Dokumentvorlage, Version vom 16.12.2021

Seladelpar (Seladelpar Gilead®)

Gilead Sciences GmbH

Modul 4A – Anhang 4-G

Zur Behandlung der primär biliären Cholangitis (PBC) in Kombination mit UDCA bei Erwachsenen, die nicht ausreichend auf UDCA alleine ansprechen, oder als Monotherapie bei Patienten, die UDCA nicht vertragen

Stand: 14.03.2025

Contents

		Seladelpar 10 mg (N=128)	Placebo (N=65)
		n (%)	n (%)
Study disposition	Completed study	117 (91.4)	57 (87.7)
	Discontinued study	11 (8.6)	8 (12.3)
Reason for Discontinuation from Study	Adverse Event	3 (2.3)	4 (6.2)
	Lost To Follow-Up	1 (0.8)	1 (1.5)
	Other	1 (0.8)	0 (0.0)
	Protocol Deviation	1 (0.8)	1 (1.5)
	Withdrawal By Subject	5 (3.9)	2 (3.1)
Treatment disposition	Completed treatment	118 (92.2)	57 (87.7)
	Discontinued treatment	10 (7.8)	8 (12.3)
Reason for Discontinuation of Treatment	Adverse Events Other Than Monitoring Criteria	2 (1.6)	3 (4.6)
	Liver Safety Monitoring	2 (1.6)	1 (1.5)
	Lost To Follow-Up	1 (0.8)	1 (1.5)
	Significant Protocol Deviation	1 (0.8)	1 (1.5)
	Withdrawal Of Informed Consent	4 (3.1)	2 (3.1)

n=Number of subjects.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Demographics and Baseline Characteristics
Intention-to-treat

		Seladelpar 10 mg (N=128)	Placebo (N=65)
Age (years)	n	128	65
	Mean (SD)	56.6 (9.99)	57.0 (9.17)
	Median	57.0	58.0
	Q1, Q3	50.0, 63.5	50.0, 63.0
	Min, Max	28.0, 75.0	33.0, 75.0
Age at screening, n (%)	< 65 years	99 (77.3)	53 (81.5)
	>= 65 years	29 (22.7)	12 (18.5)
Sex, n (%)	Female	123 (96.1)	60 (92.3)
	Male	5 (3.9)	5 (7.7)
Race, n (%)	American Indian or Alaska Native	3 (2.3)	3 (4.6)
	Asian	7 (5.5)	4 (6.2)
	Black or African American	2 (1.6)	2 (3.1)
	Missing	2 (1.6)	0 (0.0)
	White	114 (89.1)	56 (86.2)
Ethnicity, n (%)	Hispanic or Latino	29 (22.7)	27 (41.5)
	Missing	2 (1.6)	0 (0.0)
	Not Hispanic or Latino	97 (75.8)	38 (58.5)
Region, n (%)	Asia-Pacific (APAC)	5 (3.9)	6 (9.2)
	Europe, the Middle East and Africa (EMEA)	49 (38.3)	27 (41.5)
	Latin America	24 (18.8)	19 (29.2)
	North America	50 (39.1)	13 (20.0)
Height (cm)	n	128	65
	Mean (SD)	162.1 (8.17)	161.2 (7.93)
	Median	162.6	160.0
	Q1, Q3	157.7, 166.4	156.0, 166.0
	Min, Max	137.1, 185.4	145.0, 188.0
Weight (kg)	n	128	65
	Mean (SD)	71.7 (15.94)	69.9 (13.94)
	Median	69.5	66.9
	Q1, Q3	61.0, 79.4	60.6, 77.5
	Min, Max	40.6, 127.5	44.0, 105.9
BMI (kg/m^2)	n	128	65
	Mean (SD)	27.2 (5.61)	26.8 (4.81)
	Median	26.0	26.2
	Q1, Q3	23.0, 29.8	23.7, 29.3
	Min, Max	17.5, 45.0	17.4, 40.1
Cirrhosis at Baseline, n (%)	No	110 (85.9)	56 (86.2)
	Yes	18 (14.1)	9 (13.8)
Child-Pugh Class, n (%)	A	18 (100.0)	9 (100.0)
Child-Pugh Score	n	18	9
	Mean (SD)	5.1 (0.32)	5.0 (0.00)
	Median	5.0	5.0
	Q1, Q3	5.0, 5.0	5.0, 5.0
	Min, Max	5.0, 6.0	5.0, 5.0
Portal hypertension, n (%)	No	128 (100.0)	62 (95.4)
	Yes	0 (0.0)	3 (4.6)

n=Number of subjects included in the analysis, SD: Standard Deviation, Q1: 25%-Quartile, Q3: 75%-Quartile, Min: Minimum, Max: Maximum.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Demographics and Baseline Characteristics
Intention-to-treat

