



NASDAQ: ALT

# CORPORATE PRESENTATION

Q3 2021

# FORWARD-LOOKING STATEMENTS

## Safe-Harbor Statement

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# COMPANY HIGHLIGHTS

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Developing next generation peptide therapeutics for obesity and liver diseases



Multiple near-term value-driving catalysts for both obesity and NASH



>\$200M cash and investments on hand to support development

# STRONG EXECUTIVE MANAGEMENT TEAM



**Vipin K. Garg, PhD**  
President & CEO



**Will Brown, CPA, MBA**  
Chief Financial Officer



**Scott Harris, MD**  
Chief Medical Officer



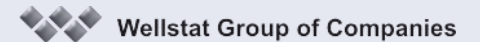
**Scot Roberts, PhD**  
Chief Scientific Officer



**Bertrand Georges, PhD**  
Chief Technology Officer



**José Ochoa, JD**  
Chief Business Officer





# FOCUS ON LIVER AND METABOLIC DISEASES

PRODUCT NAME	PRECLINICAL	PHASE 1	PHASE II	PHASE III	STATUS	PATENT TERM
ALT-801	NASH				Phase 1, 12-week data readout expected Q3 2021	2 Granted US patents Patent applications other territories Expiry > 2035
ALT-801	Obesity				US IND filing Q4 2021, with trial initiation expected Q1 2022	
HepTcell™	Chronic Hepatitis B				In Phase 2, data readout expected H2 2022	Granted US patent Patent applications other territories Expiry > 2033



# **NASH and Obesity: ALT-801**

# NASH AND NAFLD

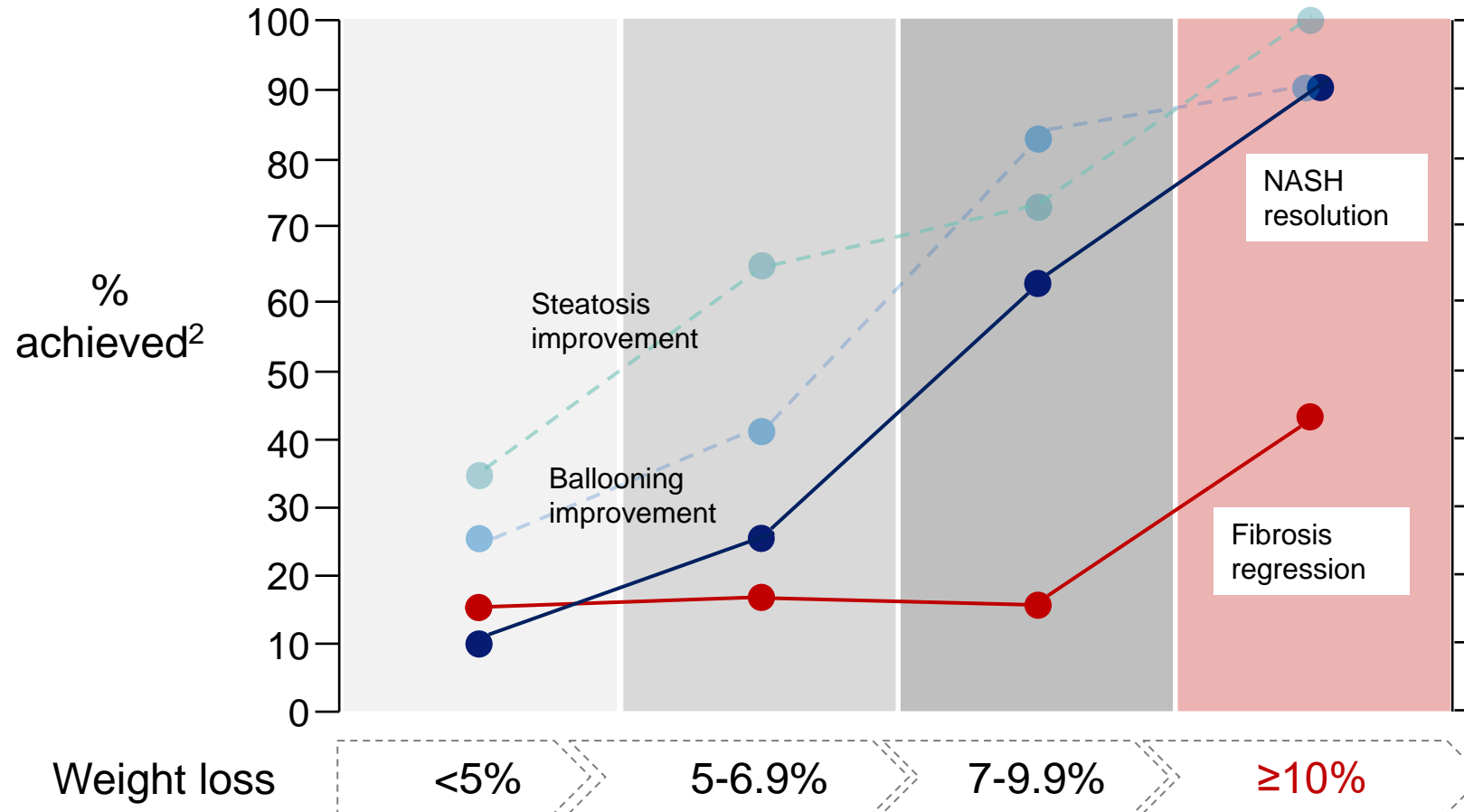
## HEPATIC MANIFESTATIONS OF OBESITY AND METABOLIC SYNDROME

- NAFLD is present in up to **90% of obese patients**, and **~20%** of NAFLD patients **progress to NASH**<sup>1</sup>
- Up to **40% of NASH patients relapse with NAFLD** an average of one year after liver transplant — consistent with the presence of underlying metabolic disease<sup>2</sup>
- The **treatment of obesity** is the cornerstone of treating NASH and the principal morbidities of NASH<sup>1,3</sup>
- Drugs in development should target the **weight loss range achieved by bariatric surgery**<sup>4</sup>

<sup>1</sup>Glass LM, Fed Pract 2019; <sup>2</sup>Dureja, P, Transplantation 2011; <sup>3</sup>Perazzo H, Liver Int 2017; <sup>4</sup>Armstrong M, Vantage December 14, 2018

# SUBSTANTIAL BODY WEIGHT LOSS IS NECESSARY TO BLUNT NASH PROGRESSION

10% OR MORE WEIGHT LOSS MUST BE ACHIEVED<sup>1</sup>



The **treatment of obesity** remains the cornerstone of NASH and NAFLD therapy

**Meaningful weight loss** is rarely achieved without medical intervention

**Current drugs have failed** to deliver the weight loss achieved by bariatric surgery

<sup>1</sup> Promrat et al Hepatology 2010; Glass et al Dig Dis Sci 2015; Vilar-Gomez et al Gastroenterology 2015; Marchesini et al Hepatology 2016; Koutoukidis et al JAMA Intern Med 2019

<sup>2</sup> Adapted from Harrison, EASL 2019, Traber, Discovery on Target: Targeting NASH 2019, and Vilar-Gomez, Gastroenterology 2015



