PEDFIC 1
Odevixibat PFIC
Phase 3 Results

Albireo

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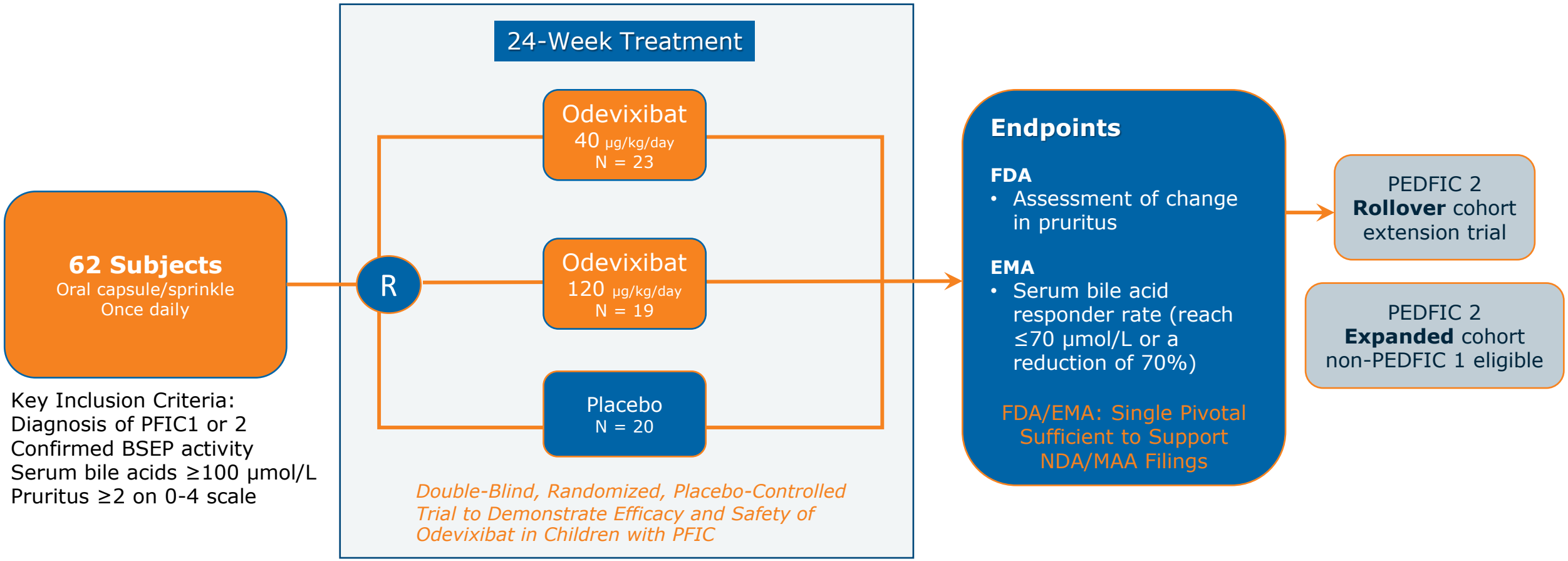
PEDFIC 1 Odevixibat PFIC Phase 3 Results

- Statistically significant improvement in pruritus assessments p=0.004
- Statistically significant improvement in serum bile acid responses p=0.003
- Both odevixibat doses statistically significant for both endpoints
- Similar efficacy in PFIC 1 and PFIC 2 patients
- Excellent tolerability profile
  - Most common non-treatment related AEs: infections and infestations 52.4% (odevixibat) vs 60.0% (placebo)
- Low rate of treatment-related diarrhea/frequent bowel movements vs placebo
  - 9.5% (odevixibat) vs 5.0% (placebo)
- Company plans to submit for approval in the U.S. and Europe

PEDFIC 1&2: Phase 3 PFIC Program Summary

Ped**iatric P**FIC (PEDFIC)



Key Inclusion Criteria:
Diagnosis of PFIC1 or 2
Confirmed BSEP activity
Serum bile acids ≥100 µmol/L
Pruritus ≥2 on 0-4 scale