		Seladelpar 10 mg (N=128)	Placebo (N=65)
Rotterdam Stage of Disease, n (%)	Mild	106 (82.8)	60 (92.3)
	Moderately Advanced	22 (17.2)	5 (7.7)
MELD Score, n (%)	< 12	128 (100.0)	65 (100.0)
MELD Score	n	128	65
	Mean (SD)	6.8 (0.97)	6.7 (0.93)
	Median	6.3	6.5
	Q1, Q3	6.0, 7.3	6.0, 7.3
	Min, Max	6.0, 11.7	6.0, 11.0
Liver Stiffness (kPa) by FibroScan	n	115	62
	Mean (SD)	9.8 (6.16)	8.7 (4.18)
	Median	8.0	7.5
	Q1, Q3	6.0, 12.4	6.0, 10.2
	Min, Max	3.1, 43.2	3.8, 23.0
Fibrosis Score Derived from Liver Stiffness, n (%)	F0	44 (38.3)	26 (41.9)
	F1	22 (19.1)	15 (24.2)
	F2	17 (14.8)	7 (11.3)
	F3	21 (18.3)	10 (16.1)
	F4	11 (9.6)	4 (6.5)
Enhanced Liver Fibrosis (ELF) Score	n	128	65
	Mean (SD)	10.2 (1.03)	10.2 (0.85)
	Median	10.1	10.0
	Q1, Q3	9.4, 10.7	9.6, 10.8
	Min, Max	8.1, 13.3	8.6, 12.3
UDCA usage at baseline, n (%)	No	8 (6.3)	4 (6.2)
	Yes	120 (93.8)	61 (93.8)
Total Daily UDCA Dose on Baseline (mg)	n	120	61
	Mean (SD)	1045.8 (243.11)	1020.5 (277.40)
	Median	1000.0	1000.0
	Q1, Q3	900.0, 1200.0	900.0, 1050.0
	Min, Max	600.0, 2000.0	600.0, 2000.0
Total Daily UDCA Dose on Baseline (mg/kg)	n	120	61
	Mean (SD)	15.0 (3.08)	14.8 (3.30)
	Median	14.9	14.4
	Q1, Q3	13.0, 16.5	12.9, 16.8
	Min, Max	7.2, 23.6	6.5, 22.7
Duration of Prior UDCA Usage (years)	n	128	65
	Mean (SD)	7.3 (6.46)	7.8 (6.24)
	Median	4.7	6.0
	Q1, Q3	2.7, 10.5	3.8, 10.0
	Min, Max	0.0, 33.0	0.0, 28.0
Prior Use of OCA and/or Fibrates, n (%)	No	108 (84.4)	52 (80.0)
	Yes	20 (15.6)	13 (20.0)
ALP (U/L)	n	128	65
	Mean (SD)	314.6 (122.96)	313.8 (117.68)
	Median	278.3	281.3
	Q1, Q3	227.8, 357.2	236.3, 353.3
	Min, Max	182.3, 786.3	160.7, 697.7

n=Number of subjects included in the analysis, SD: Standard Deviation, Q1: 25%-Quartile, Q3: 75%-Quartile, Min: Minimum, Max: Maximum.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Demographics and Baseline Characteristics
Intention-to-treat

		Seladelpar 10 mg (N=128)	Placebo (N=65)
ALP Level, n (%)	< 350 U/L	93 (72.7)	47 (72.3)
	>= 350 U/L	35 (27.3)	18 (27.7)
Direct Bilirubin (mg/dL)	n	128	65
	Mean (SD)	0.2 (0.16)	0.2 (0.14)
	Median	0.2	0.2
	Q1, Q3	0.1, 0.3	0.1, 0.3
	Min, Max	0.1, 0.9	0.1, 0.8
Total Bilirubin	n	128	65
	Mean (SD)	0.8 (0.31)	0.7 (0.31)
	Median	0.7	0.7
	Q1, Q3	0.6, 0.9	0.5, 1.0
	Min, Max	0.3, 1.9	0.3, 1.9
Total Bilirubin Level, n (%)	<= 1 x ULN	108 (84.4)	60 (92.3)
	> 1 and <= 2 x ULN	20 (15.6)	5 (7.7)
	< 0.6 x ULN	59 (46.1)	32 (49.2)
	>= 0.6 x ULN	69 (53.9)	33 (50.8)
ALT (U/L)	n	128	65
	Mean (SD)	47.4 (23.47)	48.2 (22.83)
	Median	45.3	43.0
	Q1, Q3	28.0, 63.7	31.0, 58.3
	Min, Max	13.0, 108.8	9.3, 115.3
AST (U/L)	n	128	65
	Mean (SD)	39.6 (16.14)	41.7 (16.03)
	Median	37.7	38.0
	Q1, Q3	27.0, 48.0	30.3, 49.3
	Min, Max	15.7, 94.0	16.0, 84.0
GGT (U/L)	n	128	65
	Mean (SD)	269.0 (240.04)	287.5 (249.56)
	Median	195.2	216.3
	Q1, Q3	114.2, 336.5	120.3, 338.0
	Min, Max	12.7, 1402.0	41.5, 1088.0
Platelets (10^3/uL)	n	125	65
	Mean (SD)	241.7 (78.87)	241.9 (84.46)
	Median	241.3	232.0
	Q1, Q3	178.3, 287.0	184.7, 309.7
	Min, Max	90.0, 477.0	102.7, 506.0
International normalized ratio (INR)	n	128	65
	Mean (SD)	1.0 (0.08)	1.0 (0.09)
	Median	1.0	1.0
	Q1, Q3	1.0, 1.1	1.0, 1.1
	Min, Max	0.8, 1.3	0.9, 1.5
Albumin (g/dL)	n	128	65
	Mean (SD)	4.2 (0.27)	4.1 (0.23)
	Median	4.2	4.1
	Q1, Q3	4.0, 4.3	3.9, 4.3
	Min, Max	3.0, 4.8	3.6, 4.6

n=Number of subjects included in the analysis, SD: Standard Deviation, Q1: 25%-Quartile, Q3: 75%-Quartile, Min: Minimum, Max: Maximum.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Demographics and Baseline Characteristics
Intention-to-treat