# KEY COMPOUNDS IN ADVANCED NASH DEVELOPMENT

## ONLY SEMAGLUTIDE ACHIEVED MEANINGFUL LEVELS OF WEIGHT LOSS

Agent	Author (year)	Mechanism	Weight Loss (%)
Obeticholic acid	Younossi, ZM 2019 <sup>1</sup>	FXR agonist	~2%
Resmetirom	Harrison, SA 2018 <sup>2</sup>	THR $\beta$ agonist	no change
Aldafermin (3mg) <sup>†</sup>	Harrison, SA 2019 <sup>3</sup>	FGF19 agonist	1.3%
Pegbelfermin (10 mg) <sup>††</sup>	Sanyal, A 2018 <sup>4</sup>	FGF21 agonist	~5%
AKR-001 (70 mg)	Ritchie, M 2020 <sup>5</sup>	FGF21 agonist	no change
Firsocostat	Lawitz, EJ 2018 <sup>6</sup>	ACC inhibitor	no change
Semaglutide	Newsome, PN 2020 <sup>7</sup>	GLP-1	12.5%

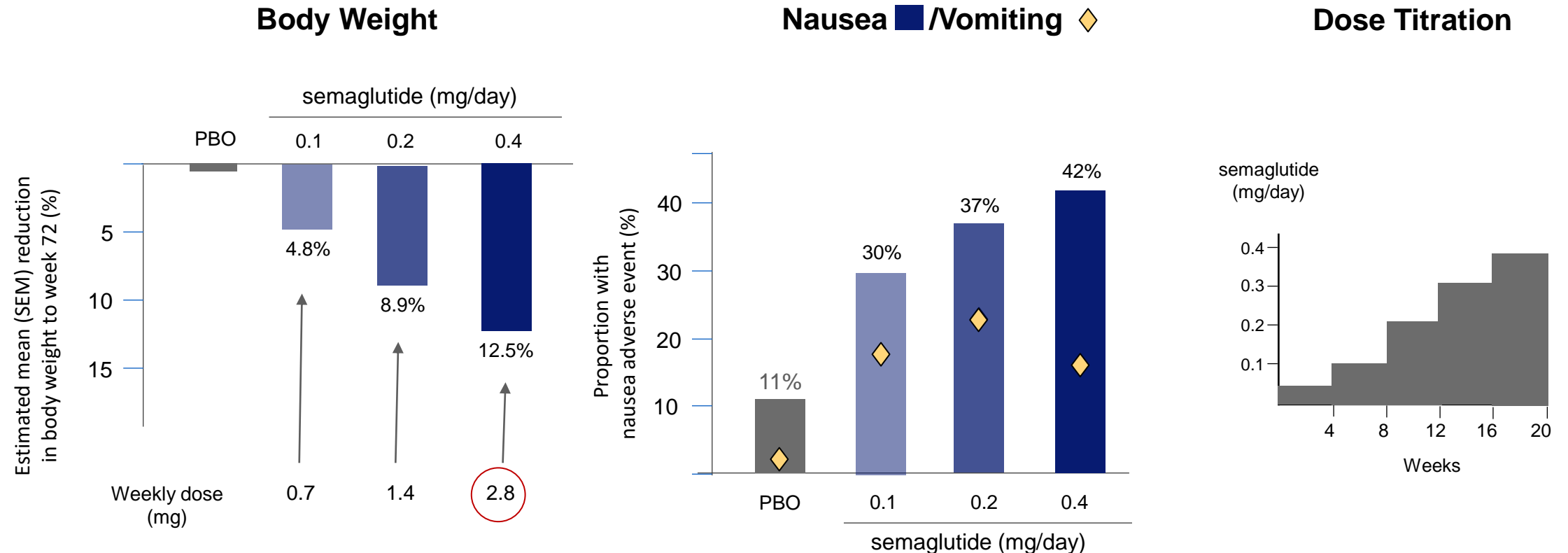
<sup>†</sup> No information has been made public on 1mg dose

<sup>††</sup> Gain of 0.6% on 20mg dose

<sup>1</sup>Younossi, YM, et al. (2019) *Lancet* 394: 2184-96; <sup>2</sup>Harrison, SA, et al. *Lancet* 394: 2012-24; <sup>3</sup>Harrison, SA, et al. (2019) *Lancet* 391:1174-85; <sup>4</sup>Sanyal, A, et al. (2018) *Lancet* 392:2705-17; <sup>5</sup>Ritchie, M, et al. (2020) *Exp Opin Invest Drugs*, 29:2, 197-204; <sup>6</sup>Lawitz, EJ, et al. (2018) *Clin Gastroenterol Hepatol* 16:1983-91; <sup>7</sup>Newsome, PM et al (2020) *NEJM* 384:1113-24

# SEMAGLUTIDE NASH TRIAL (0.1 TO 0.4 MG/DAY)

DRIVING WEIGHT LOSS AT THE COST OF GI SIDE EFFECTS AND DOSE TITRATION



Newsome, PM et al (2020) NEJM 384:1113-24 .

PBO, placebo

# ALT-801 – DIFFERENTIATED GLP-1/ GLUCAGON DUAL AGONIST

## ENCOURAGING HUMAN PROOF-OF-CONCEPT DATA AT 6-WEEKS

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- ➔ **Net 6.3% weight loss** at 6-week interim analysis of Phase 1 trial
- ➔ **No dose titration** required compared to  $\geq 16$  weeks with other agents
- ➔ **Impressive tolerability** with no discontinuations related to drug and only transient nausea observed

# ALT-801 PHASE 1 TRIAL DESIGN

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- Phase 1 SAD/ MAD conducted in Australia with approximately 100 subjects
- Patient population is overweight and obese non-diabetics with a minimum BMI of 25 who are otherwise healthy
- Phase 1 study is advancing to full 12-week data readout in Q3 2021. Data readouts expected on:
  - Weight loss
  - Safety, tolerability
  - Pharmacokinetics (PK)
  - Lean body mass, calorie intake, resting energy expenditure (REE) and FGF-21
  - Glucose homeostasis
  - Insulin resistance—HOMA-IR2, adiponectin
  - Lipids (HDL, LDL, TG, lipoprotein (a))

# ALT-801 PHASE 1 TRIAL INTERIM 6-WEEK DATA

## IMPRESSIVE WEIGHT LOSS AND TOLERABILITY WITH NO DOSE TITRATION

- 6-week interim data readout in June 2021 on safety and weight loss in multiple ascending dose cohorts:

	Dose	Mean Weight (Loss) Gain	Transient Nausea Rates	Vomiting, Constipation, Diarrhea	Discontinuations
Cohort 1	1.2 mg	(1.8%)	14.3%	0%	1*
Cohort 2	1.8 mg	(5.4%)	22.2%	0%	0
Placebo	---	0.9%	0%	0%	0

