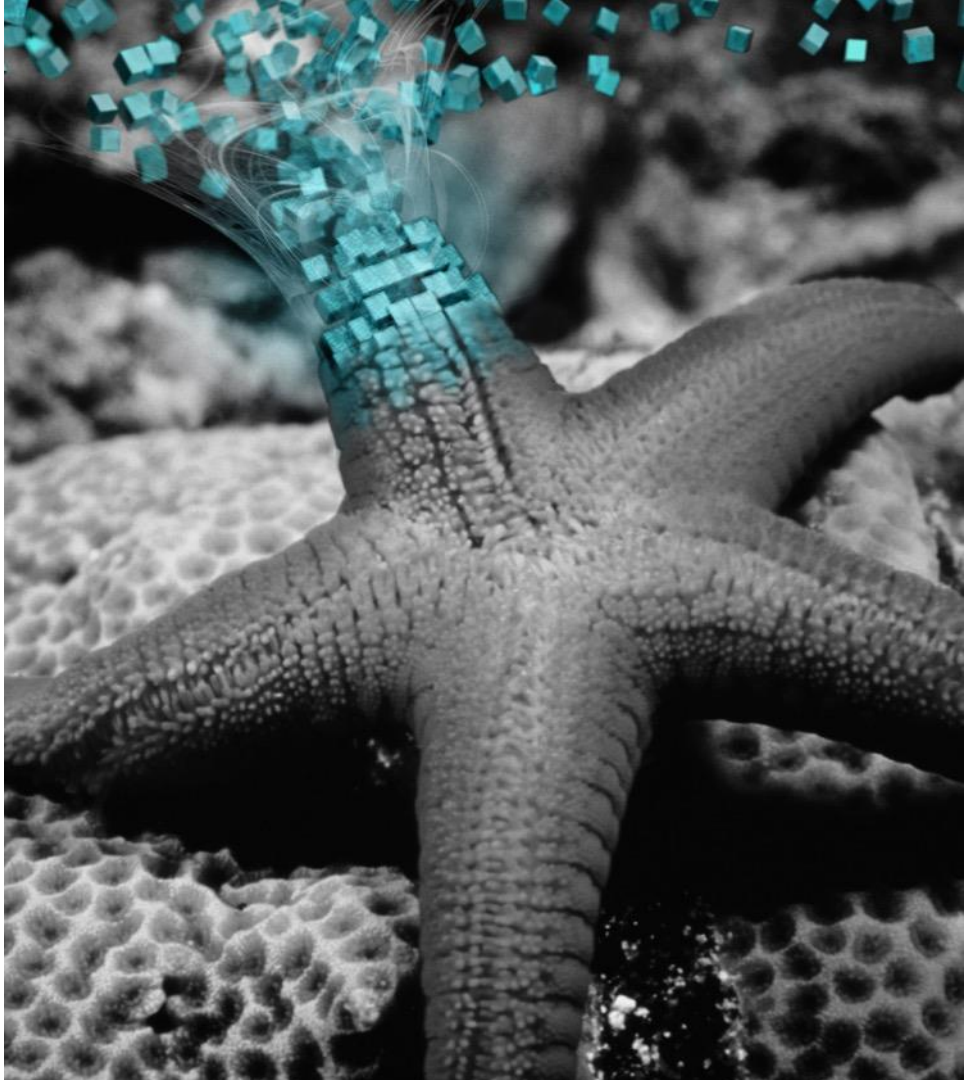
EASL Investor & Analyst Event

Thursday April 11, 2019

Vienna, Austria

Intercept



Cautionary Note Regarding Forward-Looking Statements

This presentation contains forward-looking statements, including, but not limited to, statements regarding the progress, timing and results of Intercept's clinical trials, including its clinical trials for the treatment of nonalcoholic steatohepatitis ("NASH"), the safety and efficacy of Intercept's approved product, Ocaliva (obeticholic acid or "OCA") for primary biliary cholangitis ("PBC"), and Intercept's product development candidates, including OCA for NASH, the timing and acceptance of Intercept's potential regulatory filings and potential approval of OCA for NASH or any other indications in addition to PBC, the timing and potential commercial success of OCA and any other product candidates Intercept may develop and Intercept's strategy, future operations, future financial position, future revenue, projected costs, financial guidance, prospects, plans, objectives of management and expected market growth.

These statements constitute forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "possible," "continue" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this presentation, and Intercept undertakes no obligation to update any forward-looking statement except as required by law. These forward-looking statements are based on estimates and assumptions by Intercept's management that, although believed to be reasonable, are inherently uncertain and subject to a number of risks. The following represent some, but not necessarily all, of the factors that could cause actual results to differ materially from historical results or those anticipated or predicted by Intercept's forward-looking statements: Intercept's ability to successfully commercialize Ocaliva for PBC; Intercept's ability to maintain its regulatory approval of Ocaliva for PBC in the United States, Europe, Canada, Israel, Australia and other jurisdictions in which it has or may receive marketing authorization; the initiation, timing, cost, conduct, progress and results of Intercept's research and development activities, preclinical studies and clinical trials, including any issues, delays or failures in identifying patients, enrolling patients, treating patients, meeting specific endpoints in the jurisdictions in which it intends to seek approval or completing and timely reporting the results of its NASH or PBC clinical trials; Intercept's ability to timely and cost-effectively file for and obtain regulatory approval of its product candidates, including OCA for NASH, in the United States, Europe and its other target markets; conditions that may be imposed by regulatory authorities on Intercept's marketing approvals for its products and product candidates, such as the need for clinical outcomes data (and not just results based on achievement of a surrogate endpoint), and any related restrictions, limitations and/or warnings contained in the label of any of its products or product candidates; any potential side effects associated with Ocaliva for PBC, OCA for NASH or Intercept's other product candidates that could delay or prevent approval, require that an approved product be taken off the market, require the inclusion of safety warnings or precautions or otherwise limit the sale of such product or product candidate; Intercept's ability to establish and maintain relationships with, and the performance of, third-party manufacturers, contract research organizations and other vendors upon whom it is substantially dependent for, among other things, the manufacture and supply of its products, including Ocaliva for PBC and, if approved, OCA for NASH, and its clinical trial activities; Intercept's ability to identify, develop and successfully commercialize its products and product candidates, including its ability to timely and successfully launch OCA for NASH, if approved; Intercept's ability to obtain and maintain intellectual property protection for its products and product candidates, including its ability to cost-effectively file, prosecute, defend and enforce any patent claims or other intellectual property rights; the size and growth of the markets for Intercept's products and product candidates and its ability to serve those markets; the degree of market acceptance of Ocaliva for PBC and, if approved, OCA for NASH or Intercept's other product candidates among physicians, patients and healthcare payors; the availability of adequate coverage and reimbursement from governmental and private healthcare payors for Intercept's products, including Ocaliva for PBC and, if approved, OCA for NASH, and its ability to obtain adequate pricing for such products; Intercept's ability to establish and maintain effective sales, marketing and distribution capabilities, either directly or through collaborations with third parties; competition from existing drugs or new drugs that become available; Intercept's ability to prevent system failures, data breaches or violations of data protection laws; costs and outcomes relating to any disputes, governmental inquiries or investigations, legal proceedings or litigation, including any securities, intellectual property, employment, product liability or other litigation; Intercept's collaborators' election to pursue research, development and commercialization activities; Intercept's ability to establish and maintain relationships with collaborators with development, regulatory and commercialization expertise; Intercept's need for and ability to generate or obtain additional financing; Intercept's estimates regarding future expenses, revenues and capital requirements and the accuracy thereof; Intercept's use of cash and short-term investments; Intercept's ability to acquire, license and invest in businesses, technologies, product candidates and products; Intercept's ability to attract and retain key personnel to manage its business effectively; Intercept's ability to manage the growth of its operations, infrastructure, personnel, systems and controls; Intercept's ability to obtain and maintain adequate insurance coverage; the impact of general U.S. and foreign economic, industry, market, regulatory or political conditions, including the potential impact of Brexit; and the other risks and uncertainties identified in Intercept's periodic filings filed with the U.S. Securities and Exchange Commission, including Intercept's Annual Report on Form 10-K for the year ended December 31, 2018.