Key Baseline Demographics/Baseline Characteristics

	Placebo n=20	Odevixibat n=42
Age (Years)	3.75 (0.5 - 15.0)	4.48 (0.6 - 15.9)
Sex (% Female)	40.0	54.8
PFIC Type; n (%)	5 (25.0%) Type1 15 (75.0%) Type 2	12 (28.6%) Type 1 30 (71.4%) Type 2
Bile acids and range (nl = 0 – 10 µmol/L)	247.53 (56.5 - 435)	252.1 (36 – 605)
Pruritus (0-4 scale)	3.02 (1.5 - 4.0)	3.00 (2.0 - 4.0)
Ursodeoxycholic acid; n (%)	18 (90.0%)	32 (76.2%)
Rifampicin; n (%)	17 (85.0%)	24 (57.1%)
ALT and range (nl = 0-35 U/L)	76.9 (19.0 - 236.0)	110.2 (16.0 - 798.0)
Total Bilirubin and range (nl ≤ 1.20 mg/dL)	3.12 (0.3 - 11.4)	3.18 (0.2 - 18.6)

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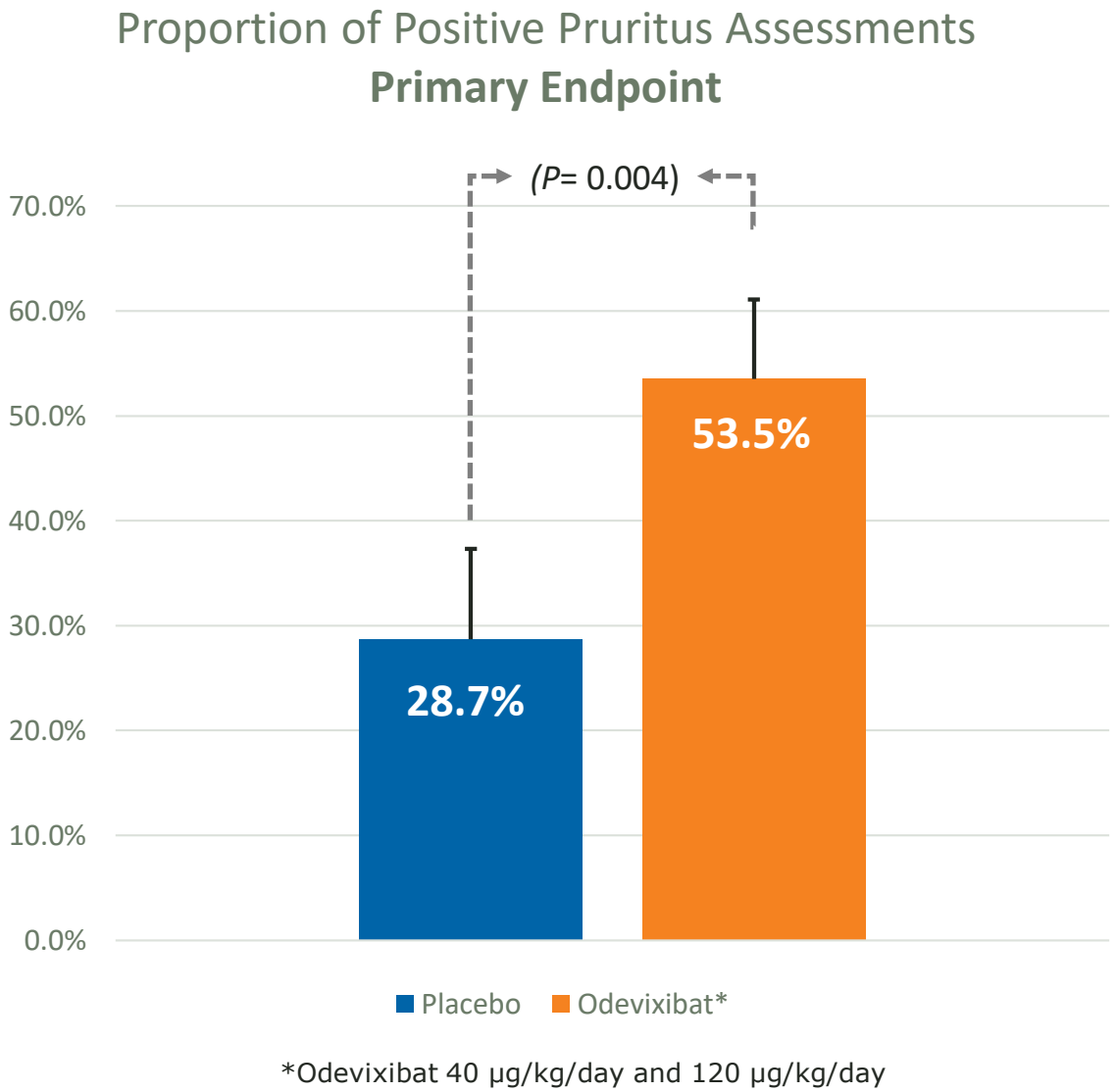
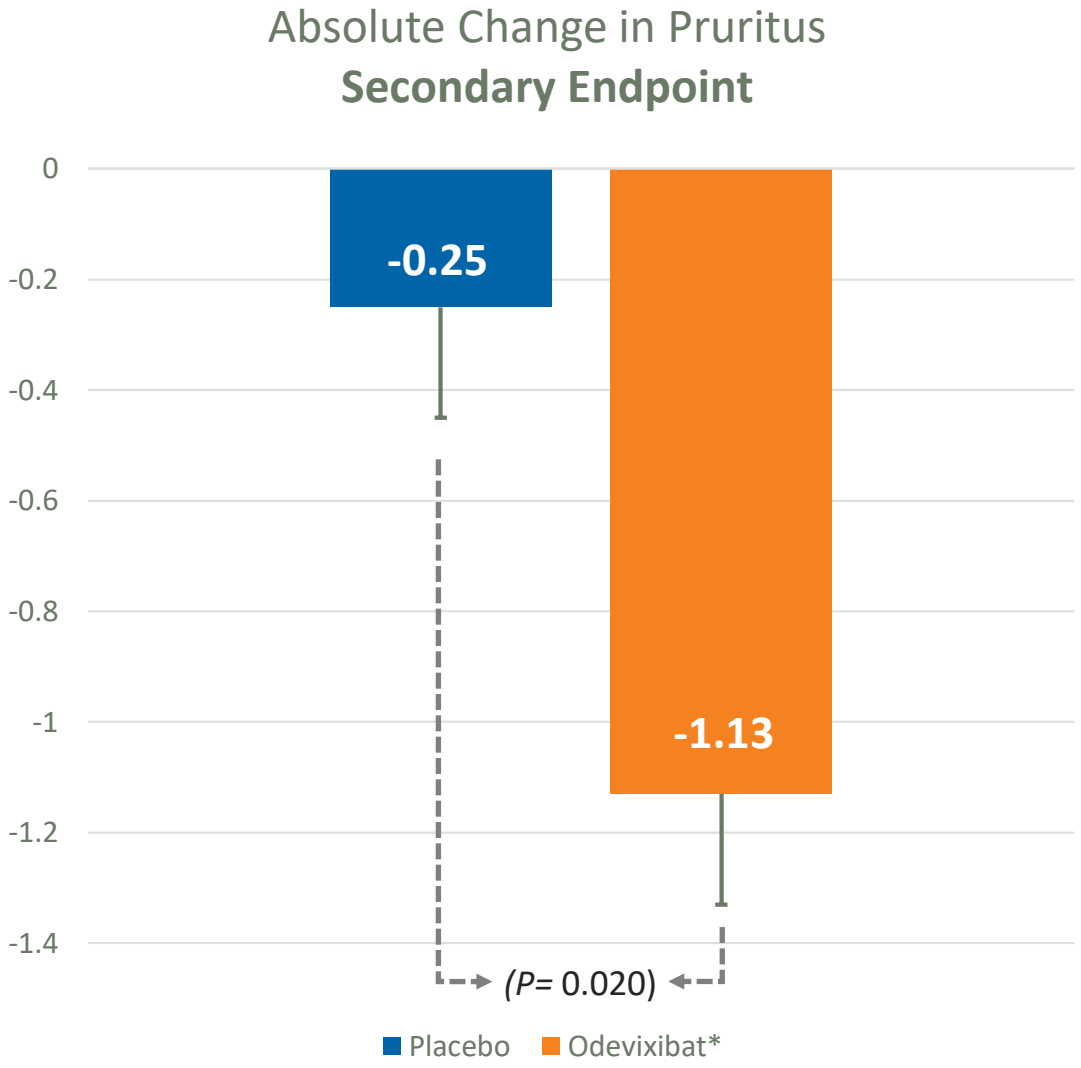
Pruritus Improvement Statistically Significant