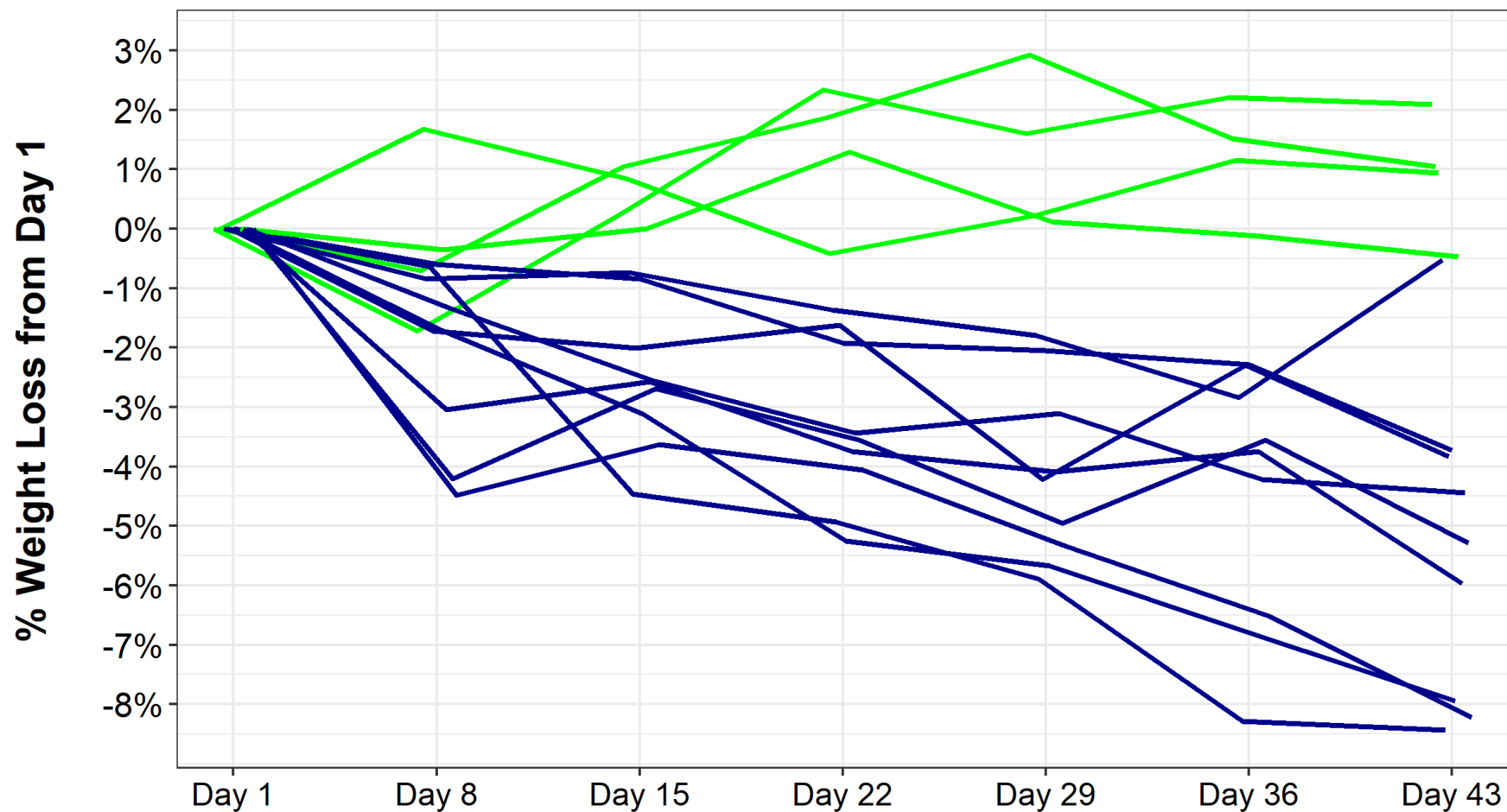
*\*Discontinuation unrelated to adverse events*

- Weight loss exceeded expectation of 2% at 6-weeks
- Study participants not on calorie restricted diet or other lifestyle modification program
- Dose titration was not required



# ALT-801 PHASE 1 TRIAL INTERIM 6-WEEK DATA

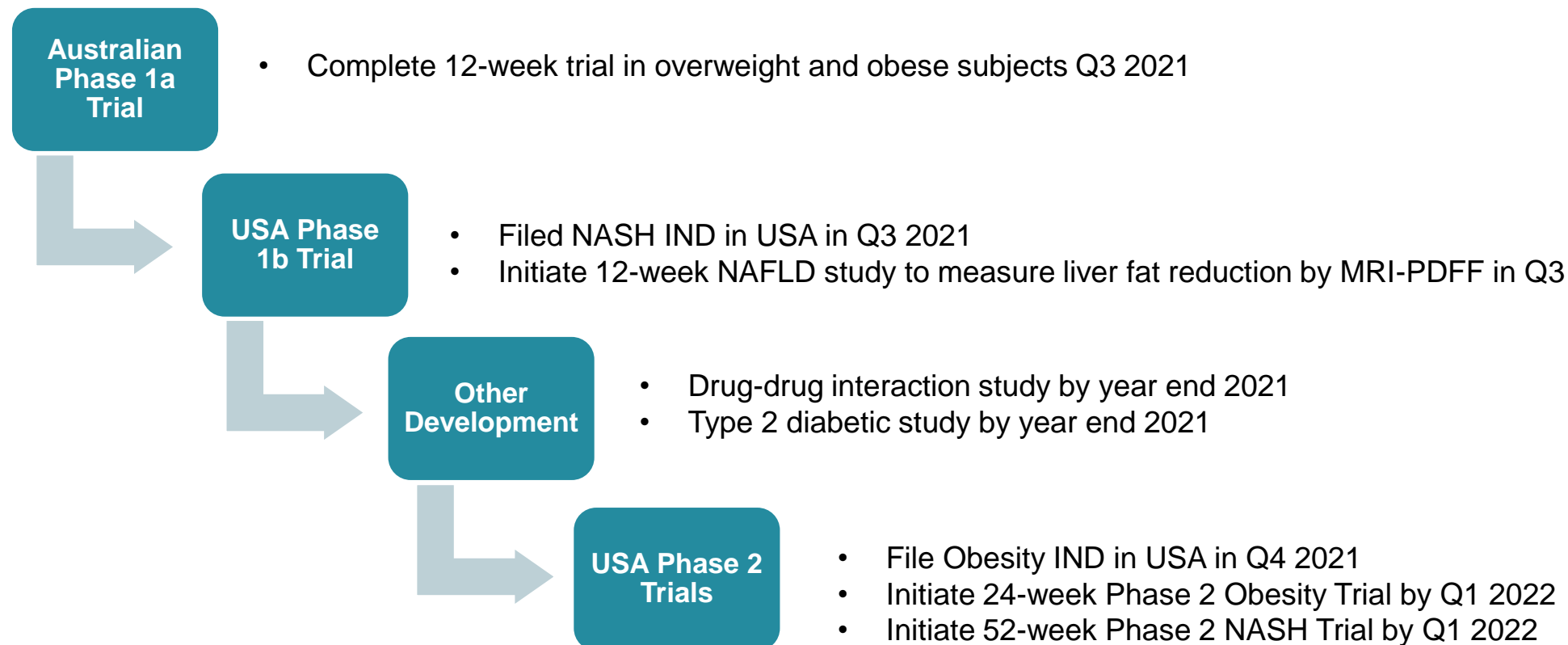
$\geq 3\%$  WEIGHT LOSS ACHIEVED IN ALL BUT 1 PARTICIPANT