		Seladelpar 10 mg (N=128)	Placebo (N=65)
Pruritus NRS	n	128	65
	Mean (SD)	3.0 (2.81)	3.0 (2.96)
	Median	2.8	1.8
	Q1, Q3	0.1, 5.3	0.2, 5.6
	Min, Max	0.0, 8.9	0.0, 9.0
Pruritus NRS Level, n (%)	< 4	79 (61.7)	42 (64.6)
	>= 4	49 (38.3)	23 (35.4)
Pruritus NRS for Subjects with Baseline Pruritus NRS >=4	n	49	23
	Mean (SD)	6.1 (1.42)	6.6 (1.44)
	Median	5.9	7.1
	Q1, Q3	4.9, 7.4	5.6, 7.7
	Min, Max	4.0, 8.9	4.3, 9.0
UK-PBC Risk Score (5 years)	n	125	65
	Mean (SD)	0.0 (0.02)	0.0 (0.02)
	Median	0.0	0.0
	Q1, Q3	0.0, 0.0	0.0, 0.0
	Min, Max	0.0, 0.1	0.0, 0.1
UK-PBC Risk Score (10 years)	n	125	65
	Mean (SD)	0.1 (0.06)	0.1 (0.06)
	Median	0.1	0.1
	Q1, Q3	0.0, 0.1	0.0, 0.1
	Min, Max	0.0, 0.3	0.0, 0.3
UK-PBC Risk Score (15 years)	n	125	65
	Mean (SD)	0.1 (0.10)	0.1 (0.09)
	Median	0.1	0.1
	Q1, Q3	0.1, 0.2	0.1, 0.1
	Min, Max	0.0, 0.5	0.0, 0.4
GLOBE Risk Score	n	125	65
	Mean (SD)	0.3 (0.66)	0.3 (0.71)
	Median	0.3	0.2
	Q1, Q3	-0.2, 0.8	-0.1, 0.8
	Min, Max	-1.2, 1.8	-1.3, 1.8
5’-nucleotidase (U/L)	n	128	65
	Mean (SD)	15.3 (11.30)	16.7 (10.60)
	Median	12.2	14.0
	Q1, Q3	8.0, 18.8	9.3, 19.3
	Min, Max	4.0, 70.0	5.0, 49.3
Total Cholesterol (mg/dL)	n	128	65
	Mean (SD)	240.8 (51.29)	236.8 (55.10)
	Median	243.7	227.0
	Q1, Q3	204.5, 273.3	197.7, 269.0
	Min, Max	141.7, 381.7	127.7, 408.7
Triglycerides (mg/dL)	n	128	65
	Mean (SD)	117.5 (51.94)	121.8 (43.25)
	Median	107.7	121.3
	Q1, Q3	84.7, 135.8	89.0, 146.3
	Min, Max	48.7, 399.7	59.0, 297.3

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Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Demographics and Baseline Characteristics
Intention-to-treat

		Seladelpar 10 mg (N=128)	Placebo (N=65)
non-HDL-C (mg/dL)	n	128	65
	Mean (SD)	160.3 (48.15)	161.8 (53.45)
	Median	157.0	150.3
	Q1, Q3	120.8, 193.0	124.0, 195.7
	Min, Max	76.3, 303.0	72.7, 308.7
HDL-C (mg/dL)	n	128	65
	Mean (SD)	80.5 (23.09)	75.1 (22.34)
	Median	79.7	71.7
	Q1, Q3	62.7, 95.8	58.7, 91.7
	Min, Max	34.0, 165.3	34.3, 126.0
LDL-C (mg/dL)	n	128	65
	Mean (SD)	136.7 (45.35)	137.4 (51.13)
	Median	135.5	131.0
	Q1, Q3	101.7, 165.3	103.0, 171.0
	Min, Max	54.3, 268.0	51.0, 295.3

n=Number of subjects included in the analysis, SD: Standard Deviation, Q1: 25%-Quartile, Q3: 75%-Quartile, Min: Minimum, Max: Maximum.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Observation duration for Efficacy endpoints
Intention-to-treat

Endpoint		Seladelpar 10 mg (N=128)	Placebo (N=65)
Study duration (weeks)	n	128	65
	Mean (SD)	52.0 (6.37)	52.5 (10.56)
	Median	52.6	52.3
	Min, Max	7.1, 59.0	13.1, 89.4
Observation duration for Alkaline Phosphatase (U/L) (weeks)	n	128	65
	Mean (SD)	50.3 (9.18)	48.8 (11.01)
	Median	52.1	52.1
	Min, Max	5.0, 59.0	6.3, 59.3
Observation duration for Bilirubin (mg/dL) (weeks)	n	128	65
	Mean (SD)	50.3 (9.18)	48.8 (11.01)
	Median	52.1	52.1
	Min, Max	5.0, 59.0	6.3, 59.3
Observation duration for Enhanced Liver Fibrosis Test (weeks)	n	128	65
	Mean (SD)	50.2 (9.39)	48.8 (11.00)
	Median	52.1	52.1
	Min, Max	4.1, 59.0	6.3, 59.3
Observation duration for Liver Stiffness (kPa) (weeks)	n	128	65
	Mean (SD)	44.2 (17.75)	46.2 (15.44)
	Median	52.1	52.0
	Min, Max	0.1, 58.3	0.1, 55.3
Observation duration for Alanine Aminotransferase (U/L) (weeks)	n	128	65
	Mean (SD)	50.3 (9.18)	48.8 (11.01)
	Median	52.1	52.1
	Min, Max	5.0, 59.0	6.3, 59.3
Observation duration for Aspartate Aminotransferase (U/L) (weeks)	n	128	65
	Mean (SD)	50.3 (9.18)	48.8 (11.01)
	Median	52.1	52.1
	Min, Max	5.0, 59.0	6.3, 59.3
Observation duration for Gamma Glutamyl Transferase (U/L) (weeks)	n	128	65
	Mean (SD)	50.3 (9.18)	48.8 (11.01)
	Median	52.1	52.1
	Min, Max	5.0, 59.0	6.3, 59.3
Observation duration for Direct Bilirubin (mg/dL) (weeks)	n	128	65
	Mean (SD)	50.3 (9.18)	48.8 (11.01)
	Median	52.1	52.1
	Min, Max	5.0, 59.0	6.3, 59.3
Observation duration for Indirect Bilirubin (mg/dL) (weeks)	n	128	65
	Mean (SD)	50.3 (9.18)	48.8 (11.01)
	Median	52.1	52.1
	Min, Max	5.0, 59.0	6.3, 59.3
Observation duration for 5 Prime Nucleotidase (U/L) (weeks)	n	128	65
	Mean (SD)	50.2 (9.40)	48.8 (11.00)
	Median	52.1	52.1
	Min, Max	4.1, 59.0	6.3, 59.3

