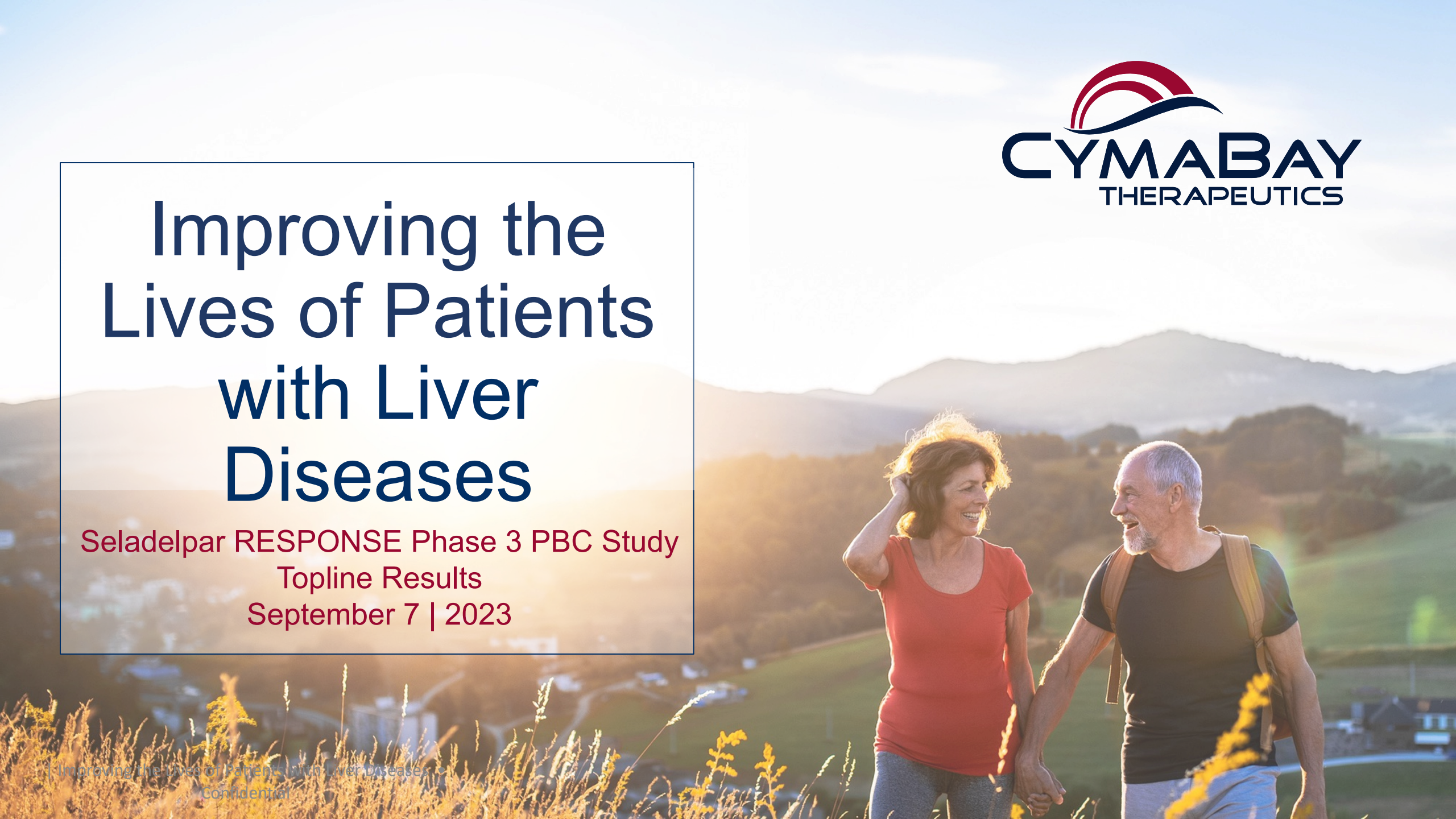
Improving the Lives of Patients with Liver Diseases

Seladelpar RESPONSE Phase 3 PBC Study
Topline Results
September 7 | 2023



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RESPONSE Phase 3 Pivotal Study in Patients with PBC