*Odevixibat 40 µg/kg/day and 120 µg/kg/day

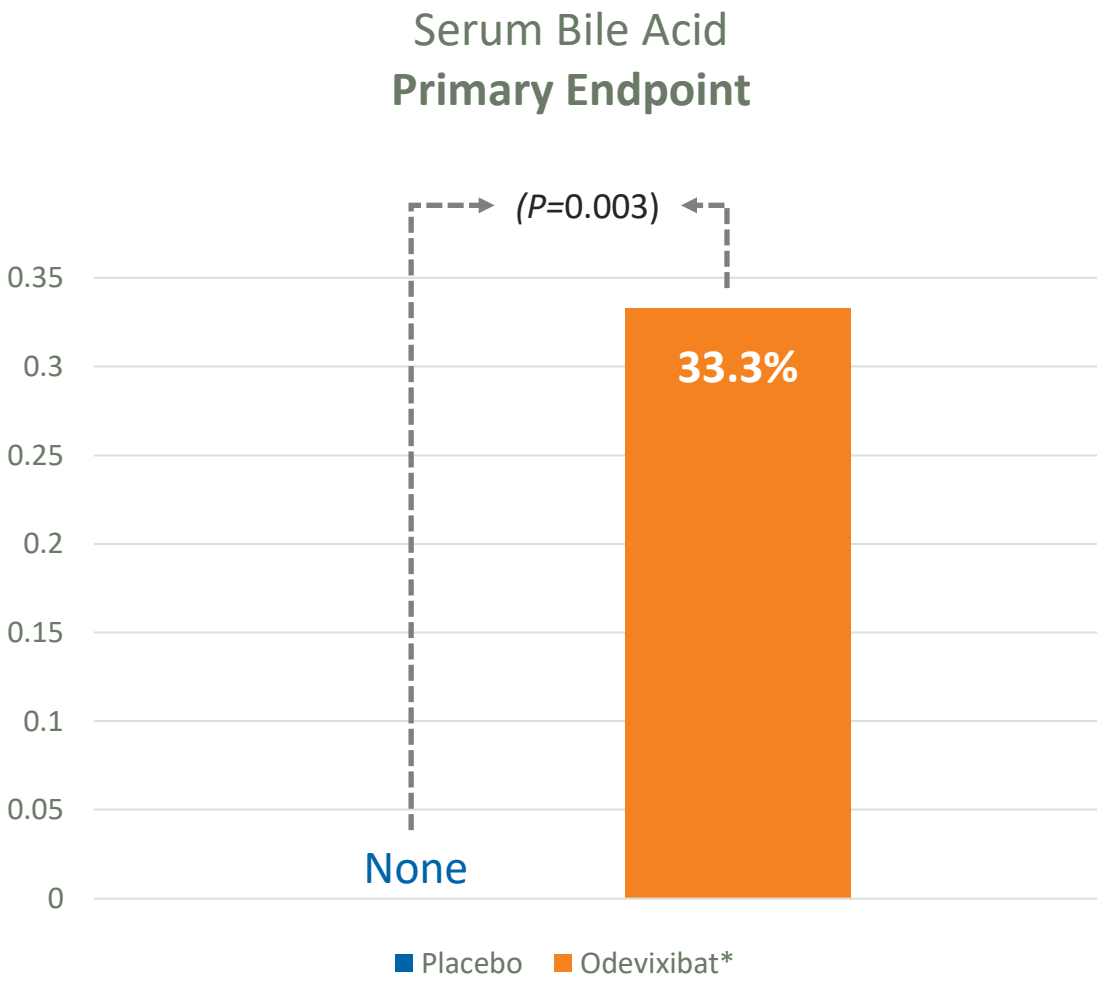
Pruritus Change in Mean From Baseline



*Odevixibat 40 µg/kg/day and 120 µg/kg/day

- Measured using PRUCISION instrument with 0-4 scale
- >1 point drop deemed clinically meaningful by external expert analysis