Doses: — 1.8 mg ALT-801 — Placebo

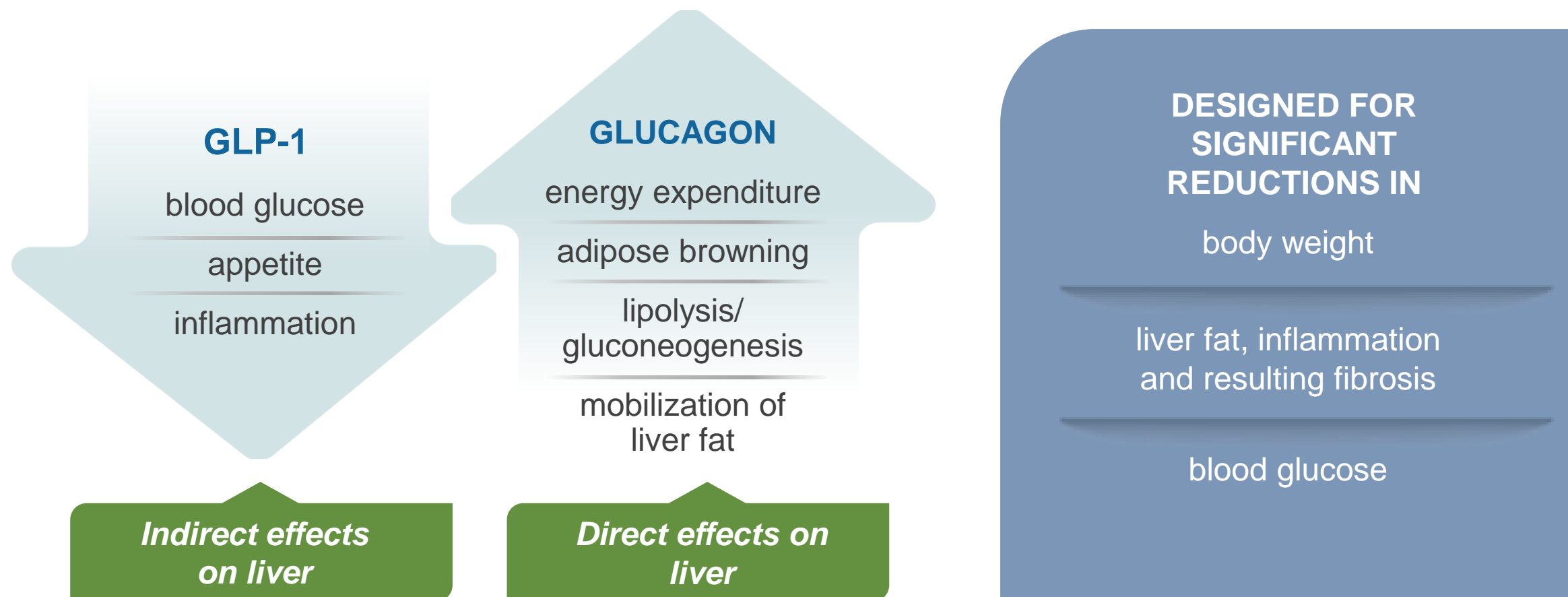
# ALT-801 CLINICAL DEVELOPMENT PLAN

RAPID DEVELOPMENT TO INITIATE ROBUST PHASE 2 TRIALS IN 2022



# ALT-801: GLP-1/GLUCAGON RECEPTOR DUAL AGONIST

## OPTIMIZED FOR NASH AND WEIGHT LOSS



# ALT-801: RATIONALLY DESIGNED AND HIGHLY DIFFERENTIATED

EuPort™ DOMAIN PROVIDES PROLONGED SERUM HALF-LIFE AND DELAYED TIME TO PEAK CONCENTRATION

## Balanced GLP-1:Glucagon Agonism



<sup>1</sup>Guarracino DA et al., Chem Rev. 2019 Sep 11;119(17):9915-9949

# ALT-801

## SUMMARY OF PRECLINICAL STUDIES

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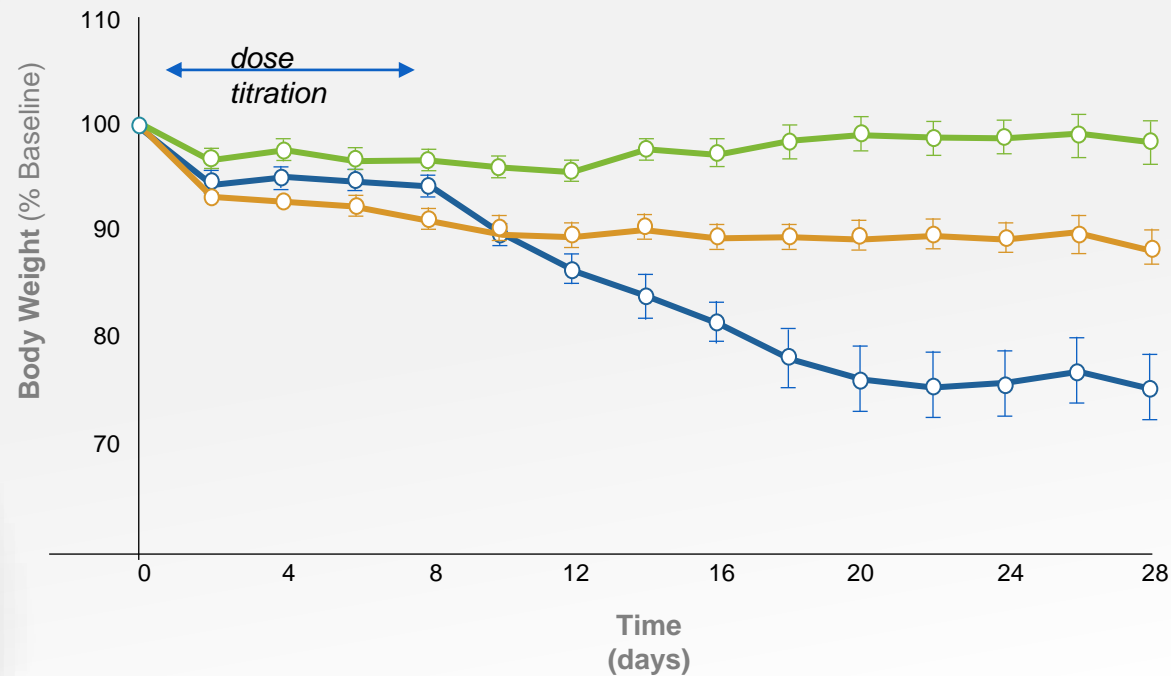
- ALT-801 preclinical results in diet induced obesity models showed superior reductions in majority of measured NASH and glucose parameters compared to semaglutide:
  - Body and liver weight
  - NAS and ALT
  - Galectin-3 content
  - Liver triglycerides and cholesterol
  - Glucose lowering effect
- ALT-801 improved metabolic function and exhibited pleiotropic effects in preclinical testing across multiple pathways involved in NASH
- ALT-801 resulted in profound suppression of genes associated with steatosis, inflammation and stellate cell fibrosis