AGENDA

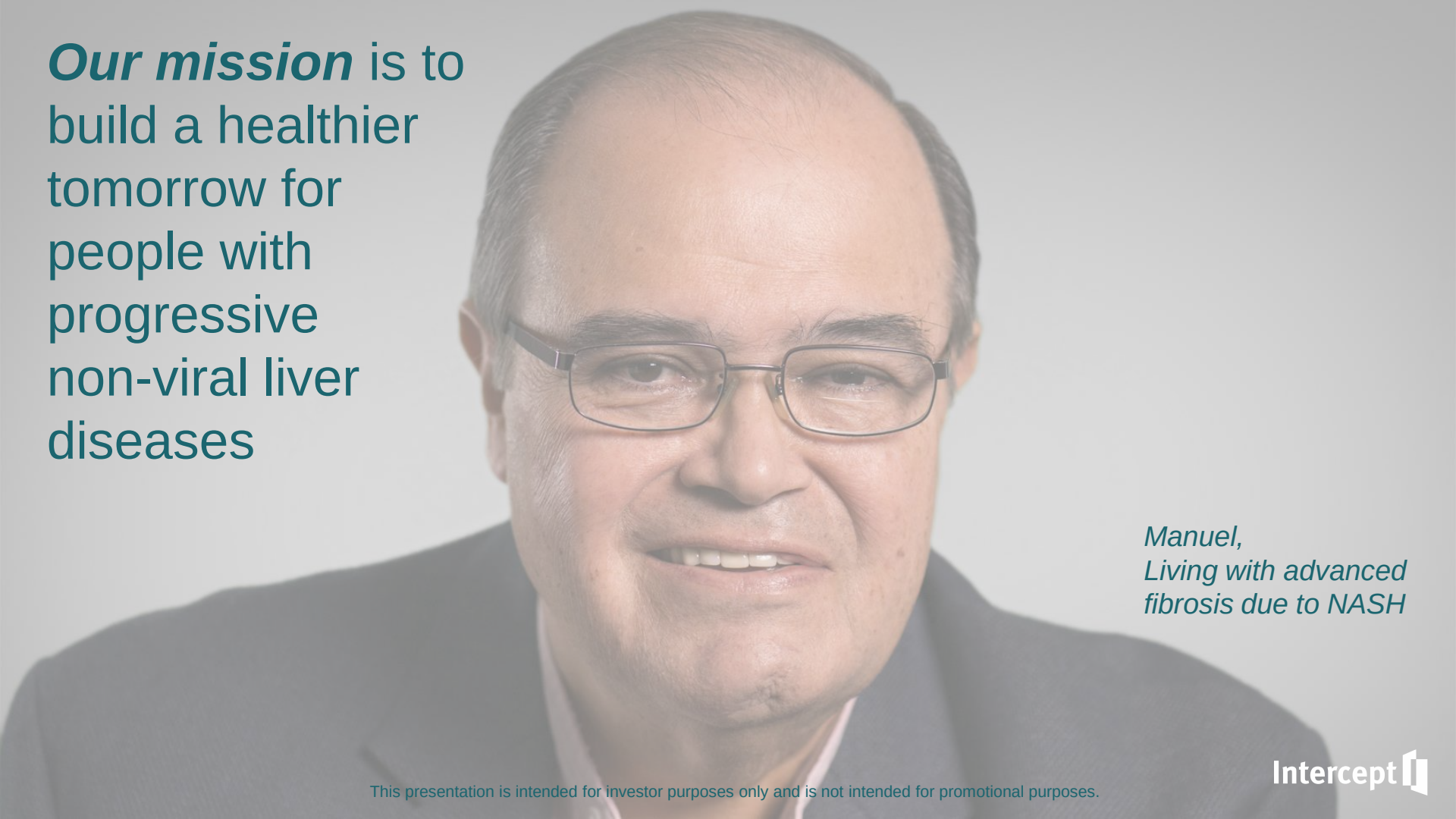
Welcome and Introduction

MARK PRUZANSKI, PRESIDENT AND CEO, INTERCEPT PHARMACEUTICALS

REGENERATE Results

DR. VLAD RATZIU, PROFESSOR OF HEPATOLOGY, UNIVERSITÉ PIERRE ET MARIE CURIE & HÔPITAL PITIÉ-SALPÊTRIÈRE MEDICAL SCHOOL

Q&A



Our mission is to build a healthier tomorrow for people with progressive non-viral liver diseases

Manuel,
Living with advanced fibrosis due to NASH

Intercept

Maintaining Our Leadership in Progressive Non-Viral Liver Disease

Our Strategic Pillars

01 Advancing our Leading NASH Program

- Deliver Phase 3 REGENERATE results and prepare for post-approval launch of OCA
- Enroll Phase 3 REVERSE trial in NASH patients with compensated cirrhosis
- Explore potential combination therapy studies

02 Building our Global PBC Business

- Continue to drive Ocaliva market penetration to maximize access for eligible patients globally
- Evaluate the potential for a next generation combination regimen with OCA for PBC patients

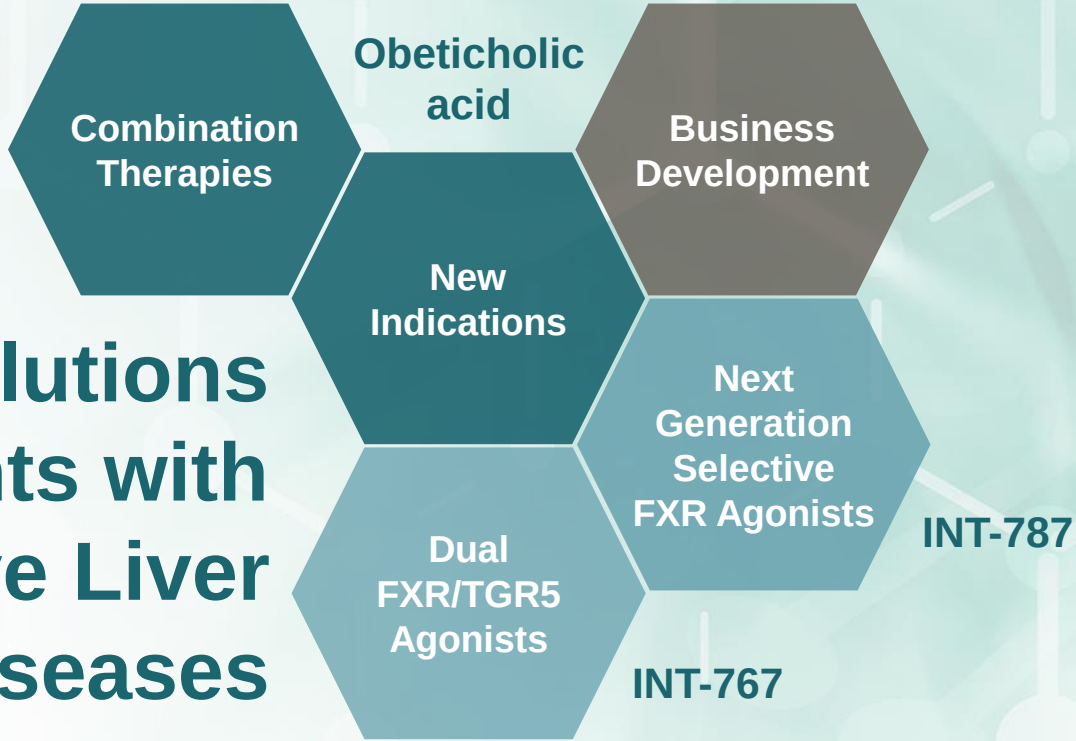
03 Expanding our Pipeline

- Build portfolio of clinical-stage programs leveraging our scientific platform
- Diversify pipeline through strategic business development

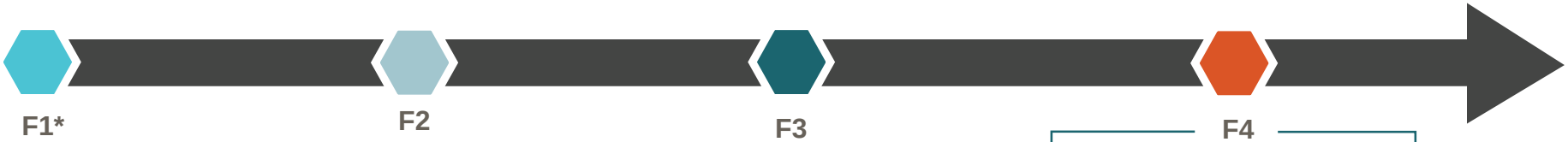
Commercial expertise and R&D innovation in liver disease

We Are Focused on Expanding Our Pipeline

Pursuing Solutions for Patients with Progressive Liver Diseases



We Have a Comprehensive, Industry-Leading NASH Development Program



Interim Analysis Population

Compensated Cirrhosis

Decompensated Cirrhosis

REGENERATE

- NASH patients with F2, F3 and high-risk F1 fibrosis
- Interim analysis on 931 F2/F3 patients
- Targeting >2,300 patients for outcomes

REVERSE

- NASH patients with compensated cirrhosis
- Targeting enrollment of ~540 patients

* Exploratory group of NASH patients with stage 1 liver fibrosis with comorbid risk factors (defined as diabetes, obesity or active liver inflammation (ALT >1.5X ULN)) will also be enrolled, but not included in the primary endpoint analyses.