Study duration defined as time from randomization until study completion/discontinuation
Observation duration of endpoints defined as time from randomization until date of last non-missing assessment
n=Number of subjects included in the analysis, SD: Standard Deviation, Min: Minimum, Max: Maximum.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Observation duration for Efficacy endpoints
Intention-to-treat

Endpoint		Seladelpar 10 mg (N=128)	Placebo (N=65)
Observation duration for Pruritus NRS Score (Weekly Averages) (weeks)	n	128	65
	Mean (SD)	42.7 (9.53)	41.4 (10.64)
	Median	46.6	46.6
	Min, Max	0.1, 46.6	0.1, 46.6
Observation duration for ITCH5D-Total Score (weeks)	n	128	65
	Mean (SD)	39.6 (9.09)	38.4 (10.69)
	Median	44.0	44.0
	Min, Max	4.1, 46.0	0.1, 45.1
Observation duration for ITCH5D-Modified Total Score (weeks)	n	128	65
	Mean (SD)	39.6 (9.09)	38.4 (10.69)
	Median	44.0	44.0
	Min, Max	4.1, 46.0	0.1, 45.1
Observation duration for ITCH5D-Distribution Total (weeks)	n	128	65
	Mean (SD)	39.6 (9.09)	38.4 (10.69)
	Median	44.0	44.0
	Min, Max	4.1, 46.0	0.1, 45.1
Observation duration for PBC40-Total Score (weeks)	n	128	65
	Mean (SD)	46.2 (12.18)	46.4 (13.47)
	Median	51.9	52.0
	Min, Max	0.1, 54.3	0.1, 55.4
Observation duration for PBC40-Cognitive Domain Score (weeks)	n	128	65
	Mean (SD)	46.2 (12.18)	46.4 (13.47)
	Median	51.9	52.0
	Min, Max	0.1, 54.3	0.1, 55.4
Observation duration for PBC40-Emotional Domain Score (weeks)	n	128	65
	Mean (SD)	46.2 (12.18)	46.4 (13.47)
	Median	51.9	52.0
	Min, Max	0.1, 54.3	0.1, 55.4
Observation duration for PBC40-Fatigue Domain Score (weeks)	n	128	65
	Mean (SD)	46.2 (12.18)	46.4 (13.47)
	Median	51.9	52.0
	Min, Max	0.1, 54.3	0.1, 55.4
Observation duration for PBC40-Itch Domain Score (weeks)	n	128	65
	Mean (SD)	46.2 (12.18)	46.4 (13.47)
	Median	51.9	52.0
	Min, Max	0.1, 54.3	0.1, 55.4
Observation duration for PBC40-Social Domain Score (weeks)	n	128	65
	Mean (SD)	46.2 (12.18)	46.4 (13.47)
	Median	51.9	52.0
	Min, Max	0.1, 54.3	0.1, 55.4
Observation duration for PBC40-Symptoms Domain Score (weeks)	n	128	65
	Mean (SD)	46.2 (12.18)	46.4 (13.47)
	Median	51.9	52.0
	Min, Max	0.1, 54.3	0.1, 55.4

Study duration defined as time from randomization until study completion/discontinuation
Observation duration of endpoints defined as time from randomization until date of last non-missing assessment
n=Number of subjects included in the analysis, SD: Standard Deviation, Min: Minimum, Max: Maximum.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Observation duration for Efficacy endpoints
Intention-to-treat

Endpoint		Seladelpar 10 mg (N=128)	Placebo (N=65)
Observation duration for PGI01-Severity (weeks)	n	128	65
	Mean (SD)	46.1 (12.52)	46.4 (13.47)
	Median	51.9	52.0
	Min, Max	0.1, 54.3	0.1, 55.4
Observation duration for PGI01-Change (weeks)	n	128	65
	Mean (SD)	45.9 (13.01)	46.4 (13.47)
	Median	51.9	52.0
	Min, Max	0.1, 54.3	0.1, 55.4

Study duration defined as time from randomization until study completion/discontinuation
Observation duration of endpoints defined as time from randomization until date of last non-missing assessment
n=Number of subjects included in the analysis, SD: Standard Deviation, Min: Minimum, Max: Maximum.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Observation duration for Safety endpoints
Safety