# ALT-801

25% REDUCTION IN BODY WEIGHT TO CHOW-FED LEAN NORMAL RANGE

## Mouse DIO Model After 4 Weeks of Treatment



More than 2x the weight loss of semaglutide

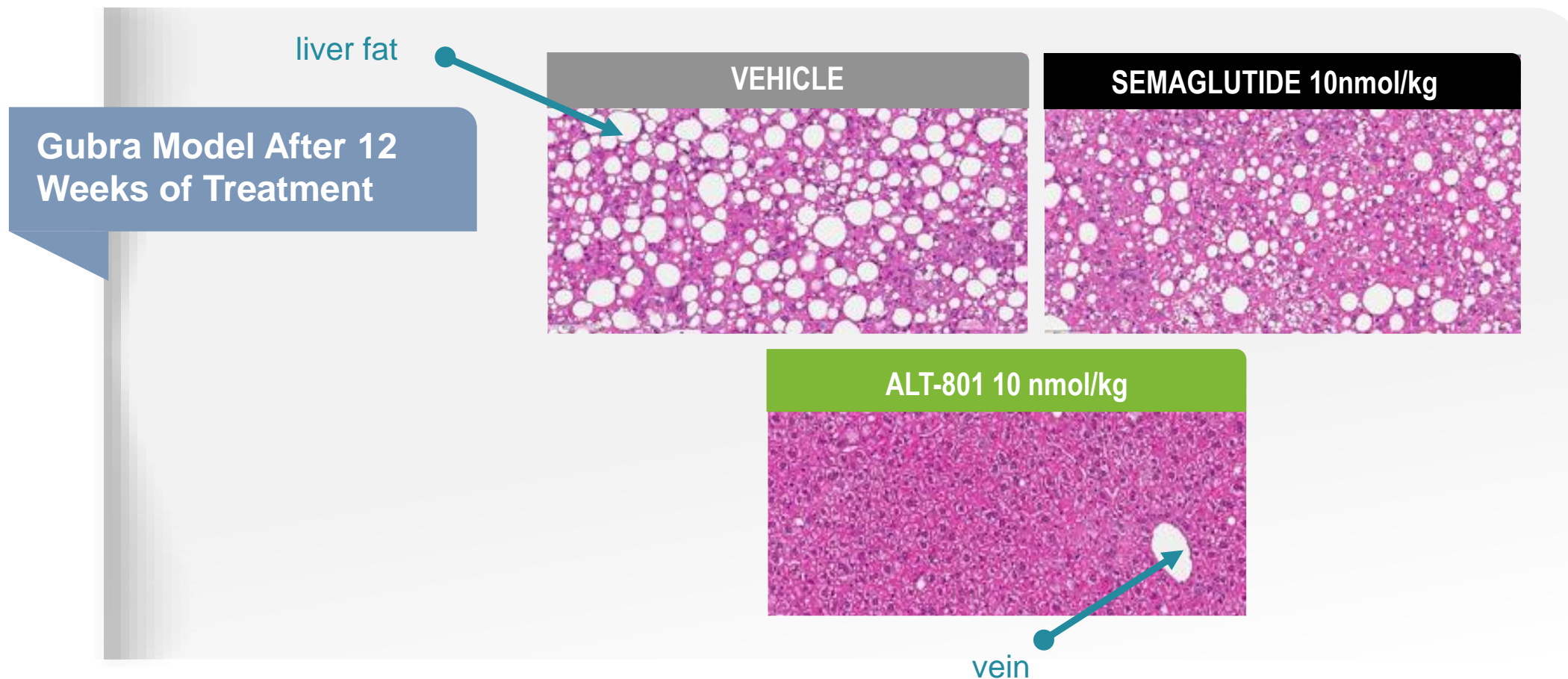
Vehicle

Semaglutide (12nmol/kg)

ALT-801 (12nmol/kg)