Dr. Vlad Ratziu

Vlad Ratziu, MD, PhD

Professor of Hepatology

Université Pierre et Marie Curie

Hôpital Pitié-Salpêtrière Medical School

Institution of Cardiometabolism and Nutrition

Paris, France

Consults for Intercept

REGENERATE
NASH FIBROSIS STUDY

Positive Results From REGENERATE: A Phase 3, International, Randomized, Placebo-Controlled Study Evaluating Obeticholic Acid Treatment for NASH

Zobair M. Younossi, *Vlad Ratziu, Rohit Loomba, Mary Rinella, Quentin M. Anstee, Zachary Goodman, Pierre Bedossa, Andreas Geier, Susanne Beckebaum, Philip Newsome, David Sheridan, James Trotter, Whitfield Knapple, Eric Lawitz, Kris Kowdley, Aldo Montano-Loza, Jerome Boursier, Philippe Mathurin, Elisabetta Bugianesi, Giuseppe Mazzella, Antonio Olveira, Helena Cortez-Pinto, Isabel Graupera, David Orr, Lise Lotte Gluud, Jean-Francois Dufour, David Shapiro, Jason Campagna, Luna Zaru, Leigh MacConell, Reshma Shringarpure, Stephen Harrison, Arun J. Sanyal on behalf of the REGENERATE Study Investigators*

Presented at EASL, April 10-14, 2019; Vienna, Austria

REGENERATE Study of OCA in NASH: Background and Rationale

NASH: A major unmet medical need

- NASH is a growing and common cause of liver-related morbidity and mortality worldwide[1]
- NASH is projected to soon become the leading indication for liver transplantation in the United States[2]
- Fibrosis stage is the strongest predictor of adverse clinical outcomes in patients with NASH[3]
- There are currently no approved pharmacological therapies for NASH

Obeticholic acid (OCA)

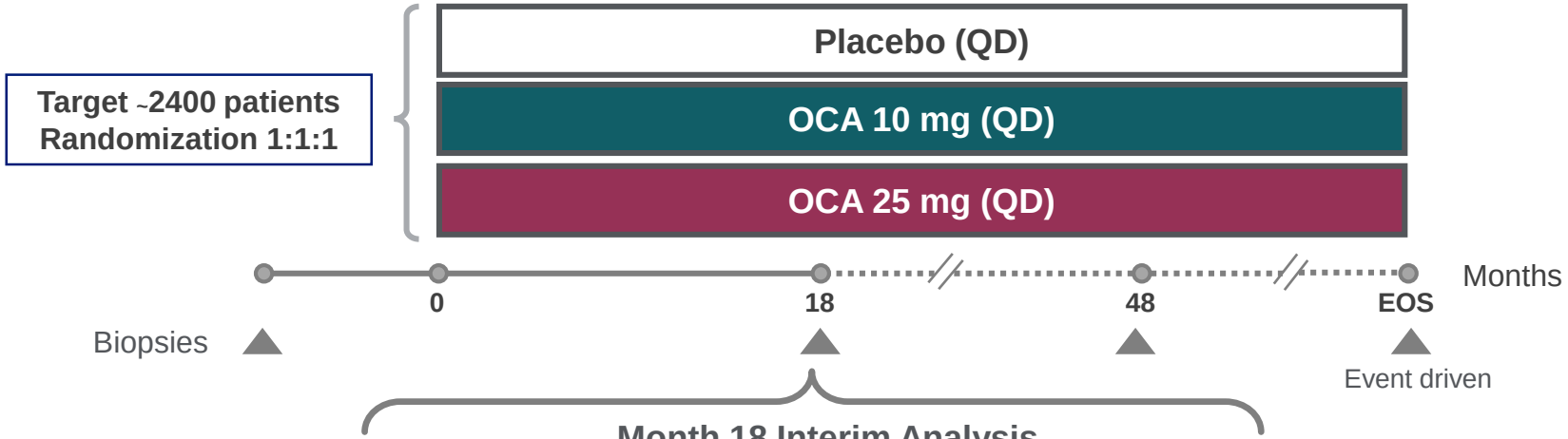
- OCA is a potent FXR agonist shown to improve NASH through multiple mechanisms in preclinical models, including a direct antifibrotic effect in the liver[4]
- In the Phase 2b FLINT study, 72 weeks of treatment with OCA 25 mg improved fibrosis and other histologic features of NASH[5]
- Based on the large unmet need and FLINT results, OCA has been designated a Breakthrough Therapy by the US FDA for the treatment of NASH patients with liver fibrosis

REGENERATE NASH FIBROSIS STUDY

FXR, farnesoid X receptor.

1. Angulo P, et al. *Gastroenterology*. 2015;149:389-397; 2. Diehl AM, et al. *N Engl J Med.* 2017;377:2063-2072; 3. Dulai PS, et al. *Hepatology*. 2017;65(5):1557–1565; 4. Albanis A, et al. *Hepatology*. 2005;42:1040A; 5. Neuschwander-Tetri BA, et al. *Lancet.* 2015;385:956-965.

REGENERATE Study Design



Fibrosis Improvement by ≥1 Stage with No Worsening of NASH

OR

NASH Resolution with No Worsening of Fibrosis

Study success was defined as achievement of one of these two primary endpoints

The interim analysis was conducted after 931 randomized patients with fibrosis stage 2 or 3 had or would have reached their actual/planned Month 18 visit (ITT population).
EOS analysis of clinical outcomes to confirm clinical benefit.
EOS, end of study; ITT, intent to treat; QD, once a day.

REGENERATE
NASH FIBROSIS STUDY

Study Eligibility Criteria

KEY INCLUSION CRITERIA

- Biopsy-confirmed NASH
- Fibrosis stage 2 or 3 (NASH CRN)
  - Exploratory cohort with fibrosis stage 1 and concomitant risk factors*
- NAFLD activity score (NAS) ≥4

KEY EXCLUSION CRITERIA

- Evidence of other chronic liver disease
- Histologic presence of cirrhosis
- Total bilirubin >1.5 mg/dL
- ALT ≥10 × ULN
- HbA1c >9.5%
- Significant alcohol consumption**

All biopsies were read centrally and at Month 18 biopsy slides were pair-read ensuring that pathologists were blinded to both treatment assignment and biopsy sequence

*Risk factors included type 2 diabetes, obesity (BMI ≥30 kg/m2) or ALT >1.5 × ULN.
**Defined as >2 units/day for females and >4 units/day for males for >3 months within 1 year before screening.
ALT, alanine aminotransferase; BMI, body mass index; CRN, clinical research network; HbA1c, glycated hemoglobin; NAFLD, nonalcoholic fatty liver disease; NAS, NAFLD activity score; ULN, upper limit of normal.

Patient Disposition

ITT Population, N=931

Disposition, n (%)	Placebo (n=311)	OCA 10 mg (n=312)	OCA 25 mg (n=308)
Completed Month 18 biopsy	252 (81)	253 (81)	243 (79)
Study discontinuation	50 (16)	54 (17)	47 (15)
Treatment discontinuation	73 (23)	71 (23)	77 (25)
Withdrawal of consent	26 (8)	20 (6)	14 (5)
Adverse event	24 (8)	23 (7)	42 (14)
Physician decision	3 (<1)	1 (<1)	8 (3)
Lost to follow-up	7 (2)	7 (2)	5 (2)

Demographic and Baseline Characteristics

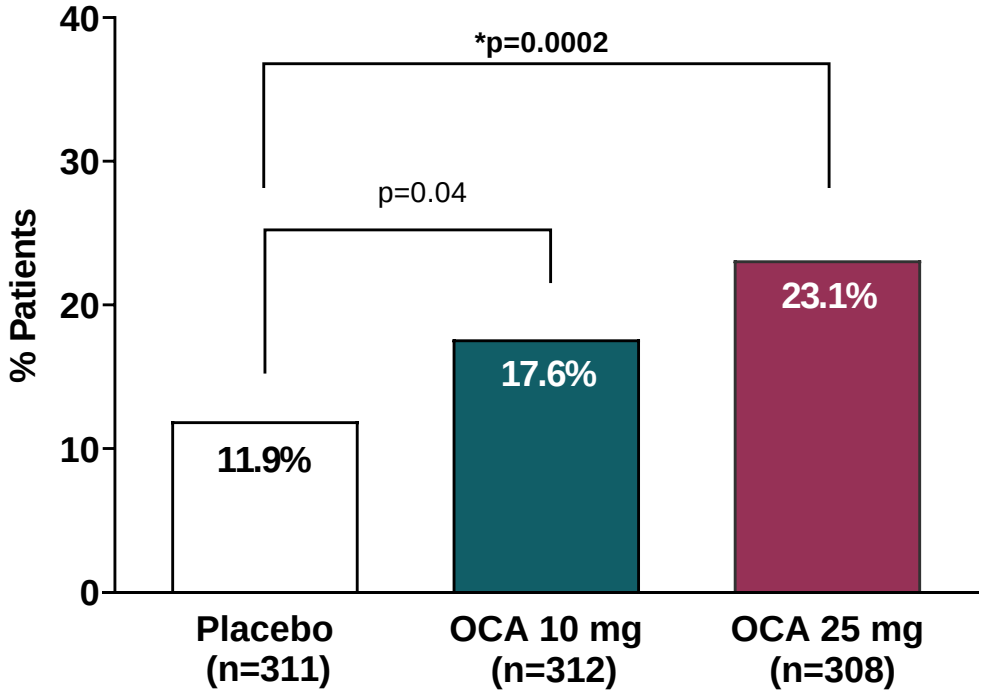
ITT Population

Characteristics	Placebo (n=311)	OCA 10 mg (n=312)	OCA 25 mg (n=308)
Age, years, mean (SD)	55 (12)	55 (11)	55 (11)
Female, n (%)	187 (60)	177 (57)	175 (57)
White, n (%)	264 (94)	263 (92)	249 (87)
Hispanic ethnicity, n (%)	52 (18)	42 (15)	47 (17)
Fibrosis stage 3, n (%)	169 (54)	182 (58)	169 (55)
NAS ≥6, n (%)	215 (70)	211 (68)	208 (68)
Type 2 diabetes,* n (%)	175 (56)	171 (55)	171 (56)
Laboratory parameters, mean (SD)			
ALT, U/L	80 (57)	76 (47)	80 (56)
AST, U/L	59 (41)	57 (34)	57 (34)
Concomitant medication use			
Lipid lowering, n (%)	175 (56)	170 (54)	160 (52)
Statins, n (%)	144 (46)	142 (46)	127 (41)
Antidiabetic medication, n (%)	167 (54)	171 (55)	159 (52)
TZD,* n (%)	5 (2)	9 (3)	4 (1)
Vitamin E,* n (%)	42 (14)	34 (11)	32 (10)

ITT population, N=931.
*Randomization was stratified based on presence of type 2 diabetes and treatment with glitazones (TZDs) or Vitamin E.
AST, aspartate transaminase; SD, standard deviation; TZD, thiazolidinediones; U/L, units per liter.