Placebo-Controlled, Double-Blind 52-week Study Design

Primary Outcome:

- Composite responder rate (ALP < 1.67 x ULN, ≥ 15% decrease in ALP, total bilirubin ≤ ULN)

Secondary Outcomes:

- Proportion of patients with ALP ≤ 1.0 x ULN at 12 months
- Change from baseline in pruritus in patients with baseline Numerical Rating Scale (NRS) ≥ 4 using e-diary at 6 months

CYMABAY THERAPEUTICS

Demographic and Baseline Characteristics

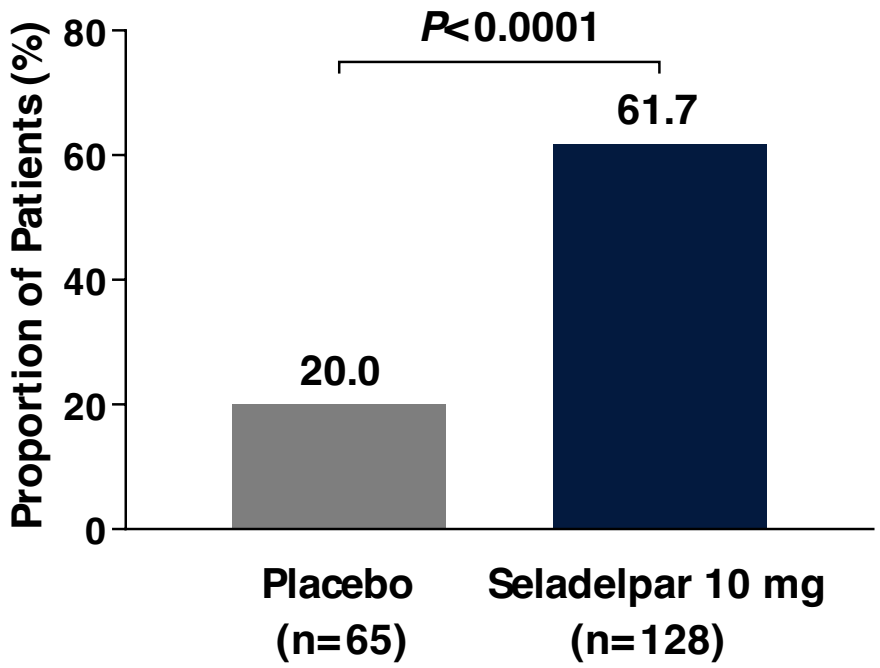
ITT Population

		Placebo (n=65)	Seladelpar 10 mg (n=128)
Female, n (%)		60 (92.3)	123 (96.1)
Age, years		57.0 (9.17)	56.6 (9.99)
Pruritus NRS ≥ 4, n (%)		23 (35.4)	49 (38.3)
UDCA Intolerant, n (%)		4 (6.2)	8 (6.3)
ALP	ULN: 116 U/L	313.8 (117.68)	314.6 (122.96)
Total bilirubin	ULN: 1.1 mg/dL	0.74 (0.31)	0.77 (0.31)

Mean (SD) unless noted as n (%).