# ALT-801

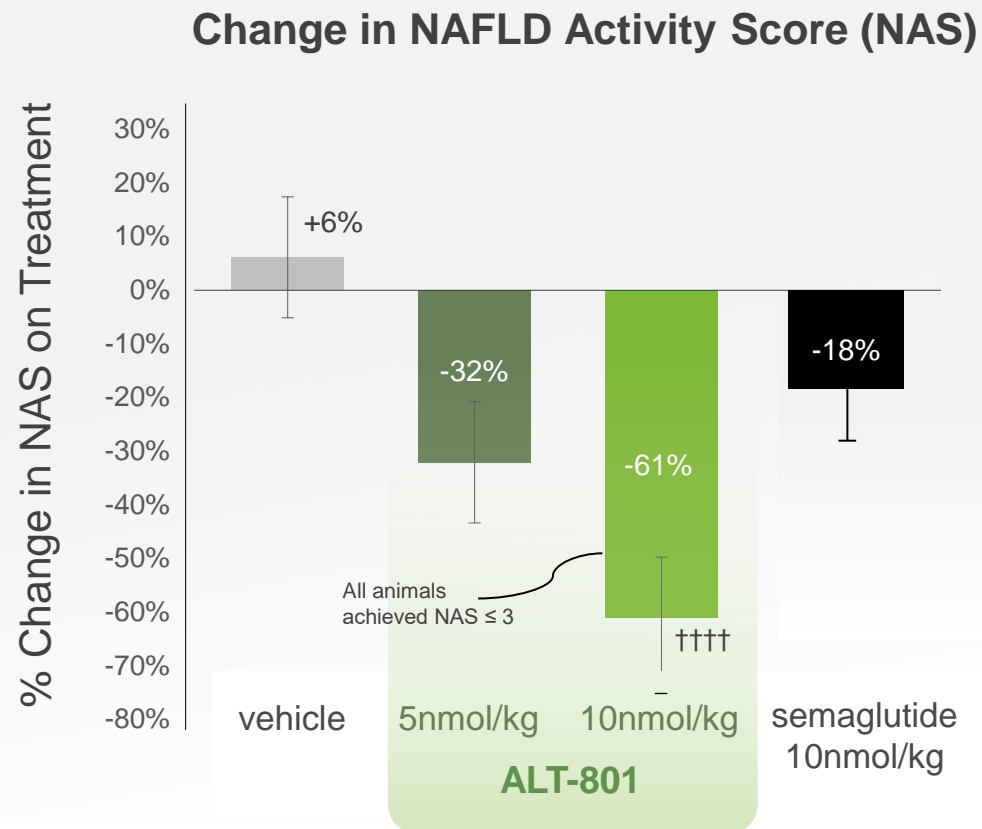
## REDUCTION IN LIVER FAT AND LIVER WEIGHT TO LEAN NORMAL RANGE



# ALT-801

## IMPROVEMENT IN NAFLD ACTIVITY SCORE (NAS)

Gubra Model After 12 Weeks of Treatment

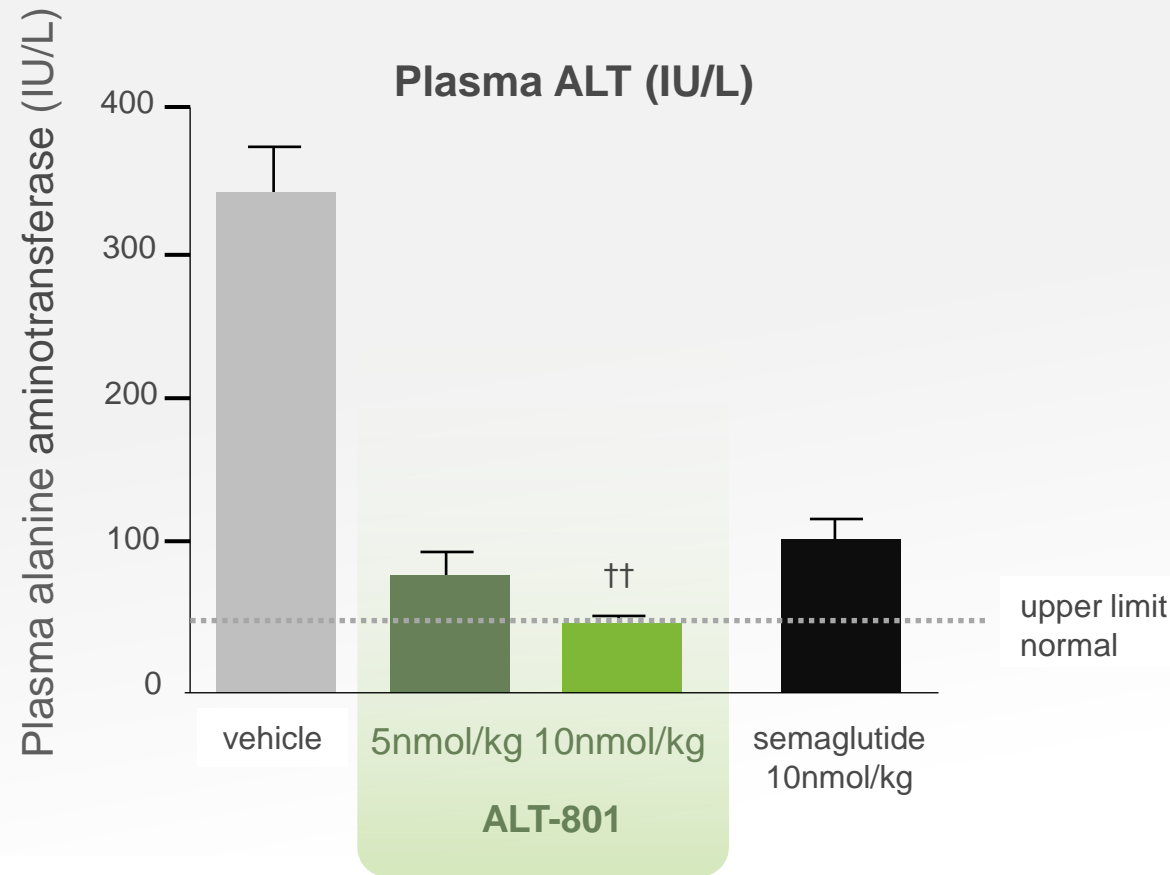


Mean (SE), 1-way ANOVA with Dunnett's adjustment for multiplicity  
††  $p < .01$ , †††  $p < .001$ , ††††,  $p < .0001$  vs. semaglutide (n=11-12)

# ALT-801

## NORMALIZATION OF PLASMA ALT

Gubra Model After 12 Weeks of Treatment

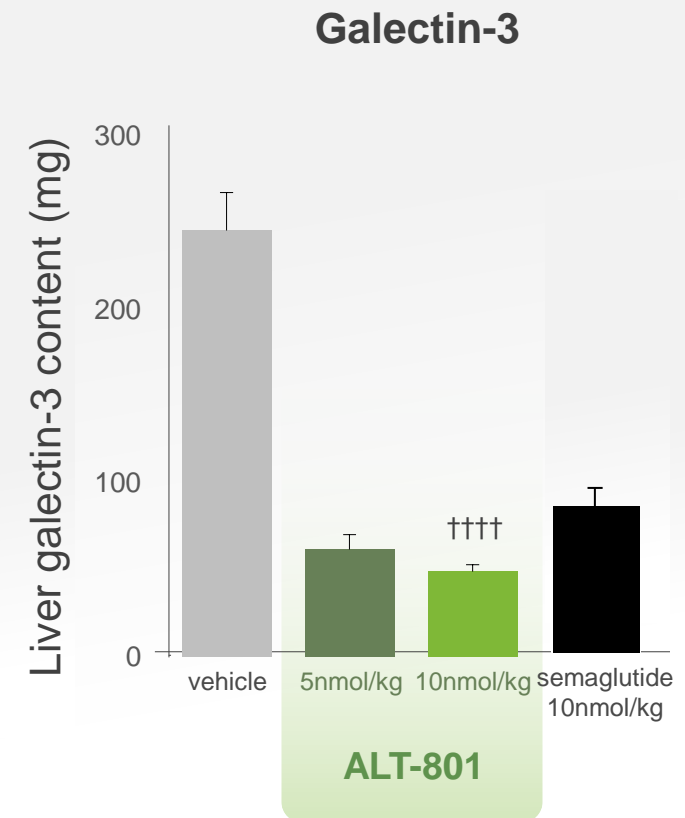
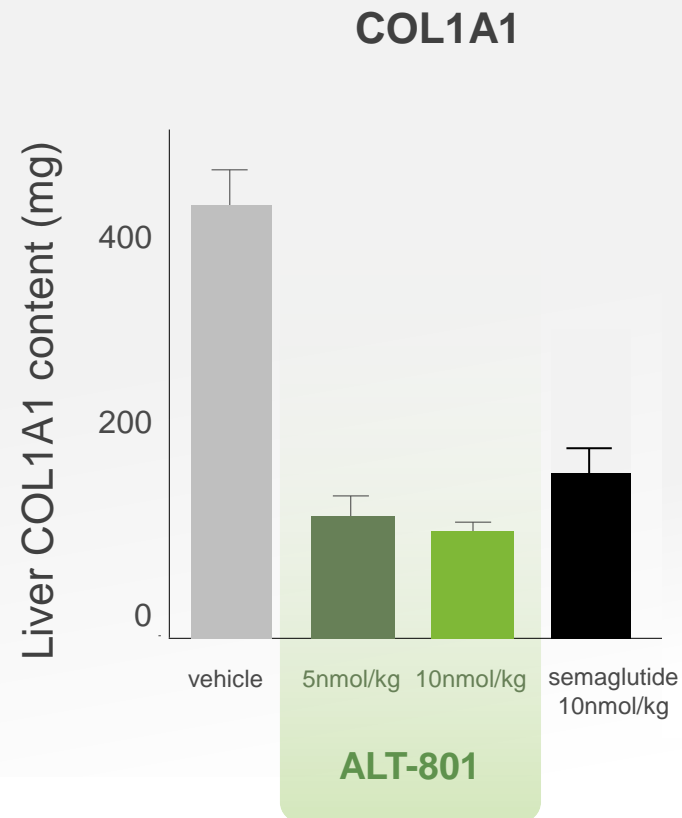


Mean (SE), 1-way ANOVA with Dunnett's adjustment for multiplicity  
††  $p < .01$ , †††  $p < .001$ , ††††,  $p < .0001$  vs. semaglutide (n=11-12)

