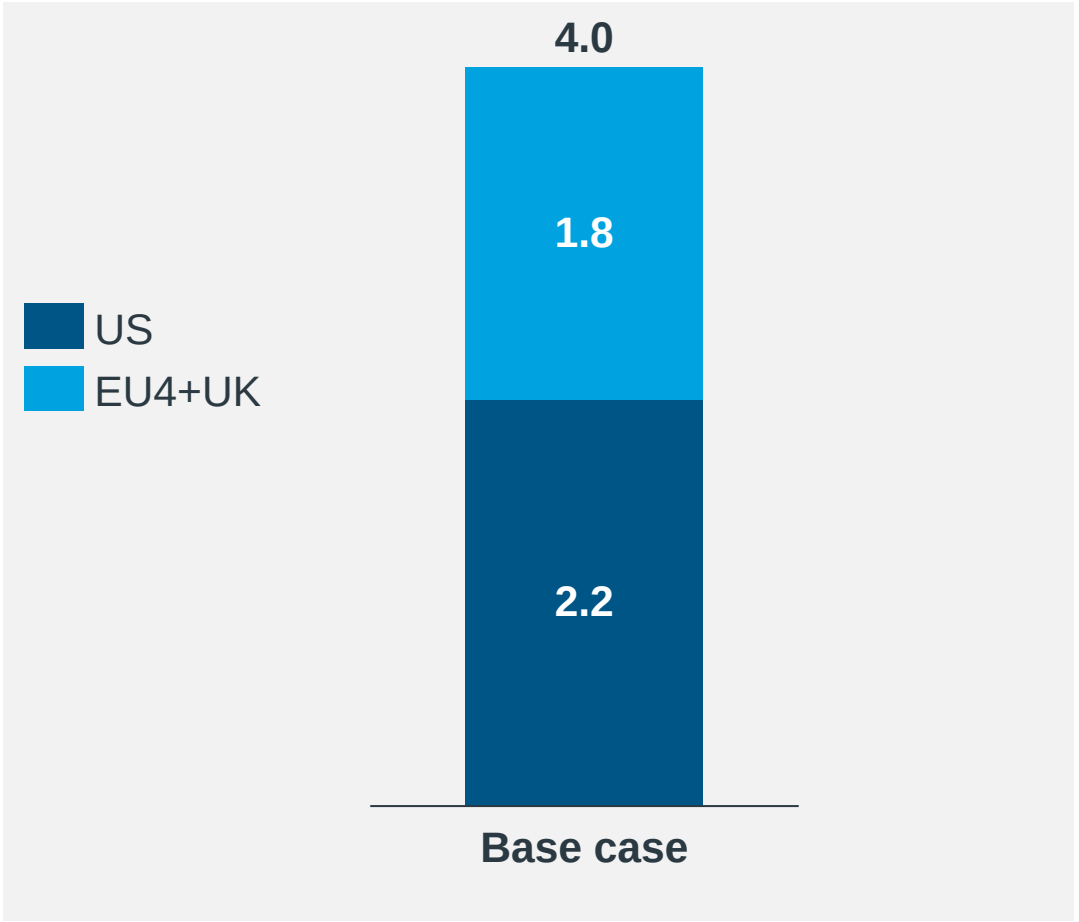
Analogues considered

- To **identify relevant price range for the ACLF drugs**, different analogues were considered
  - **Type of rare** disease (i.e. life threating vs chronic)
  - Onset of **acute** episodes
  - **Setting of treatment** (hospitals vs out-patient care)
  - **Benefit provided** (significant mortality benefit vs slower progression over hard endpoint)
- **IQVIA identified a 100-200k$ in US** as **potential upside range for an upcoming ACLF therapy** with mortality benefit targeting more severe patients