Fibrosis Improvement by ≥1 Stage with No Worsening of NASH

Primary Endpoint: ITT Population, N=931



Primary endpoint definition: fibrosis improvement by ≥1 stage (NASH CRN) with no worsening of NASH (defined as no worsening of hepatocellular ballooning, lobular inflammation or steatosis).
Study success was defined as achievement of one of the two primary endpoints evaluated in the Month 18 interim analysis.
*Statistically significant in accordance with the statistical analysis plan as agreed with the FDA. All other p values are nominal.

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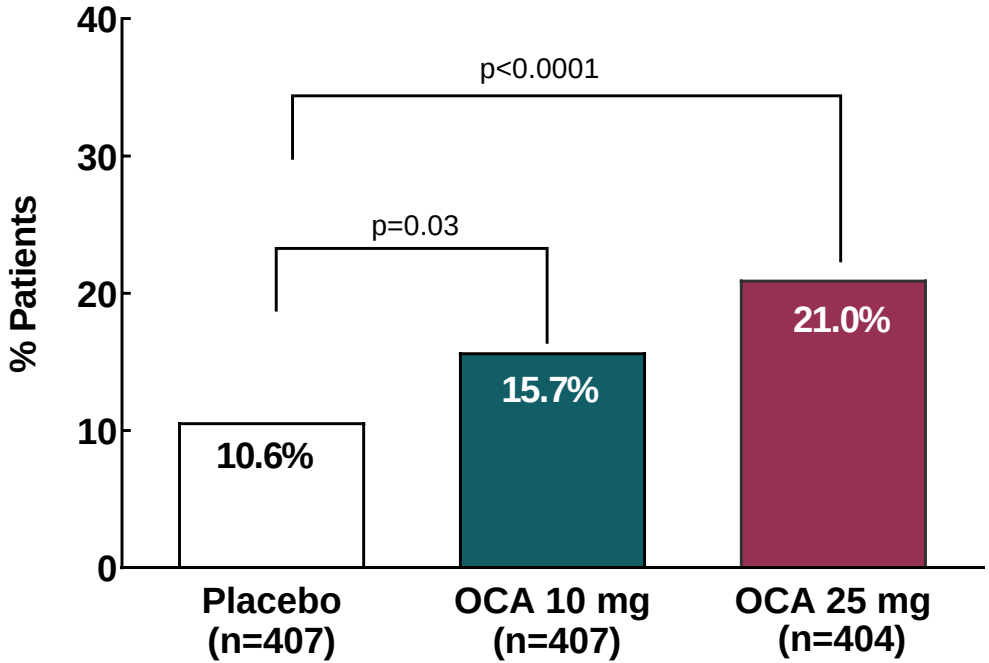
NASH FIBROSIS STUDY

Fibrosis Improvement by ≥1 Stage with No Worsening of NASH

Primary Endpoint: Full Efficacy Analysis Population, N=1218

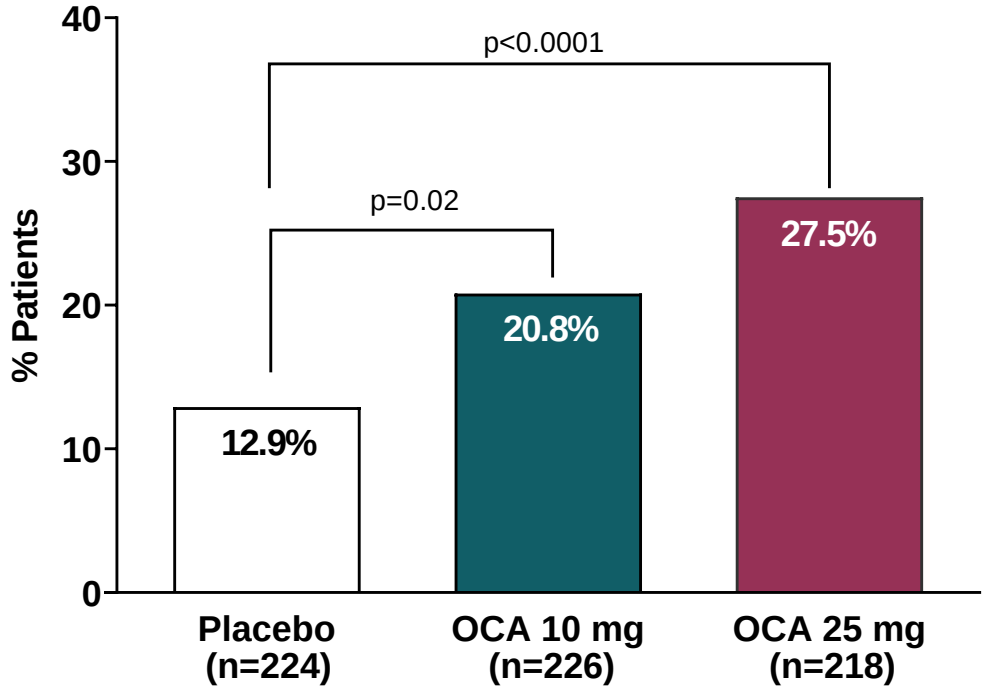


Primary endpoint definition: fibrosis improvement by ≥1 stage (NASH CRN) with no worsening of NASH (defined as no worsening of hepatocellular ballooning, lobular inflammation or steatosis).
Full efficacy analysis population defined as all interim analysis cohort patients randomized by the predefined cutoff date, including all fibrosis stages (stages 1, 2, and 3) who received at least 1 dose of study treatment.
P values are nominal.

REGENERATE
NASH FIBROSIS STUDY

Fibrosis Improvement by ≥1 Stage with No Worsening of NASH

Primary Endpoint: Per Protocol Population, N=668

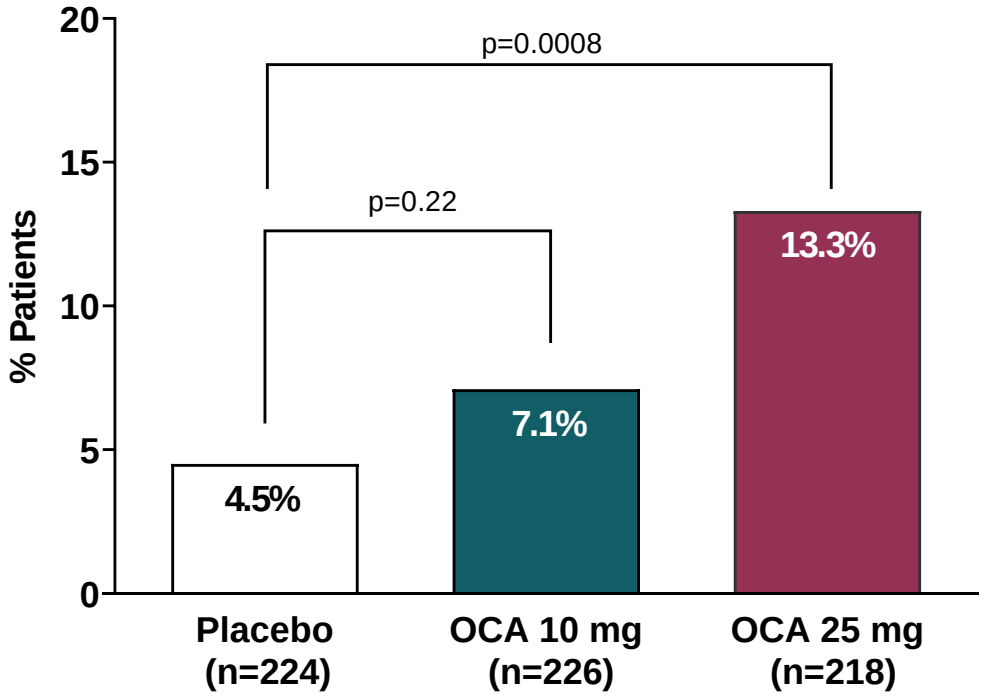


Primary endpoint definition: fibrosis improvement by ≥1 stage (NASH CRN) with no worsening of NASH (defined as no worsening of hepatocellular ballooning, lobular inflammation or steatosis).
Per protocol population defined as all patients from the ITT population who completed ≥15 months of treatment and had a Month 18/end of treatment (EOT) biopsy, were on treatment for at least 30 days immediately preceding the biopsy, and did not have any major protocol deviation.
P values are nominal.

REGENERATE
NASH FIBROSIS STUDY

Fibrosis Improvement by ≥2 Stages

Per Protocol Population



P values are nominal.
Per protocol population (N=668).