Endpoint		Seladelpar 10 mg (N=128)	Placebo (N=65)
Treatment duration (weeks)	n	128	65
	Mean (SD)	49.8 (9.20)	48.3 (11.57)
	Median	52.1	52.0
	Min, Max	0.1, 54.7	1.3, 55.4
Observation duration for Safety (weeks)	n	128	65
	Mean (SD)	51.0 (8.89)	49.5 (10.94)
	Median	52.4	52.1
	Min, Max	4.4, 58.3	5.6, 58.1
UDCA Exposure Duration (weeks)	n	120	62
	Mean (SD)	50.3 (9.00)	48.3 (11.38)
	Median	52.1	52.1
	Min, Max	5.0, 59.0	6.3, 55.4

Treatment duration defined as time from first until last exposure date.
Observation duration for safety defined as time from first exposure to study treatment until minimum of study completion/discontinuation and last exposure + 30 days.
n=Number of subjects included in the analysis, SD: Standard Deviation, Min: Minimum, Max: Maximum.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Combined response: Number and Proportion of patients with ALP < 1.67 x ULN, total bilirubin <= ULN and ALP reduction of >= 15 %) at 6 and 12 months
Intention-to-treat

Timepoint		Seladelpar 10 mg	Placebo
Month 6	Number of subjects with reponse, n/N (%)	85/128 (66.4)	12/ 65 (18.5)
	Number of missing values imputed as Non-Response	6	4
	Stratified Analysis Seladelpar 10 mg vs. Placebo		
	Relative Risk (95% CI)	3.60 (2.16, 6.01)	
	p-value	<.0001	
	Odds Ratio (95% CI)	12.92 (5.56, 30.03)	
	p-value	<.0001	
	Risk Difference (95% CI)	0.48 (0.36, 0.60)	
	p-value	<.0001	
	Unstratified Analysis Seladelpar 10 mg vs. Placebo		
	Relative Risk (95% CI)	3.60 (2.13, 6.08)	
	p-value	<.0001	
	Odds Ratio (95% CI)	8.73 (4.22, 18.05)	
	p-value	<.0001	
	Peto Odds Ratio (95% CI)	6.74 (3.72, 12.22)	
	p-value	<.0001	
	Risk Difference (95% CI)	0.48 (0.35, 0.60)	
	p-value	<.0001	

RR, OR and RD estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
Stratification factors: Baseline ALP level: < 350 U/L and >= 350 U/L; baseline pruritus NRS: < 4 and >= 4.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Combined response: Number and Proportion of patients with ALP < 1.67 x ULN, total bilirubin <= ULN and ALP reduction of >= 15 %) at 6 and 12 months
Intention-to-treat

Timepoint		Seladelpar 10 mg	Placebo
Month 12	Number of subjects with reponse, n/N (%)	79/128 (61.7)	13/ 65 (20.0)
	Number of missing values imputed as Non-Response	14	8
	Stratified Analysis Seladelpar 10 mg vs. Placebo		
	Relative Risk (95% CI)	3.09 (1.87, 5.10)	
	p-value	<.0001	
	Odds Ratio (95% CI)	7.26 (3.42, 15.41)	
	p-value	<.0001	
	Risk Difference (95% CI)	0.42 (0.29, 0.54)	
	p-value	<.0001	
	Unstratified Analysis Seladelpar 10 mg vs. Placebo		
	Relative Risk (95% CI)	3.09 (1.86, 5.11)	
	p-value	<.0001	
	Odds Ratio (95% CI)	6.45 (3.19, 13.05)	
	p-value	<.0001	
	Peto Odds Ratio (95% CI)	5.28 (2.91, 9.58)	
	p-value	<.0001	
	Risk Difference (95% CI)	0.42 (0.29, 0.55)	
	p-value	<.0001	

RR, OR and RD estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
Stratification factors: Baseline ALP level: < 350 U/L and >= 350 U/L; baseline pruritus NRS: < 4 and >= 4.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Combined response: Number and Proportion of patients with ALP < 1.67 x ULN, total bilirubin <= ULN and ALP reduction of >= 15 %) at 6 and 12 months - Subgroup analysis
Intention-to-treat