Serum Bile Acid Reduction Statistically Significant

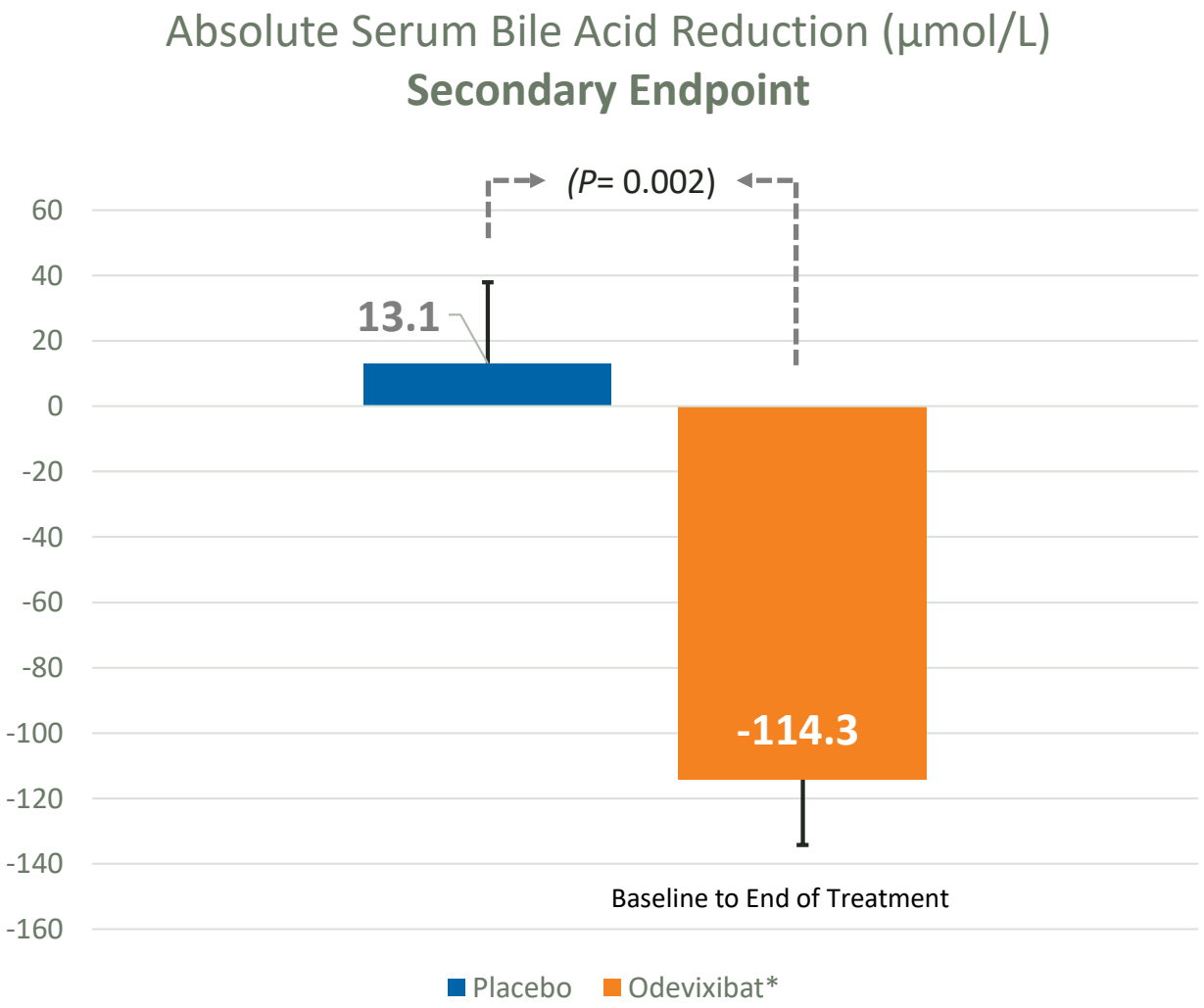


*Odevixibat 40 µg/kg/day and 120 µg/kg/day

Albireo Definition for Bile Acid Reduction Endpoint

- Reduction of 70% or greater serum bile acids or
- Reaching ≤70 µmol/L serum bile acid level