Composite Responder Rate at Month 12

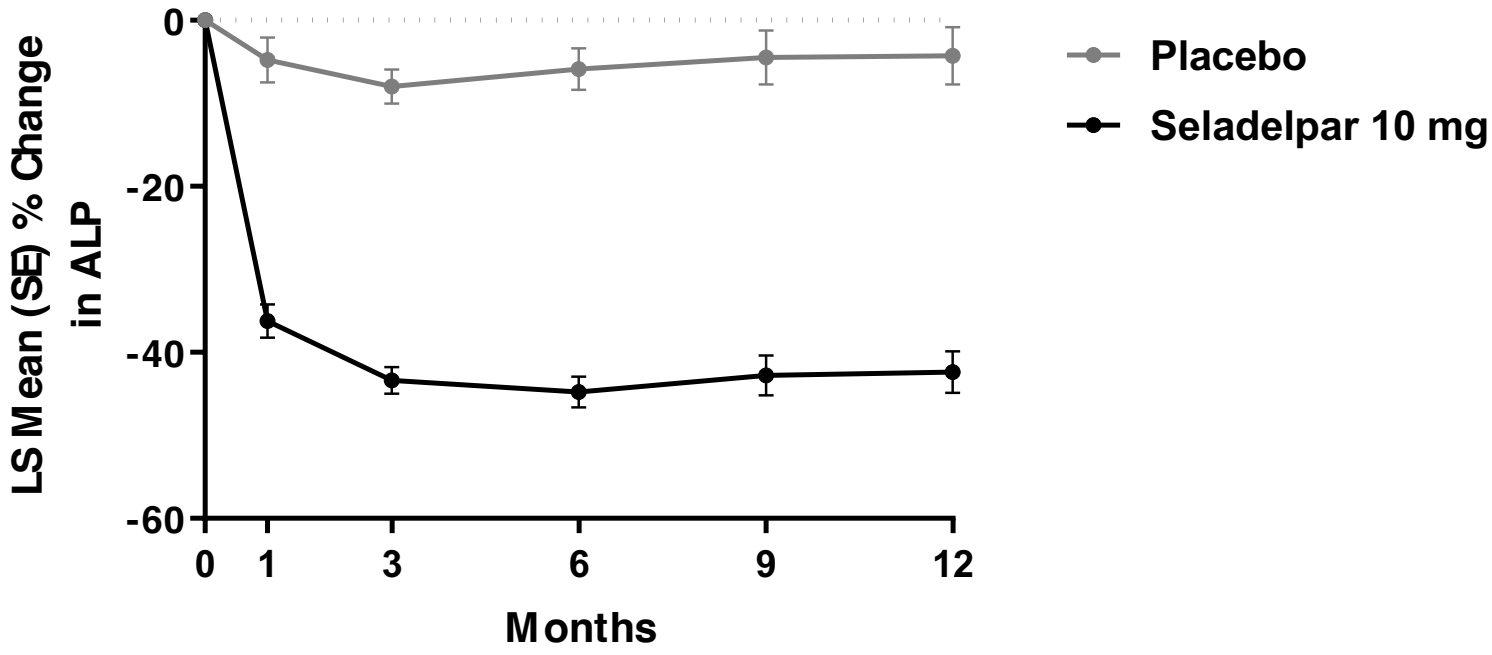
ALP < 1.67 x ULN, ALP ≥ 15% Decrease and Total Bilirubin ≤ ULN



6 out of 10 patients on seladelpar achieved the primary composite endpoint

P value by Cochran-Mantel-Haenszel (CMH) test.