Timepoint	Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	OR (95% CI); p-Value	RD (95% CI); p-Value	Interaction p-Value
Month 6	Age at screening						0.7247
	< 65 years	63/ 99 (63.6)	9/ 53 (17.0)	3.75 (2.03, 6.92); p<.0001	8.56 (3.75, 19.54); p=<.0001	0.47 (0.33, 0.61); p=<.0001	
	>= 65 years	22/ 29 (75.9)	3/ 12 (25.0)	3.03 (1.11, 8.26); p=0.0298	9.43 (1.98, 44.83); p=0.0048	0.51 (0.22, 0.80); p=0.0006	
	Age at PBC diagnosis						0.2144
	< 50 years	34/ 61 (55.7)	7/ 32 (21.9)	2.55 (1.28, 5.09); p=0.0081	4.50 (1.69, 11.97); p=0.0026	0.34 (0.15, 0.53); p=0.0005	
	>= 50 years	51/ 67 (76.1)	5/ 33 (15.2)	5.02 (2.22, 11.39); p=0.0001	17.85 (5.91, 53.89); p=<.0001	0.61 (0.45, 0.77); p=<.0001	
	Sex						0.9111
	female	81/ 123 (65.9)	11/ 60 (18.3)	3.59 (2.07, 6.22); p<.0001	8.59 (4.05, 18.24); p=<.0001	0.48 (0.35, 0.60); p=<.0001	
	male	4/ 5 (80.0)	1/ 5 (20.0)	4.00 (0.66, 24.37); p=0.1327	16.00 (0.72, 354.80); p=0.0795	0.60 (0.10, 1.00); p=0.0177	
	Race						
	white	75/ 114 (65.8)	12/ 56 (21.4)				
	black	0/ 2 (0.0)	0/ 2 (0.0)				
	asian	7/ 7 (100.0)	0/ 4 (0.0)				
	other	3/ 5 (60.0)	0/ 3 (0.0)				
	Region						0.7562
	North America	33/ 50 (66.0)	2/ 13 (15.4)	4.29 (1.18, 15.59); p=0.0270	10.68 (2.12, 53.75); p=0.0041	0.51 (0.27, 0.74); p=<.0001	
	Europe	28/ 39 (71.8)	4/ 24 (16.7)	4.31 (1.72, 10.77); p=0.0018	12.73 (3.54, 45.78); p=<.0001	0.55 (0.35, 0.76); p=<.0001	
	Rest-of-World	24/ 39 (61.5)	6/ 28 (21.4)	2.87 (1.35, 6.09); p=0.0059	5.87 (1.93, 17.79); p=0.0018	0.40 (0.19, 0.62); p=0.0003	
	Cirrhosis						0.4568
	yes	9/ 18 (50.0)	2/ 9 (22.2)	2.25 (0.61, 8.31); p=0.2238	3.50 (0.57, 21.67); p=0.1780	0.28 (-0.08, 0.63); p=0.1268	
	no	76/ 110 (69.1)	10/ 56 (17.9)	3.87 (2.18, 6.88); p<.0001	10.28 (4.65, 22.76); p=<.0001	0.51 (0.38, 0.64); p=<.0001	
	UDCA						0.7990
	UDCA Use	80/ 120 (66.7)	12/ 62 (19.4)	3.44 (2.04, 5.81); p<.0001	8.33 (3.99, 17.39); p=<.0001	0.47 (0.34, 0.60); p=<.0001	
	UDCA Intolerance	5/ 8 (62.5)	0/ 3 (0.0)	4.89 (0.35, 68.83); p=0.2396	11.00 (0.43, 284.30); p=0.1484	0.63 (0.29, 0.96); p=0.0003	
	Prior Use of OCA and/or Fibrates						0.5048
	yes	10/ 20 (50.0)	1/ 13 (7.7)	6.50 (0.94, 44.93); p=0.0578	12.00 (1.30, 110.52); p=0.0283	0.42 (0.16, 0.69); p=0.0016	
	no	75/ 108 (69.4)	11/ 52 (21.2)	3.28 (1.91, 5.63); p<.0001	8.47 (3.88, 18.50); p=<.0001	0.48 (0.34, 0.62); p=<.0001	
	Therapy						0.6722
	Monotherapy (SEL)	5/ 8 (62.5)	0/ 4 (0.0)	6.11 (0.42, 89.20); p=0.1857	14.14 (0.57, 352.00); p=0.1062	0.63 (0.29, 0.96); p=0.0003	
	Combinationtherapy (SEL + UDCA)	80/ 120 (66.7)	12/ 61 (19.7)	3.39 (2.01, 5.72); p<.0001	8.17 (3.91, 17.06); p=<.0001	0.47 (0.34, 0.60); p=<.0001	
	Stratification variable: Baseline Pruritus NRS						0.7400
	< 4	58/ 79 (73.4)	9/ 42 (21.4)	3.43 (1.89, 6.21); p<.0001	10.13 (4.16, 24.66); p=<.0001	0.52 (0.36, 0.68); p=<.0001	
	>= 4	27/ 49 (55.1)	3/ 23 (13.0)	4.22 (1.43, 12.50); p=0.0092	8.18 (2.15, 31.18); p=0.0021	0.42 (0.22, 0.62); p=<.0001	
	Stratification variable: Baseline ALP Level						0.8862
	< 350 U/L	77/ 93 (82.8)	11/ 47 (23.4)	3.54 (2.09, 5.98); p<.0001	15.75 (6.64, 37.36); p=<.0001	0.59 (0.45, 0.74); p=<.0001	
	>= 350 U/L	8/ 35 (22.9)	1/ 18 (5.6)	4.11 (0.56, 30.39); p=0.1656	5.04 (0.58, 43.92); p=0.1434	0.17 (-0.00, 0.35); p=0.0524	

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of subjects with event; N=Number of patients included in the analysis; CI=Confidence Interval; OR=Odds Ratio; RR=Relative Risk; RD=Risk Difference; NE=Not estimable

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Combined response: Number and Proportion of patients with ALP < 1.67 x ULN, total bilirubin <= ULN and ALP reduction of >= 15 %) at 6 and 12 months - Subgroup analysis
Intention-to-treat