Analogue	MoA	Features	List Price (US)
Andexxa	Recombinant modified human factor Xa (FXa) protein	• Adults with **life threating bleeds** due to use of blood thinner therapies (apixaban and rivaroxaban) • IV infusion by HCP • Immediate, significant reverse blood thinning	• 25-50k$ per treatment, depending on patient features
Cablivi	Monoclonal antibody	• Treatment of **acute episode** in **life threating disease** (i.e. acquired thrombotic thrombocytopenic purpura) • **Orphan drug** • **Hospital** setting • Significantly **reduced potentially fatal and serious disease** related events	• 270k$ per year
CAR – T cell	Chimeric Antigen Receptor	• **One off cycle** for the treatment of acute/ **severe conditions patients** with blood cancer with **limited life expectancy** • **Mortality benefit** over a sustained period of time	• 371$k average cost
Bylvay	Reversible inhibitor of ileal bile acid transporter	• The first non-surgical treatment for severe itching (pruritus) in PFIC • Orphan drug • Highly **significant sustained improvements in pruritus** • Small patient population (adult & pediatric) with high unmet need	• 385k$ per year

Overall, grade 1-2 ACLF may represent a potential ~4 bn USD addressable market opportunity in the US and EU4+UK by 2030

Ballpark overall market size by 2030, bn USD[1]



Assumptions / considerations

- **Prevalence: 150K (EU4 + UK) / 90k (US) for grade 1-2 ACLF patients[2]**
- **Drug price could amount to $30-40k per patient in US and $10-20k in EU** given the economic burden of hospitalizations and duration of treatment; the range was estimated based on:
  - Available robust data on hospitalization costs (i.e. 16 days average stay, 52k$ average associated costs in US)
  - Likely price range for orphan drugs for life treating disease with uncertain mortality benefit over the target population
- **An upside scenario can be achieved** assuming the therapy provides significant mortality benefit for a restricted subpopulation (assuming 100-200k in US, 50-80k in EU price based on analogues assessment)
- **Potential upside of market opportunity** *(irrespective of price point):* ACLF incidence likely to slightly increase due to higher prevalence of lifestyle diseases, drug-induced liver injuries and raising disease awareness, market opportunity could be higher

Note: 1) *Figures based on secondary research / literature review conducted in January 2023 – not a forecast and represents an estimated overall market size. No primary market research was conducted (e.g., pricing research);* ***2)*** *There is limited availability of recent US epi studies; lower prevalence vs EU is believed to be driven by differences in underlying population, Estimation includes compliance rate and gross-to-net price estimate*

Detailed overview of assumptions used to estimate addressable market in 2030 in US & EU4+UK

Assumptions / considerations

Input		Base	Upside	Rationale / Sources
Prevalence		~100K ~190		• US: Hernaez, et al., J of Hepatol (2019) • EU4+UK: Moreau, R., et al., (2013) Table 10;
ACLF 1 prevalence *ACLF 2 prevalence*	%	45% 35%	45% 3%	• IQVIA Internal reference (PMR 2022); • Moreau, R., et al., (2013) CANONIC study Supplemental Table 10
Total addressable market	#	**~90K** **~150K**		
Compliance	%	~75%	~75%	• IQVIA expertise
Potential price		**~40K** **~20K**	**150K (subpop)** **65K (subpop)**	• ***Base case:*** Hospitalization costs assessment and price of rare disease drugs without mortality benefit • ***Upside case:*** Price of rare disease analogues with mortality benefit for a subpopulation with severe ACLF
Gross to net	%	90%	90%	• IQVIA expertise
2030 Addressable market (USD)	$	**2.2 Bn** **1.9 Bn**	**>4 Bn** **>2.5 Bn**	

Note: *European countries in scope included only EU4+UK*

ACLF is an attractive market opportunity with upside potential given significant unmet need for urgent treatment and easier clinical development

ACLF is an attractive opportunity for Biotechs to address an untapped patient population with high unmet need for urgent treatment

Possibility to **lead ACLF market growth with therapies** being **launched** at a **price** fully **representing** their **value**