# ALT-801

## GREATER EFFECTS ON FIBROSIS

Gubra Model After 12 Weeks of Treatment



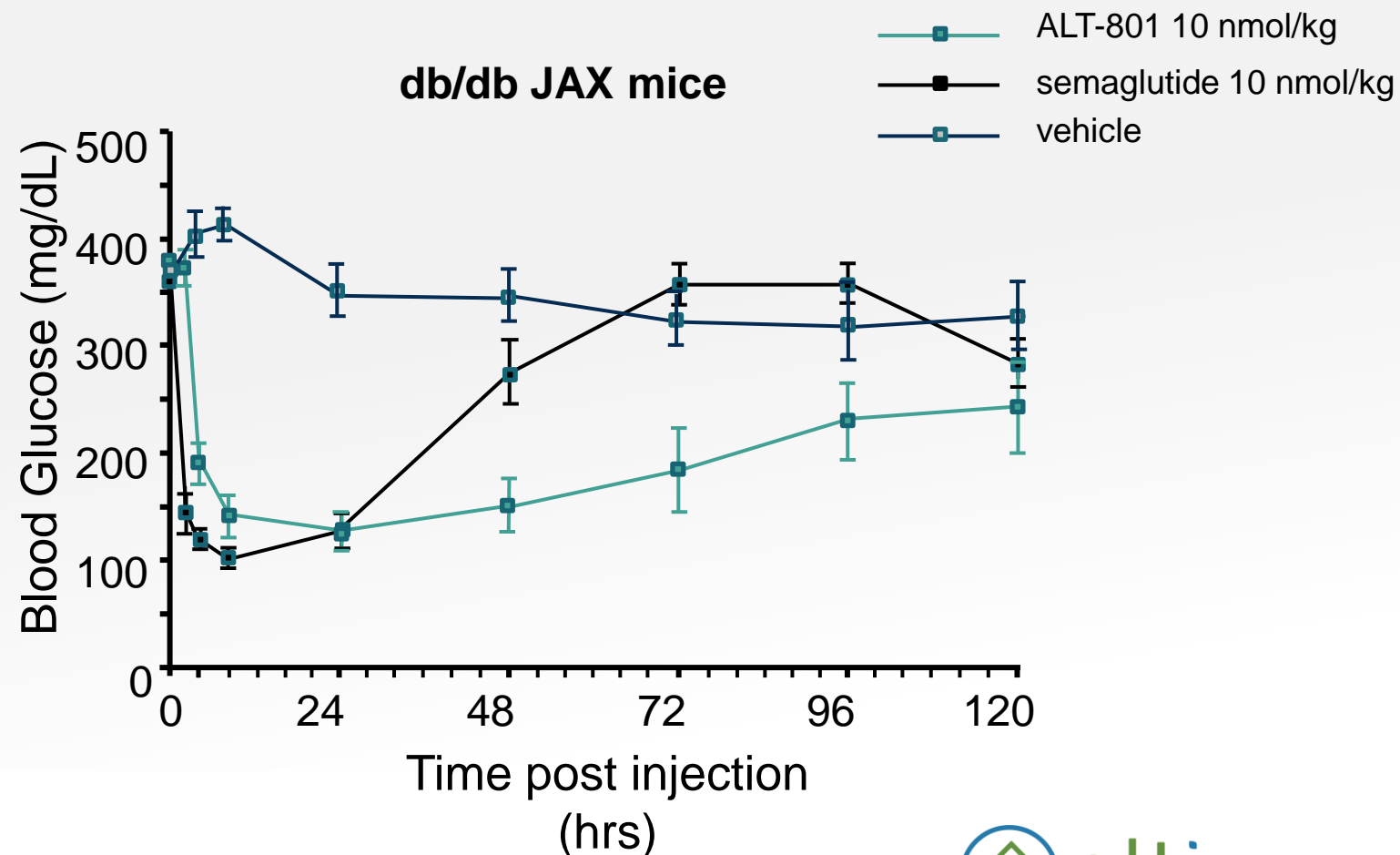
Mean (SE), 1-way ANOVA with Dunnett's adjustment for multiplicity  
††  $p < .01$ , †††  $p < .001$ , ††††,  $p < .0001$  vs. semaglutide (n=11-12)



# ALT-801 SIGNIFICANTLY IMPROVED GLUCOSE CONTROL

## INCREASED POTENCY AND DURATION OF ACTION AFTER A SINGLE INJECTION

### Control of Blood Glucose in db/db Diabetes Model



## ALT-801 – IND FILING FOR OBESITY IN Q4 2021

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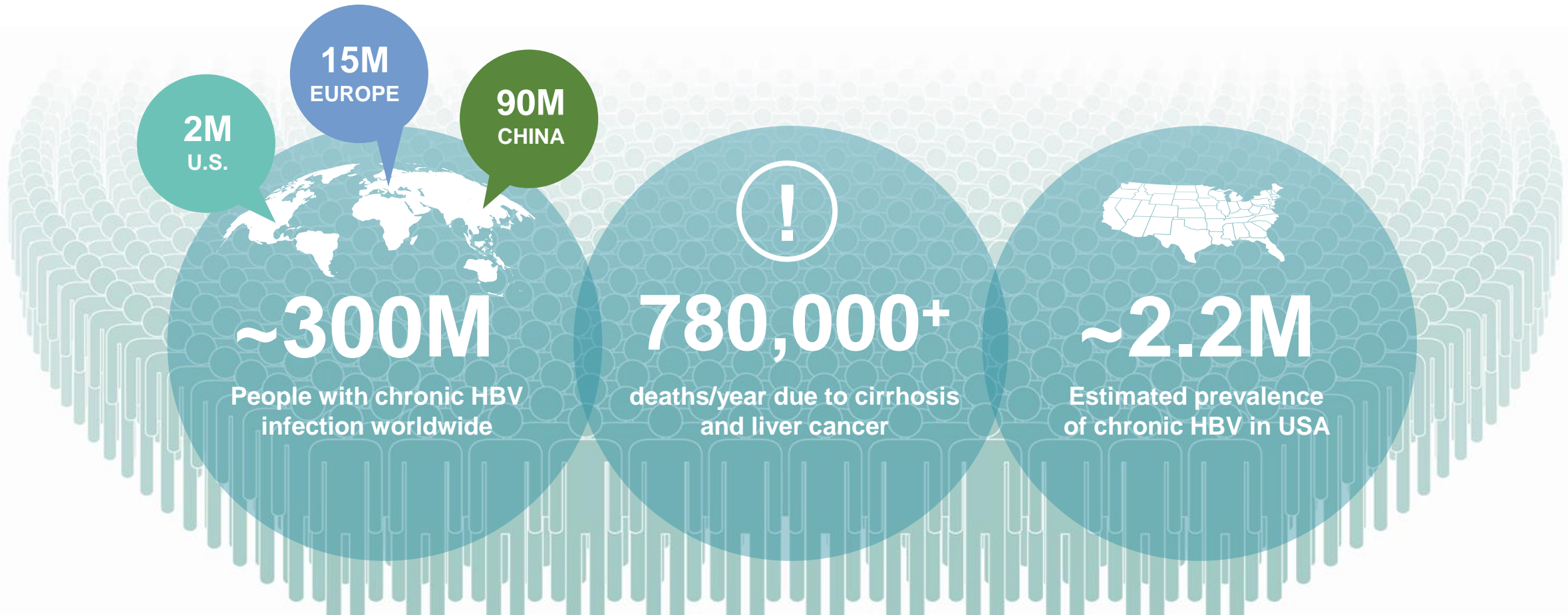
- ➔ **Novo Nordisk (semaglutide) and Lilly (tirzepatide)** have executed successful Phase 3 programs and significantly de-risked the regulatory path for approval for GLP-1 therapeutics for obesity
- ➔ **GI intolerability has been problematic for GLP-1 based treatments**, with side effects leading to high rates of treatment discontinuation
- ➔ **If the impressive weight loss and tolerability** of ALT-801 in the Phase 1 interim data are reflected in larger studies, ALT-801 could be ideally suited for this indication
- ➔ **ALT-801 IND in obesity to be filed in Q4 2021** with initiation of Phase 2 trial anticipated in Q1 2022