Timepoint	Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	Seladelpar 10 mg vs. Placebo OR (95% CI); p-Value	Seladelpar 10 mg vs. Placebo RD (95% CI); p-Value	Interaction p-Value
Month 6	Gamma-GT (GGT)						0.4878
	<= 3.2 x ULN	30/ 38 (78.9)	5/ 18 (27.8)	2.84 (1.33, 6.09); p=0.0073	9.75 (2.68, 35.53); p=0.0006	0.51 (0.27, 0.76); p=<.0001	
	> 3.2 x ULN	55/ 90 (61.1)	7/ 47 (14.9)	4.10 (2.03, 8.29); p<.0001	8.98 (3.62, 22.26); p=<.0001	0.46 (0.32, 0.61); p=<.0001	
	Total Bilirubin I						0.9033
	<= 1 x ULN	78/ 108 (72.2)	12/ 60 (20.0)	3.61 (2.15, 6.07); p<.0001	10.40 (4.86, 22.24); p=<.0001	0.52 (0.39, 0.65); p=<.0001	
	> 1 x ULN	7/ 20 (35.0)	0/ 5 (0.0)	4.29 (0.28, 64.74); p=0.2935	6.11 (0.30, 126.42); p=0.2416	0.35 (0.14, 0.56); p=0.0010	
	Total Bilirubin II						0.4333
	< 0.6 x ULN	45/ 59 (76.3)	8/ 32 (25.0)	3.05 (1.65, 5.65); p=0.0004	9.64 (3.55, 26.21); p=<.0001	0.51 (0.33, 0.70); p=<.0001	
	>= 0.6 x ULN	40/ 69 (58.0)	4/ 33 (12.1)	4.78 (1.87, 12.25); p=0.0011	10.00 (3.17, 31.57); p=<.0001	0.46 (0.30, 0.62); p=<.0001	

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of subjects with event; N=Number of patients included in the analysis; CI=Confidence Interval; OR=Odds Ratio; RR=Relative Risk; RD=Risk Difference; NE=Not estimable

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Combined response: Number and Proportion of patients with ALP < 1.67 x ULN, total bilirubin <= ULN and ALP reduction of >= 15 %) at 6 and 12 months - Subgroup analysis
Intention-to-treat

Timepoint	Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	Seladelpar 10 mg vs. Placebo OR (95% CI); p-Value	Seladelpar 10 mg vs. Placebo RD (95% CI); p-Value	Interaction p-Value
Month 12	Age at screening						0.6471
	< 65 years	61/ 99 (61.6)	10/ 53 (18.9)	3.27 (1.83, 5.83); p<.0001	6.90 (3.11, 15.34); p=<.0001	0.43 (0.29, 0.57); p=<.0001	
	>= 65 years	18/ 29 (62.1)	3/ 12 (25.0)	2.48 (0.89, 6.89); p=0.0807	4.91 (1.09, 22.15); p=0.0385	0.37 (0.07, 0.67); p=0.0161	
	Age at PBC diagnosis						0.7806
	< 50 years	32/ 61 (52.5)	5/ 32 (15.6)	3.36 (1.45, 7.78); p=0.0047	5.96 (2.03, 17.52); p=0.0012	0.37 (0.19, 0.55); p=<.0001	
	>= 50 years	47/ 67 (70.1)	8/ 33 (24.2)	2.89 (1.55, 5.40); p=0.0008	7.34 (2.83, 19.04); p=<.0001	0.46 (0.28, 0.64); p=<.0001	
	Sex						0.9766
	female	76/ 123 (61.8)	12/ 60 (20.0)	3.09 (1.83, 5.22); p<.0001	6.47 (3.12, 13.42); p=<.0001	0.42 (0.29, 0.55); p=<.0001	
	male	3/ 5 (60.0)	1/ 5 (20.0)	3.00 (0.45, 19.93); p=0.2555	6.00 (0.35, 101.57); p=0.2145	0.40 (-0.15, 0.95); p=0.1573	
	Race						
	white	68/ 114 (59.6)	13/ 56 (23.2)				
	black	0/ 2 (0.0)	0/ 2 (0.0)				
	asian	7/ 7 (100.0)	0/ 4 (0.0)				
	other	4/ 5 (80.0)	0/ 3 (0.0)				
	Region						0.6063
	North America	29/ 50 (58.0)	1/ 13 (7.7)	7.54 (1.13, 50.30); p=0.0369	16.57 (2.00, 137.49); p=0.0093	0.50 (0.30, 0.70); p=<.0001	
	Europe	27/ 39 (69.2)	6/ 24 (25.0)	2.77 (1.34, 5.71); p=0.0058	6.75 (2.14, 21.26); p=0.0011	0.44 (0.22, 0.67); p=0.0001	
	Rest-of-World	23/ 39 (59.0)	6/ 28 (21.4)	2.75 (1.29, 5.86); p=0.0087	5.27 (1.75, 15.92); p=0.0032	0.38 (0.16, 0.59); p=0.0007	
	Cirrhosis						0.3869
	yes	7/ 18 (38.9)	2/ 9 (22.2)	1.75 (0.45, 6.77); p=0.4174	2.23 (0.36, 13.96); p=0.3924	0.17 (-0.19, 0.52); p=0.3545	
	no	72/ 110 (65.5)	11/ 56 (19.6)	3.33 (1.93, 5.76); p<.0001	7.75 (3.60, 16.70); p=<.0001	0.46 (0.32, 0.59); p=<.0001	
	UDCA						0.8322
	UDCA Use	75/ 120 (62.5)	13/ 62 (21.0)	2.98 (1.80, 4.93); p<.0001	6.28 (3.07, 12.83); p=<.0001	0.42 (0.28, 0.55); p=<.0001	
	UDCA Intolerance	4/ 8 (50.0)	0/ 3 (0.0)	4.00 (0.28, 57.98); p=0.3095	7.00 (0.27, 178.47); p=0.2389	0.50 (0.15, 0.85); p=0.0047	
	Prior Use of OCA and/or Fibrates						0.4747
	yes	9/ 20 (45.0)	1/ 13 (7.7)	5.85 (0.84, 40.89); p=0.0750	9.82 (1.06, 90.59); p=0.0439	0.37 (0.11, 0.63); p=0.0052	
	no	70/ 108 (64.8)	12/ 52 (23.1)	2.81 (1.68, 4.70); p<.0001	6.14 (2.88, 13.08); p=<.0001	0.42 (0.27, 0.56); p=<.0001	
	Therapy						0.7043
	Monotherapy (SEL)	4/ 8 (50.0)	0/ 4 (0.0)	5.00 (0.33, 75.11); p=0.2443	9.00 (0.37, 220.93); p=0.1785	0.50 (0.15, 0.85); p=0.0047	
	Combinationtherapy (SEL + UDCA)	75/ 120 (62.5)	13/ 61 (21.3)	2.93 (1.78, 4.84); p<.0001	6.15 (3.01, 12.59); p=<.0001	0.41 (0.28, 0.55); p=<.0001	
	Stratification variable: Baseline Pruritus NRS						0.9635
	< 4	53/ 79 (67.1)	9/ 42 (21.4)	3.13 (1.72, 5.70); p=0.0002	7.47 (3.12, 17.91); p=<.0001	0.46 (0.29, 0.62); p=<.0001	
	>= 4	26/ 49 (53.1)	4/ 23 (17.4)	3.05 (1.21, 7.72); p=0.0186	5.37 (1.59, 18.11); p=0.0067	0.36 (0.15, 0.57); p=0.0008	
	Stratification variable: Baseline ALP Level						0.5562
	< 350 U/L	71/ 93 (76.3)	11/ 47 (23.4)	3.26 (1.92, 5.54); p<.0001	10.56 (4.62, 24.16); p=<.0001	0.53 (0.38, 0.68); p=<.0001	
	>= 350 U/L	8/ 35 (22.9)	2/ 18 (11.1)	2.06 (0.49, 8.70); p=0.3267	2.37 (0.45, 12.57); p=0.3106	0.12 (-0.08, 0.32); p=0.2522	