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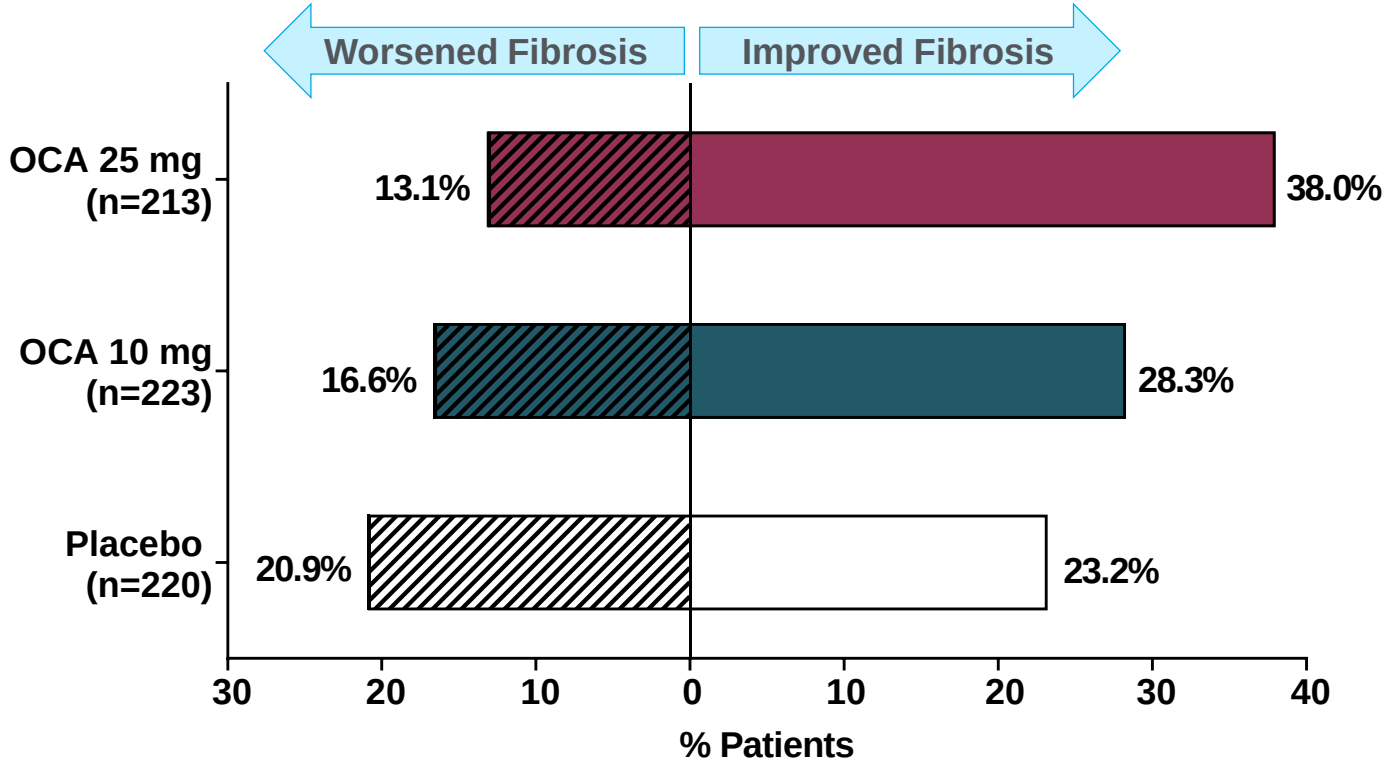
NASH FIBROSIS STUDY

Regression or Progression of Fibrosis by ≥1 Stage

*Per Protocol Population**



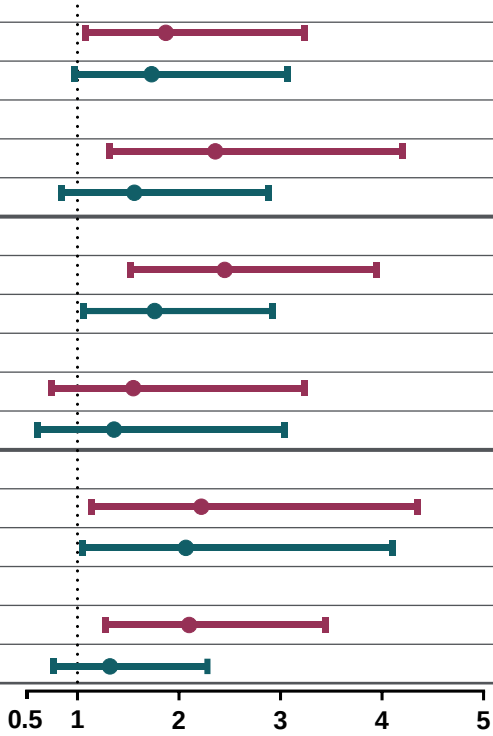
*Per protocol population with available fibrosis stage data at Month 18/EOT (n=656).

REGENERATE NASH FIBROSIS STUDY

Fibrosis Improvement by ≥1 Stage with No Worsening of NASH

Subgroup Analyses: Per Protocol Population

Subgroups	OCA : Placebo Response Ratio (95% CI)	P Value
Fibrosis Stage 2		
25 mg (n=101)	1.87 (1.08, 3.24)	0.02
10 mg (n=91)	1.73 (0.97, 3.07)	0.06
Fibrosis Stage 3		
25 mg (n=117)	2.36 (1.32, 4.20)	0.003
10 mg (n=135)	1.56 (0.84, 2.88)	0.15
NAS ≥6		
25 mg (n=144)	2.45 (1.52, 3.95)	0.0001
10 mg (n=152)	1.76 (1.06, 2.92)	0.03
NAS <6		
25 mg (n=74)	1.55 (0.74, 3.24)	0.24
10 mg (n=74)	1.36 (0.61, 3.04)	0.45
Type 2 Diabetes		
25 mg (n=119)	2.22 (1.14, 4.35)	0.02
10 mg (n=121)	2.07 (1.05, 4.11)	0.03
No Type 2 Diabetes		
25 mg (n=99)	2.10 (1.28, 3.44)	0.002
10 mg (n=105)	1.32 (0.76, 2.28)	0.32

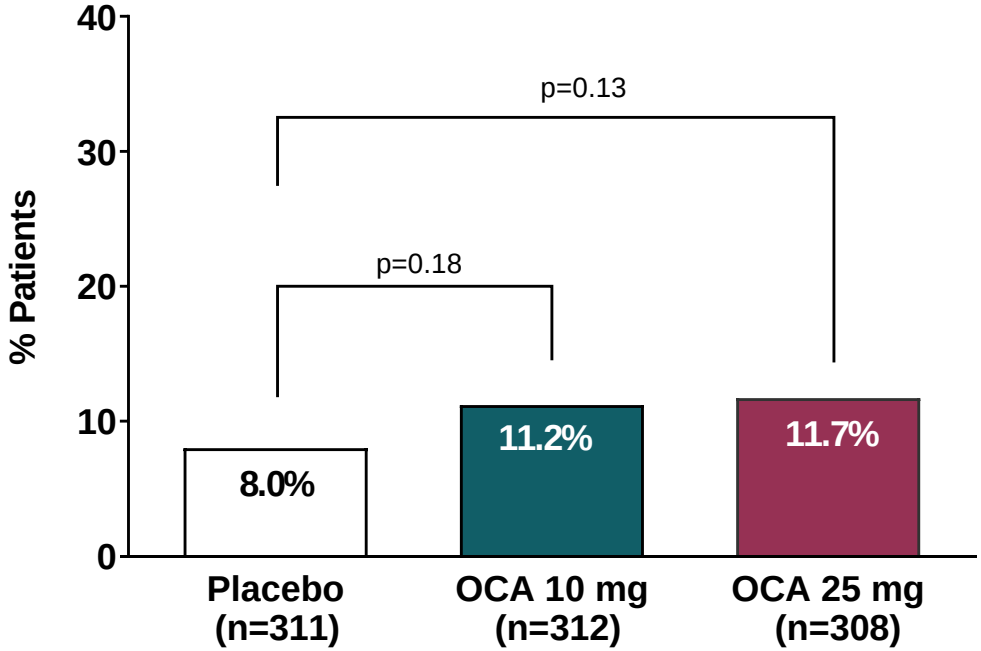


REGENERATE NASH FIBROSIS STUDY

Per protocol population (N=668).
P values are nominal.

NASH Resolution with No Worsening of Fibrosis

Additional Primary Endpoint: ITT Population, N=931



Primary endpoint definition:
(i) overall pathologist assessment of “no steatohepatitis,” and (ii) hepatocellular ballooning = 0 and lobular inflammation = 0 or 1, and (iii) no increase in fibrosis stage from baseline.
Study success was defined as achievement of one of the two primary endpoints evaluated in the Month 18 interim analysis.