Absolute Serum Bile Acid Reduction Statistically Significant

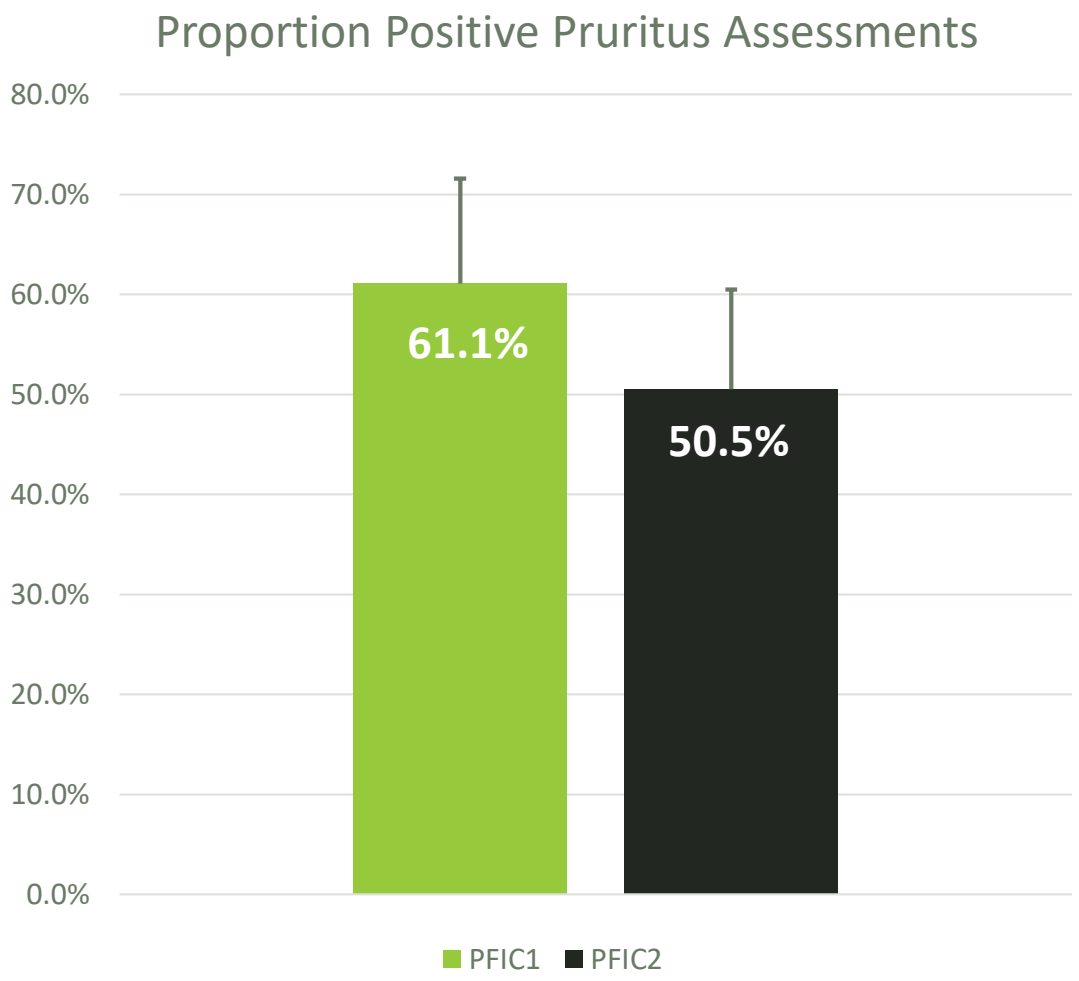


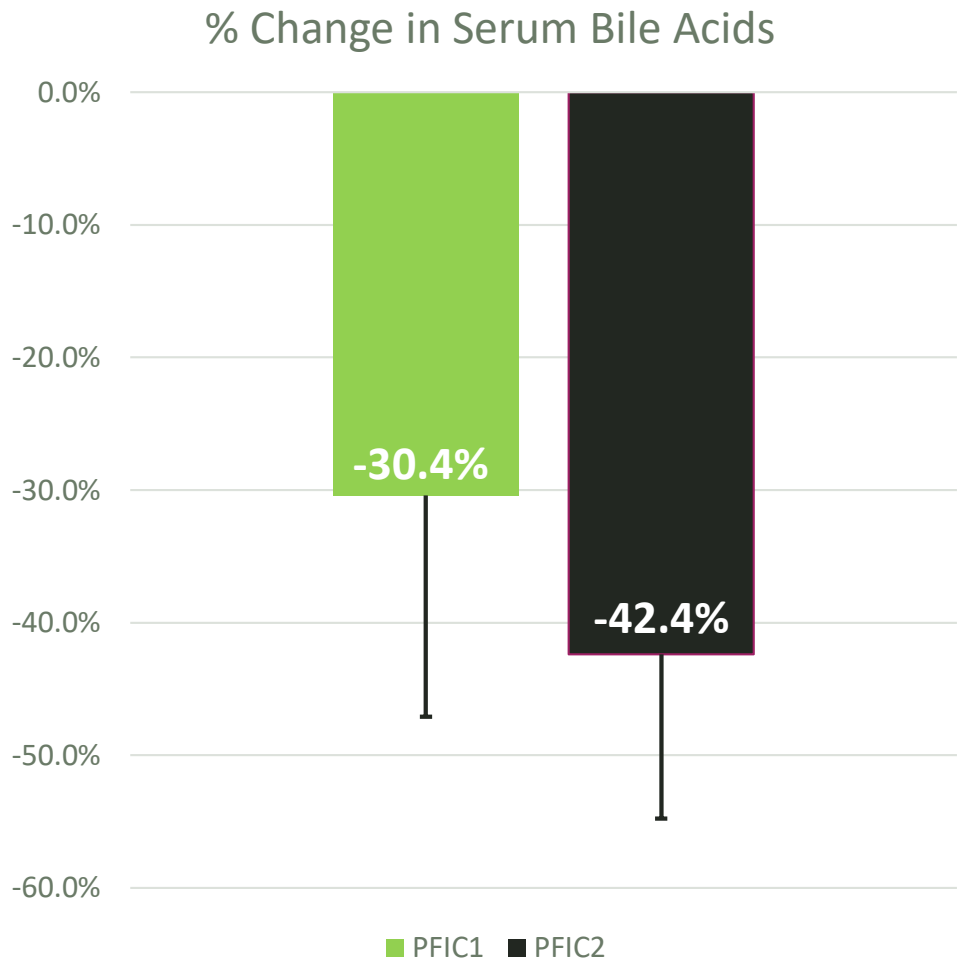
*Odevixibat 40 µg/kg/day and 120 µg/kg/day

38%

Reduction from baseline serum bile acids

Similar Response in PFIC1 and PFIC2 Patients





Summary of Treatment Emergent Adverse Events (TEAE)

	Placebo N=20 n (%)	Odevixibat All N=42 n (%)
Any TEAE	17 (85.0)	35 (83.3)
Severe TEAE	2 (10.0)	3 (7.1)
Serious Adverse Events (SAE)	5 (25.0)	3 (7.1)
Drug-related SAE	0	0
TEAEs leading to discontinuation	0	1 (2.4)
All-cause mortality	0	0

Well Tolerated with a Low Incidence of Diarrhea

Treatment-related gastrointestinal adverse events	Placebo N=20 n (%)	Odevixibat N=42 n (%)
Patients with any Drug-Related TEAEs	3 (15.0)	14 (33.3)
Gastrointestinal disorders	2 (10.0)	5 (11.9)
Abdominal pain	0	1 (2.4)
Abdominal pain upper	0	1 (2.4)
Constipation	1 (5.0)	0
Diarrhea/Frequent bowel movements	1 (5.0)	4 (9.5)

Odevixibat PEDFIC 1 Study Conclusions

- Achieved high statistical significance in the pruritus and serum bile acid primary endpoints
- Demonstrated similar efficacy in PFIC1 and PFIC2 patients
- Excellent tolerability profile with low diarrhea rate
- Plans to complete regulatory filings in early 2021
- First and largest randomized, placebo-controlled prospective trial in PFIC
- Sustained efficacy with once-daily, non-systemic, highly potent IBAT inhibitor