# **Chronic HBV: HepTcell**

# HepTcell: T CELL IMMUNOTHERAPEUTIC FOR CHRONIC HEPATITIS B

## SIGNIFICANT OPPORTUNITY TO IMPROVE CURRENT HBV CURE RATES



# CURRENTLY APPROVED HBV THERAPEUTICS DO NOT LEAD TO A CURE

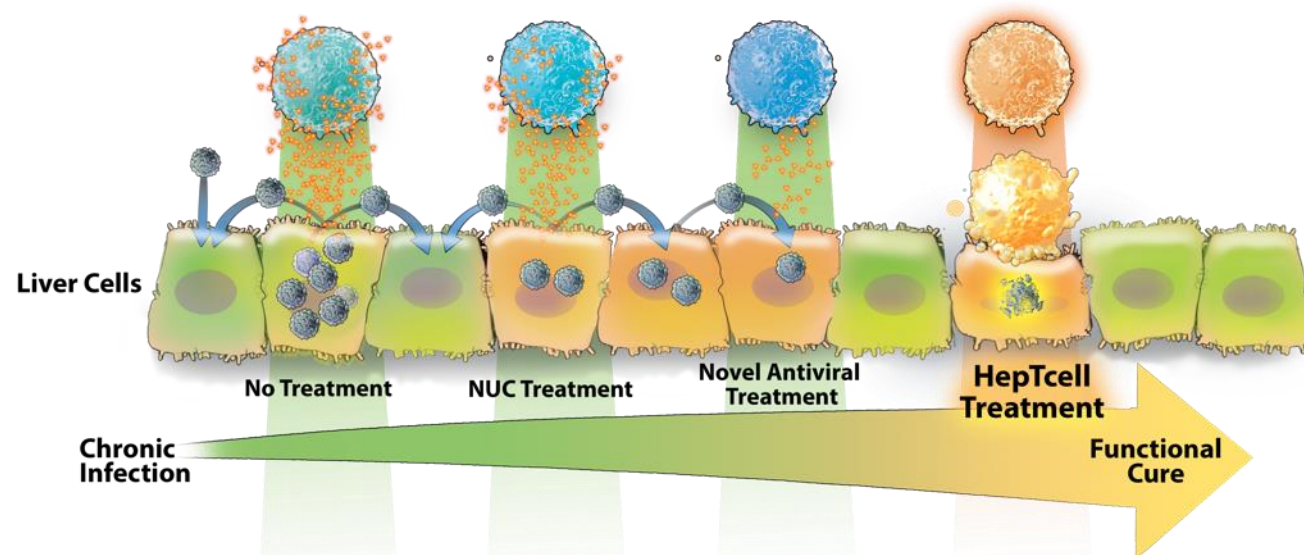
## IMMUNE ACTIVATION WILL BE REQUIRED FOR SIGNIFICANT IMPACT

Current antivirals prevent disease progression but **rarely clear chronic infection**

**Breaking T cell immune tolerance is key** to functional cure

Newer direct-acting antivirals **unlikely to result in immune reactivation alone**

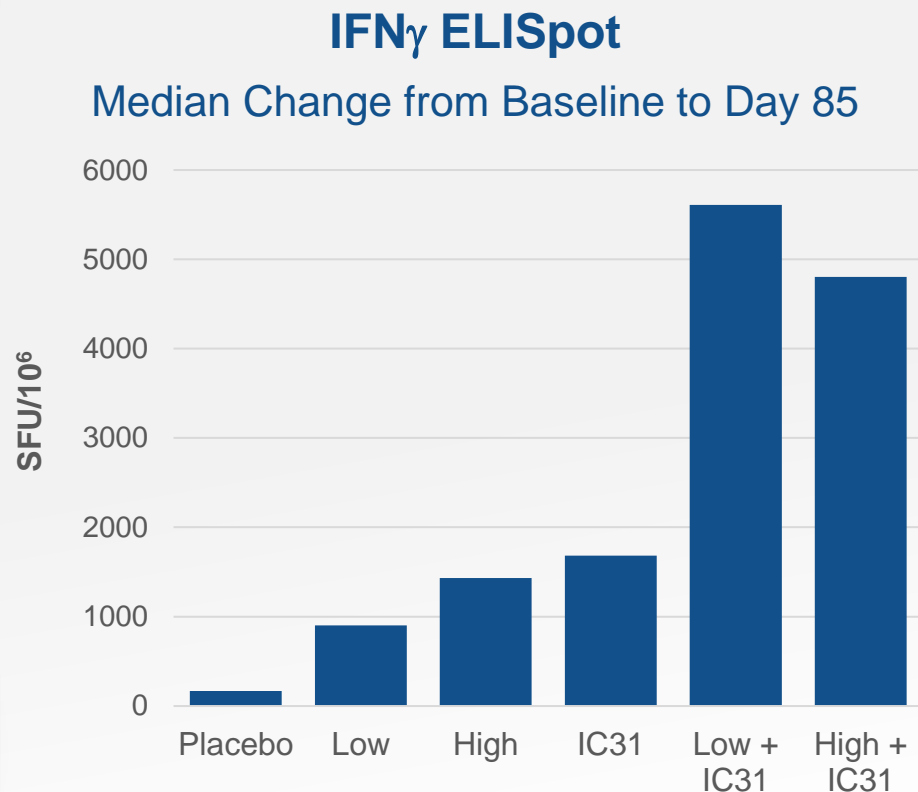
**HepTcell is designed to “wake up” dormant T-cells** to eliminate infection





# HepTcell: PHASE 1 SAFETY AND IMMUNOGENICITY STUDY

## Anti-HBV T-cell Response After 3 Injections



HepTcell is designed to break immune tolerance in chronic hepatitis B patients

T cell responses strongest when combined with IC31™ adjuvant

HepTcell dose and use of adjuvant confirmed for Phase 2 studies

# HepTcell: PHASE 2 CLINICAL TRIAL

## MULTINATIONAL, MULTICENTER TRIAL OF HEPTCELL IN INACTIVE CHRONIC HEPATITIS B

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- Trial designed to evaluate response in population with unmet need and to model the response to HepTcell as used in combination therapy in broader CHB population
- 80 patients with HBeAg negative inactive chronic hepatitis B and HBsAg  $\leq 100$  IU/mL randomized 1:1 to HepTcell or placebo administered every 4 weeks for 24 weeks
- Follow-up study phase of 48 weeks after the last dose will assess the safety and durability of response of treatment
- Study to be conducted at 20 sites in the US, Canada and Europe
- Efficacy endpoints
  - Primary endpoint: proportion of patients with 1.0-log reduction in HBsAg from baseline at Week 24
  - Secondary endpoints: HBsAg clearance, changes from baseline in HBsAg, HBV DNA, HBcrAg, pg-RNA at Week 24
- Phase 2 data readout expected H2 2022



# Summary

# SUMMARY OF NEAR-TERM CATALYSTS

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1

US IND Filings  
for NASH &  
obesity in H2  
2021

2

Phase 1  
12-week MAD  
data readout in  
Q3 2021

3

Initiate 12-week  
US NAFLD study  
in Q3 2021

4

Initiate 24-  
week Phase 2  
obesity trial  
Q1 2022

5

Initiate 52-  
week biopsy  
driven Phase 2  
NASH Study in  
Q1 2022

# ALTIMMUNE: INVESTMENT HIGHLIGHTS

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- 1 Developing portfolio with 3 multibillion-dollar indications**  
*Obesity, NASH and Chronic Hepatitis B*
- 2 Recently generated impressive human data with ALT-801**  
*>5% weight loss in 6 weeks using well-tolerated regimen without dose titration*
- 3 Multiple catalysts anticipated over the next 12 months**  
*Data read-outs from multiple clinical programs*
- 4 Strong cash position to reach value-generating milestones**  
*~\$227 million as of March 31, 2021*



NASDAQ: ALT

**THANK YOU**