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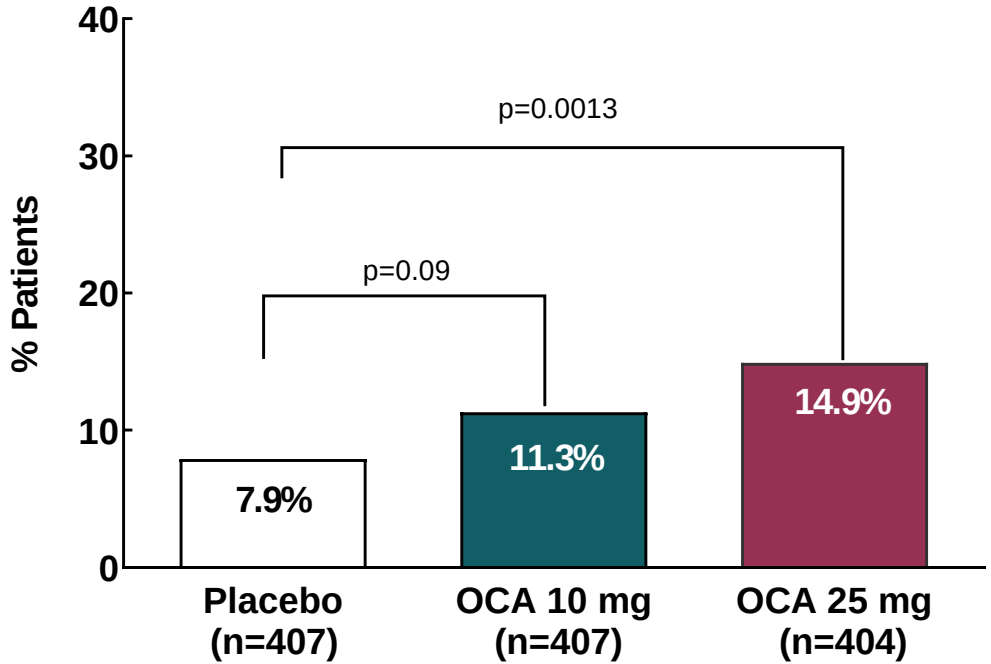
NASH FIBROSIS STUDY

NASH Resolution Without Worsening of Fibrosis

Additional Primary Endpoint: Full Efficacy Analysis Population, N=1218



Primary endpoint definition:
(i) overall pathologist assessment of "no steatohepatitis," and (ii) hepatocellular ballooning = 0 and lobular inflammation = 0 or 1, and (iii) no increase in fibrosis stage from baseline.
P values are nominal.

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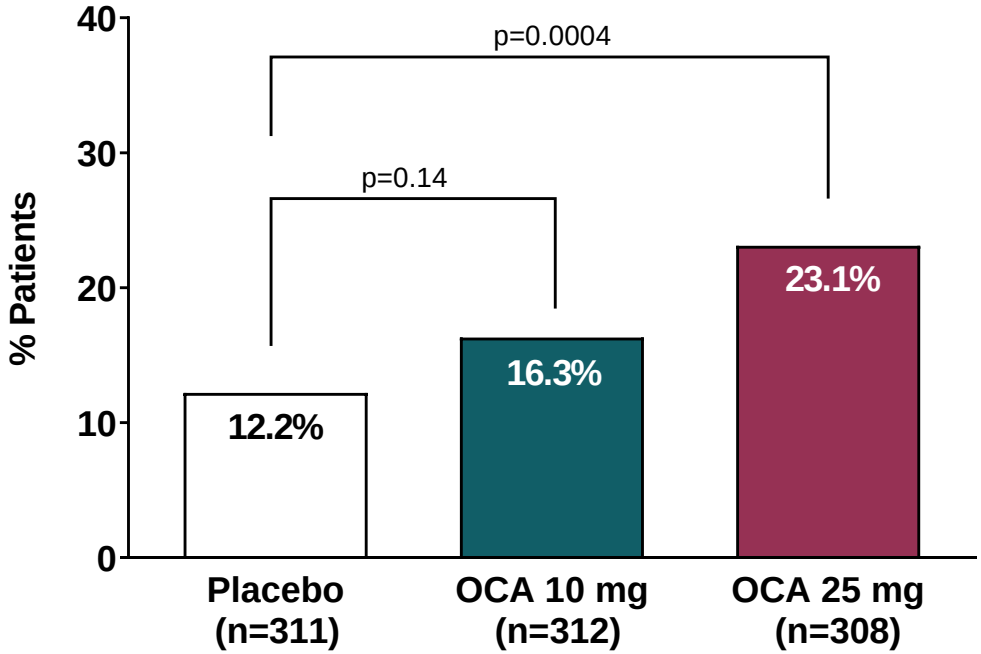
Resolution of Definite NASH with No Worsening of Fibrosis

*Overall Pathologist Assessment: ITT Population**



*Post-hoc analysis with endpoint defined as: (i) overall pathologist assessment of “no steatohepatitis,” and (ii) no increase in fibrosis stage from baseline. P values are nominal.

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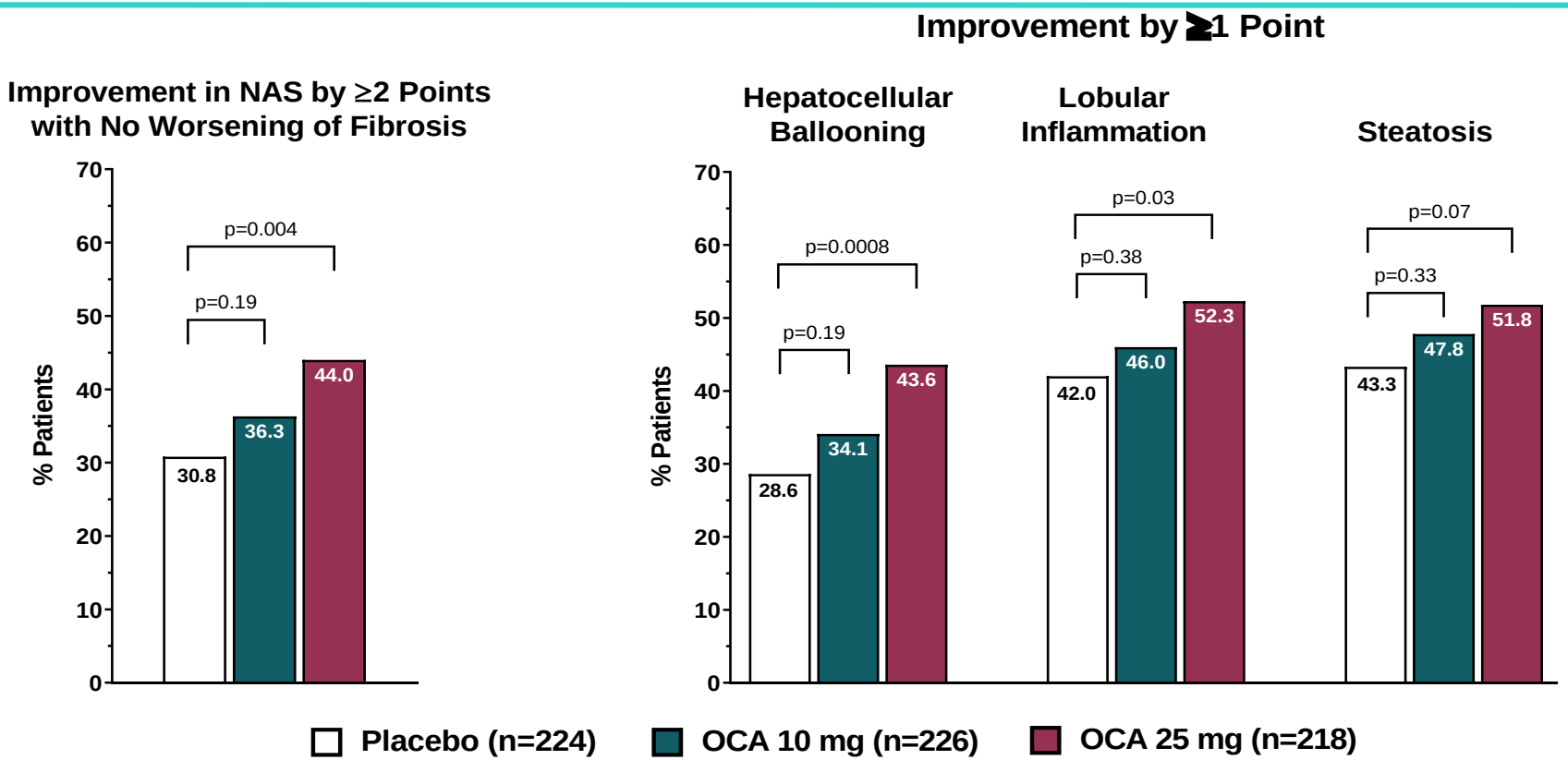
NASH FIBROSIS STUDY