Potential orphan designation **leading to easier clinical development**

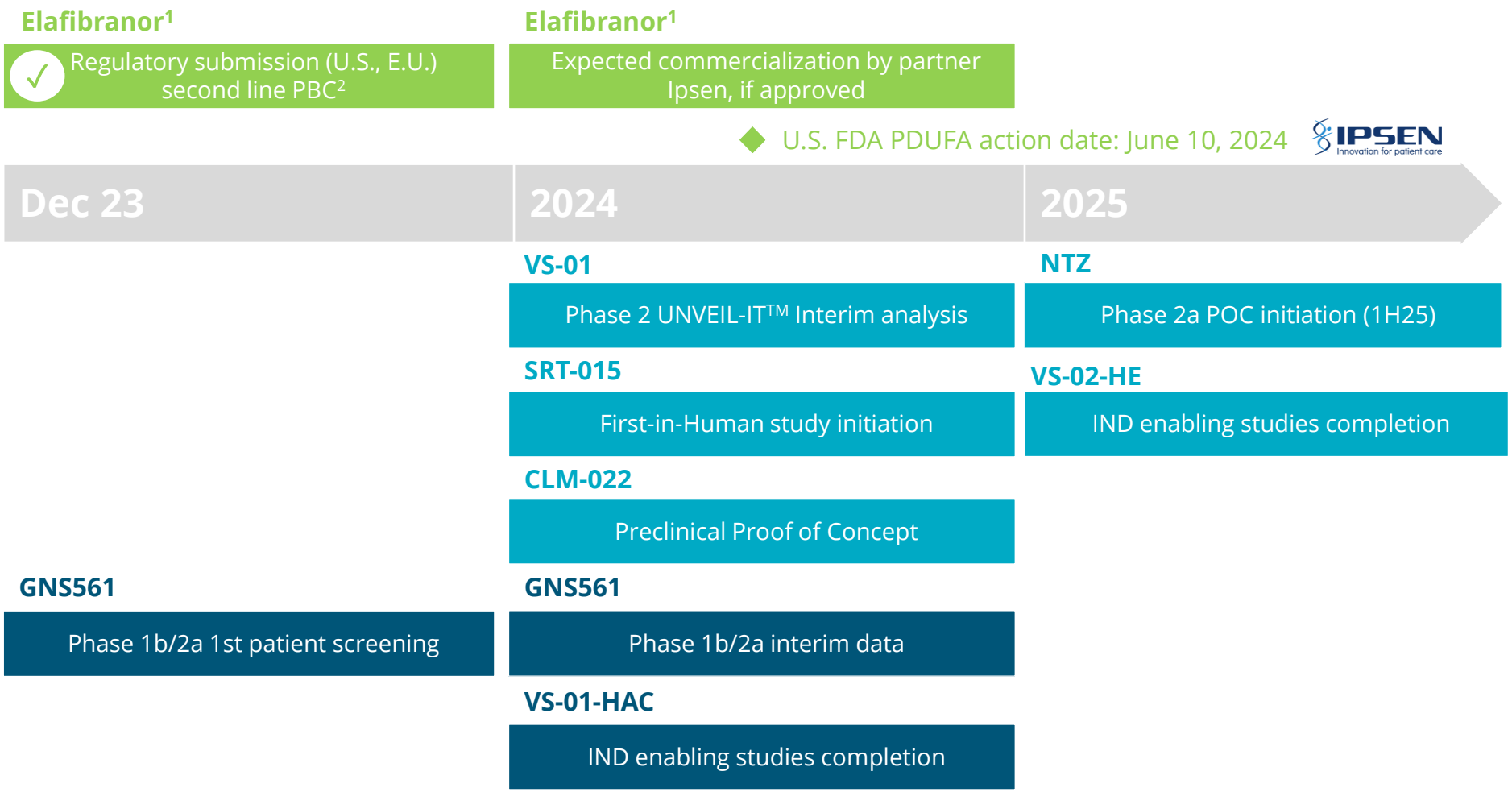
Possibility to consider commercialization on the condition that industry collaborates with the scientific community to **increase disease awareness**

- Towards a new GENFIT
- ACLF disease state
- GENFIT's approach to ACLF
- ACLF market opportunity

Highlights on newsflow

Pascal Prigent, CEO

Highlights on newsflow



These targeted timelines are indicative only (based on best estimates by management and current level of knowledge)

1: Elafibranor program has been out-licensed to partner in 2021 (press release)
2: https://ir.genfit.com/news-releases/news-release-details/ipsen-confirms-us-fda-grants-priority-review-new-drug

- ACLF (Acute On-Chronic Liver Failure)
- Other life-threatening liver diseases
- PBC (Primary Biliary Cholangitis)

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THANK YOU