ALP % Change over 12 Months

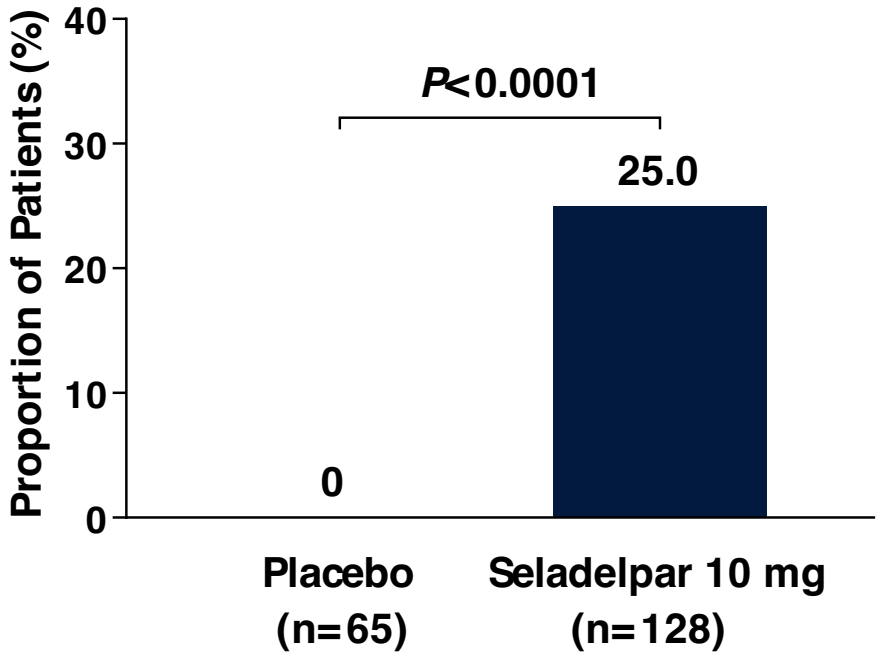


Decrease in ALP is about 10-fold greater in the seladelpar group than placebo at Month 12

P<0.0001 at all timepoints
LS Mean and *P* values by Mixed-Effect Model Repeated Measure (MMRM) model.

Normalization Rate of ALP at Month 12

ALP ≤ ULN

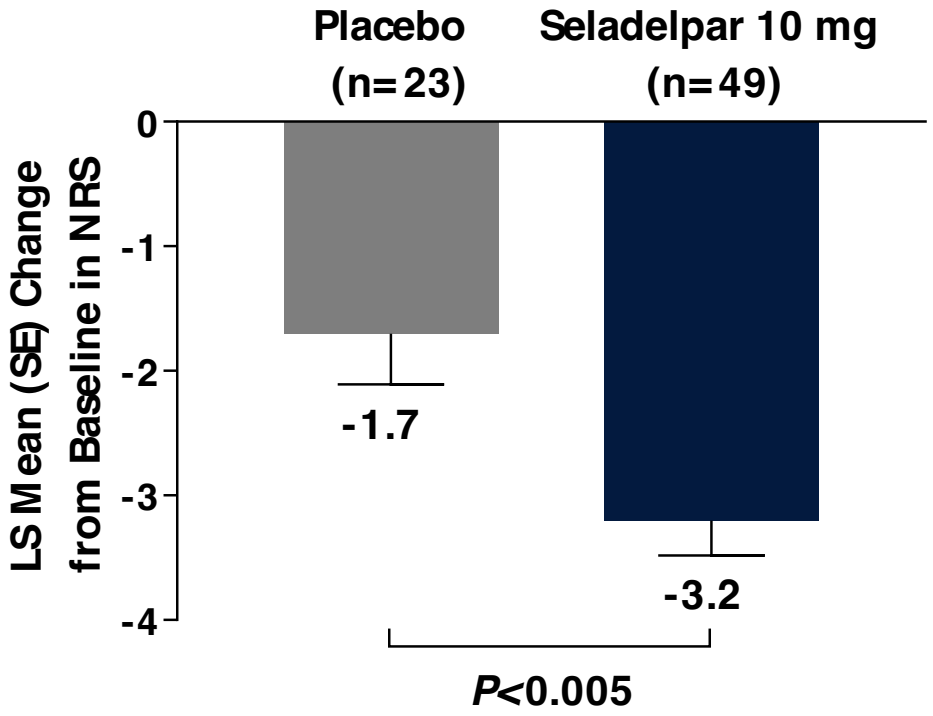


1 out of 4 patients on seladelpar normalized ALP

P value by CMH test.

Improvement in Pruritus NRS at Month 6

Patients with Baseline NRS ≥ 4*



Patients with moderate-to-severe pruritus treated with seladelpar decreased pruritus NRS by an average of 3.2 points

*The mean baseline NRS was 6.3 for all patients having a baseline NRS ≥ 4
LS Mean and P values by MMRM model.

RESPONSE Efficacy and Safety Summary

- **61.7% of patients achieved primary composite endpoint** in the seladelpar group
- Seladelpar **normalized ALP in 25.0% of patients**
- Patients with moderate-to-severe pruritus treated with seladelpar had a **statistically significant reduction in pruritus** versus those on placebo
- **Safety and tolerability were comparable between placebo and seladelpar** groups and consistent with previous studies
  - Treatment-emergent adverse events, serious adverse events and patient discontinuations were generally balanced across the treatment and placebo arms
  - There were no treatment-related serious adverse events in the study

Thank You