Improvement in NAS ≥2 with No Worsening of Fibrosis and NAS Parameters ≥1

Per Protocol Population

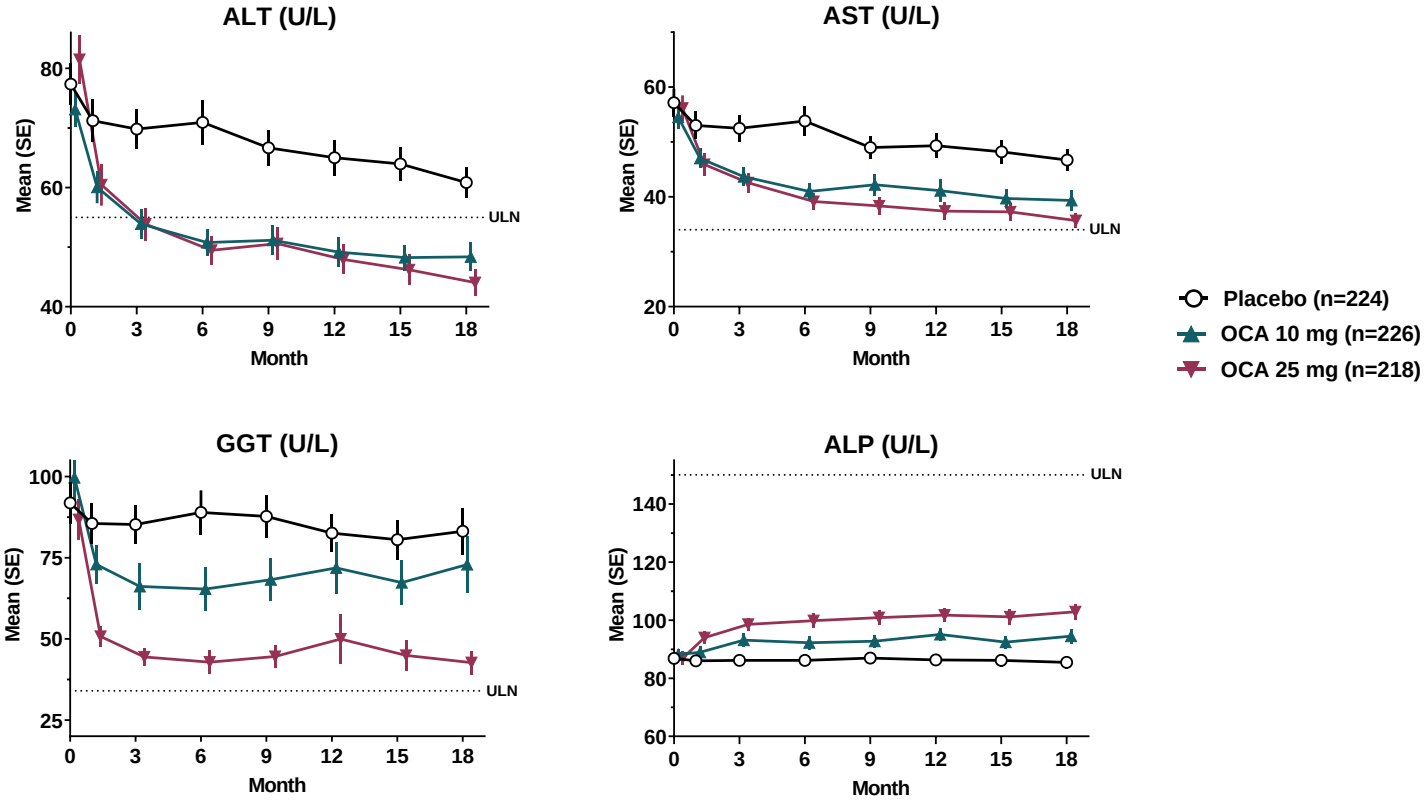


P values are nominal.
Per protocol population (N=668).

REGENERATE NASH FIBROSIS STUDY

Changes in Liver Biochemistry Over Time

Per Protocol Population

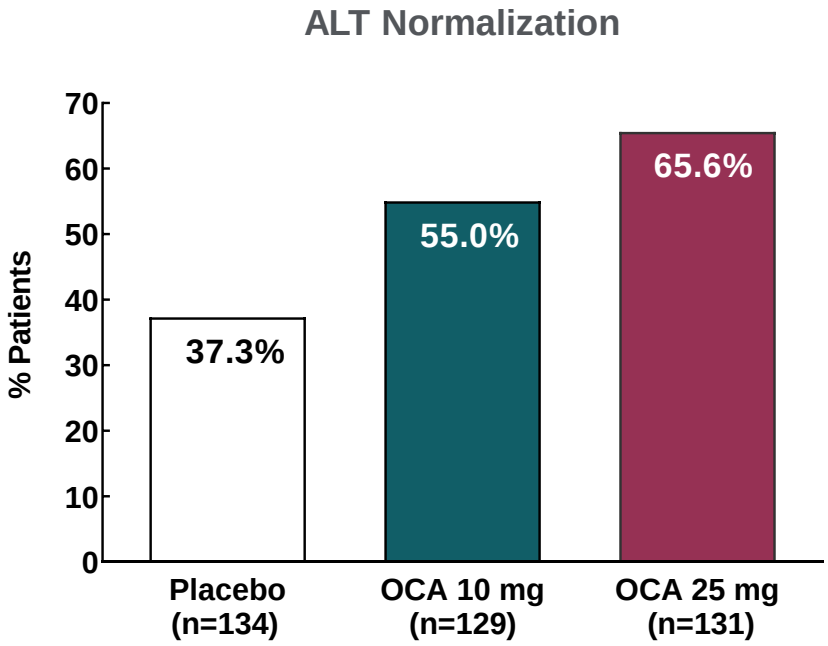


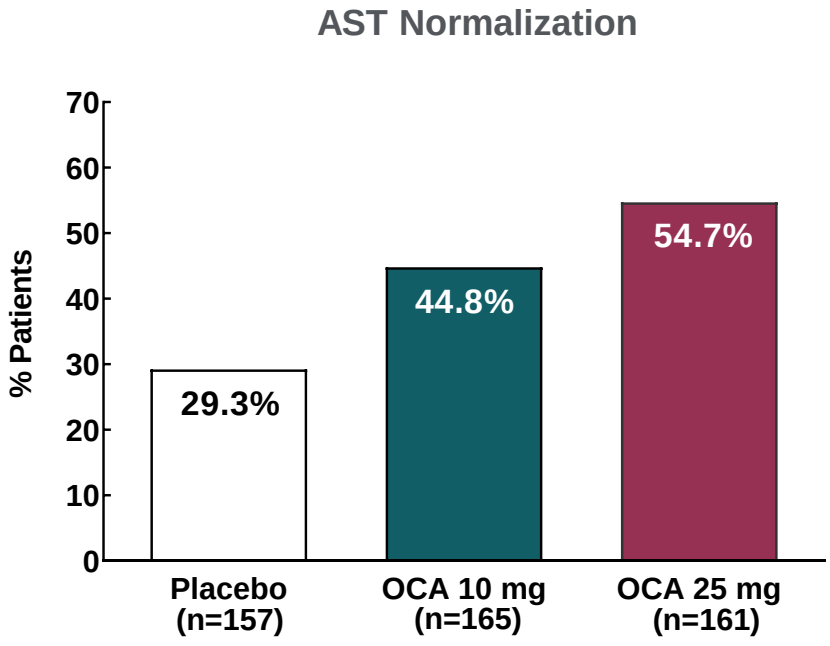
Per protocol population (N=668). ALP, alkaline phosphatase; GGT, gamma-glutamyl transferase; SE, standard error.

REGENERATE
NASH FIBROSIS STUDY

Normalization of Transaminases in Patients With Elevated Baseline Values

*Per Protocol Population**

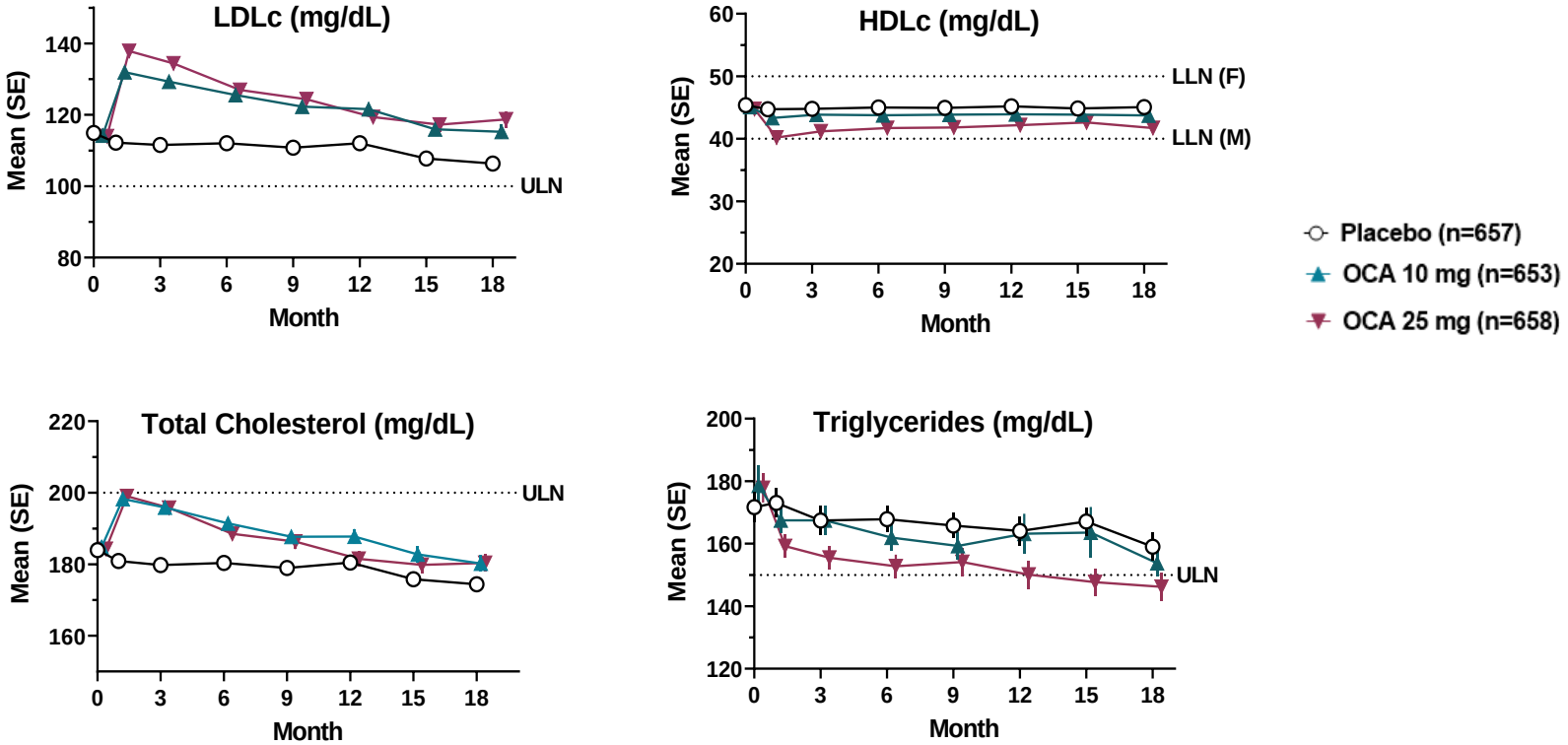




Data are for normalization by Month 18 based on ULNs established by central laboratories: 55 U/L (ALT) and 34 U/L (AST).
*Subset of the per protocol population with elevated ALT and AST at baseline.

Changes in Lipid Parameters Over Time

Safety Population, N=1968



Safety population defined as all randomized patients with stage 1, 2 or 3 fibrosis who received at least 1 dose of study treatment.
LDLc, low density lipoprotein cholesterol; HDLc, high density lipoprotein cholesterol.

REGENERATE
NASH FIBROSIS STUDY

Summary of Treatment-Emergent Adverse Events

Safety Population

Patients, n (%)	Placebo (n=657)	OCA 10 mg (n=653)	OCA 25 mg (n=658)
≥1 Treatment-Emergent Adverse Event (TEAE)	548 (83)	579 (89)	601 (91)
TEAEs by Severity			
Mild	160 (24)	163 (25)	130 (20)
Moderate	294 (45)	323 (49)	338 (51)
Severe	87 (13)	89 (14)	130 (20)
TEAEs Leading to Treatment Discontinuation	41 (6)	39 (6)	83 (13)
Serious Adverse Events (SAEs)	75 (11)	72 (11)	93 (14)
Deaths	2 (<1)	0	1 (<1)

AEs were mostly mild to moderate in severity
The frequency of SAEs was similar across treatment arms
No single SAE occurred in >1% of patients in any treatment arm

REGENERATE NASH FIBROSIS STUDY

Safety population (N=1968).
AE, adverse event.

Most Frequent Treatment-Emergent Adverse Events

Safety Population: Events Occurring in ≥10% of Patients in Any Treatment Group

n (%)	Placebo (n=657)	OCA 10 mg (n=653)	OCA 25 mg (n=658)
Pruritus (all pooled terms)	123 (19)	183 (28)	336 (51)
LDL increased	47 (7)	109 (17)	115 (17)
Nausea	77 (12)	72 (11)	83 (13)
Fatigue	88 (13)	78 (12)	71 (11)
Constipation	36 (5)	65 (10)	70 (11)
Abdominal pain	62 (9)	66 (10)	67 (10)
Diarrhea	79 (12)	44 (7)	49 (7)

Most frequent TEAEs were mild to moderate in severity and consistent with the known profile of OCA

Data are presented in decreasing order of occurrence in the OCA 25 mg group. All data are based on investigator-reported events.
Safety population (N=1968).
LDL, low density lipoprotein.

Additional Safety and Tolerability Information

Safety Population

Pruritus

- Incidence was highest in the first 3 months and decreased thereafter
- In patients on OCA 25 mg reporting pruritus, 93% of events were mild to moderate
- 9% of patients on OCA 25 mg discontinued due to pruritus: more than half of these were protocol mandated and overall discontinuation rates were similar across the treatment arms

Hepatobiliary

- Hepatic TEAEs were balanced across treatment groups (Placebo, 13%; OCA 10 mg, 13%; OCA 25 mg, 11%)
- Hepatic SAEs were rare (<1% in all treatment groups): more occurred in the OCA 25 mg group with no pattern attributable to OCA (based on eDISH and case review)
- Incidence of cholelithiasis or cholecystitis AEs* was low (Placebo, <1%; OCA 10 mg, 1%; OCA 25 mg, 3%)

Cardiovascular

Incidence of CV** SAEs was low and balanced across groups (Placebo, 2%; OCA 10 mg, 1%; OCA 25 mg, 2%)

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*Gallbladder SMQ includes TEAEs and SAEs.
**By SMQ and preferred term.
CV, cardiovascular; eDISH, Evaluation of Drug-Induced Serious Hepatotoxicity; SMQ, standardized MedDRA queries.

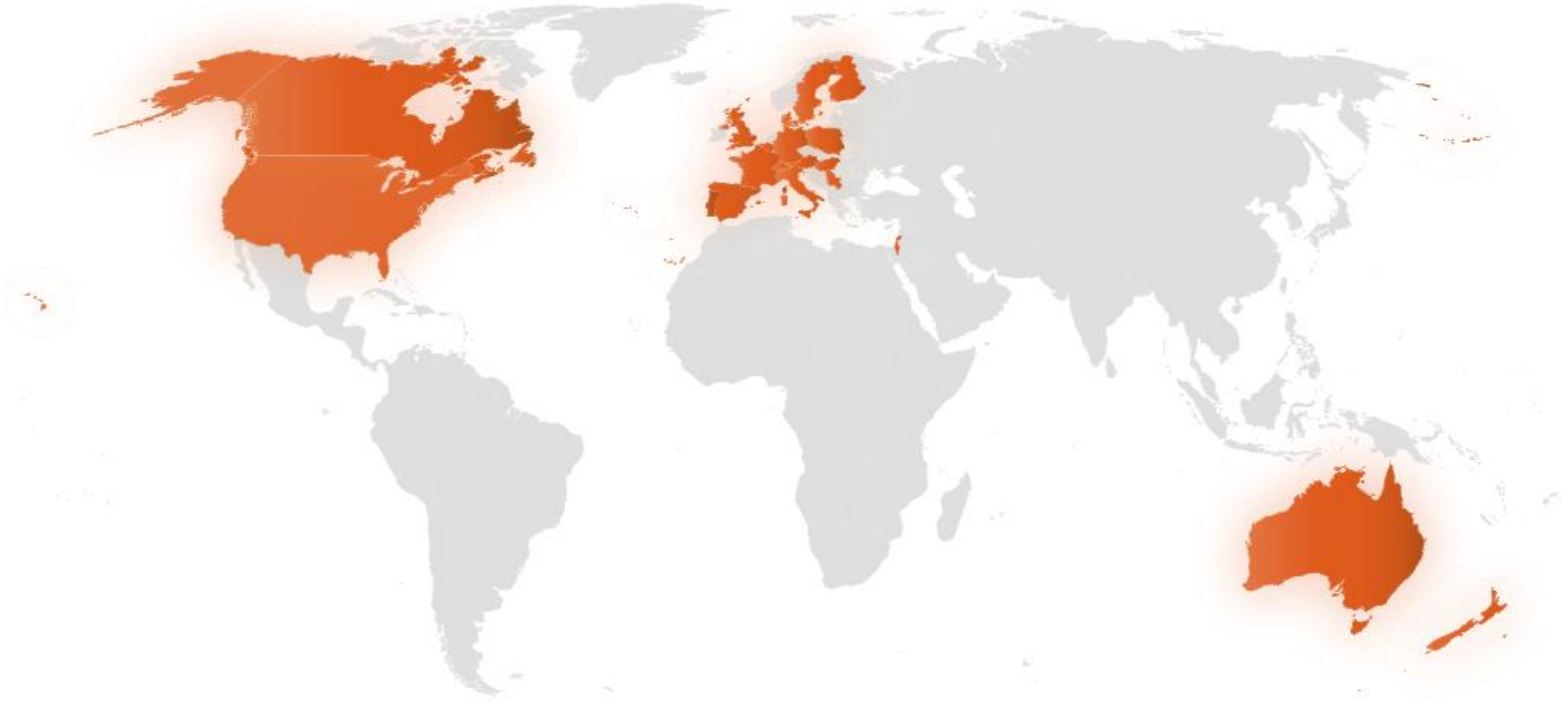
REGENERATE Is the First Successful Phase 3 Study in Patients with NASH

Summary and Conclusion

- OCA 25 mg met the primary fibrosis endpoint at the Month 18 interim analysis
- The antifibrotic effect was dose dependent and consistent across endpoints and key subgroups
- Although the primary NASH resolution endpoint was not met, OCA ameliorated steatohepatitis based on pathologist overall assessment and improvement in key disease activity parameters
- OCA rapidly and sustainably improved ALT, AST and GGT
- AEs were mostly mild to moderate; the most common were consistent with the known profile of OCA
- The study is ongoing to confirm benefit on clinically important outcomes

Acknowledgments

We are grateful to the patients and their families, the investigators and the healthcare providers who are participating in the ongoing REGENERATE study across ~350 sites in 20 countries



Q&A

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Back-Up

Analysis Populations

Population	N	Definition
Intent to Treat (ITT)	931	Patients with stage 2 or stage 3 fibrosis who received at least 1 dose of study treatment enrolled by predefined cut-off date
Per Protocol (PP)	668	All patients from the ITT population who • Completed ≥15 months of treatment *and* • Had a Month 18/end-of-treatment biopsy *and* • Were on treatment for at least 30 days immediately preceding the biopsy *and* • Did not have any major protocol deviation
Full Efficacy	1218	All IA Cohort patients randomized by the predefined cutoff date, including all fibrosis stages (stages 1, 2, and 3) who received at least 1 dose of study treatment
Safety	1968	All patients (with stage 1, 2, or 3 fibrosis) who received at least 1 dose of study treatment

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IA, interim analysis.