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of subjects with event; N=Number of patients included in the analysis; CI=Confidence Interval; OR=Odds Ratio; RR=Relative Risk; RD=Risk Difference; NE=Not estimable

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Combined response: Number and Proportion of patients with ALP < 1.67 x ULN, total bilirubin <= ULN and ALP reduction of >= 15 %) at 6 and 12 months - Subgroup analysis
Intention-to-treat

Timepoint	Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	Seladelpar 10 mg vs. Placebo OR (95% CI); p-Value	Seladelpar 10 mg vs. Placebo RD (95% CI); p-Value	Interaction p-Value
Month 12	Gamma-GT (GGT)						0.3844
	<= 3.2 x ULN	30/ 38 (78.9)	6/ 18 (33.3)	2.37 (1.21, 4.65); p=0.0121	7.50 (2.14, 26.24); p=0.0016	0.46 (0.20, 0.71); p=0.0004	
	> 3.2 x ULN	49/ 90 (54.4)	7/ 47 (14.9)	3.66 (1.80, 7.43); p=0.0003	6.83 (2.77, 16.86); p=<.0001	0.40 (0.25, 0.54); p=<.0001	
	Total Bilirubin I						0.7985
	<= 1 x ULN	69/ 108 (63.9)	12/ 60 (20.0)	3.19 (1.89, 5.40); p<.0001	7.08 (3.36, 14.90); p=<.0001	0.44 (0.30, 0.57); p=<.0001	
	> 1 x ULN	10/ 20 (50.0)	1/ 5 (20.0)	2.50 (0.41, 15.23); p=0.3203	4.00 (0.38, 42.37); p=0.2496	0.30 (-0.11, 0.71); p=0.1550	
	Total Bilirubin II						0.2807
	< 0.6 x ULN	41/ 59 (69.5)	9/ 32 (28.1)	2.47 (1.38, 4.41); p=0.0022	5.82 (2.25, 15.04); p=0.0003	0.41 (0.22, 0.61); p=<.0001	
	>= 0.6 x ULN	38/ 69 (55.1)	4/ 33 (12.1)	4.54 (1.77, 11.67); p=0.0017	8.89 (2.82, 28.01); p=0.0002	0.43 (0.27, 0.59); p=<.0001	

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of subjects with event; N=Number of patients included in the analysis; CI=Confidence Interval; OR=Odds Ratio; RR=Relative Risk; RD=Risk Difference; NE=Not estimable

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Number and Proportion of subjects with ALP reduction of >= 15 % at 6 and 12 months
Intention-to-treat

Timepoint		Seladelpar 10 mg	Placebo
Month 6	Number of subjects with reponse, n/N (%)	118/128 (92.2)	26/ 65 (40.0)
	Number of missing values imputed as Non-Response	6	4
	Stratified Analysis Seladelpar 10 mg vs. Placebo		
	Relative Risk (95% CI)	2.31 (1.71, 3.13)	
	p-value	<.0001	
	Odds Ratio (95% CI)	18.67 (8.11, 42.98)	
	p-value	<.0001	
	Risk Difference (95% CI)	0.52 (0.40, 0.65)	
	p-value	<.0001	
	Unstratified Analysis Seladelpar 10 mg vs. Placebo		
	Relative Risk (95% CI)	2.30 (1.70, 3.12)	
	p-value	<.0001	
	Odds Ratio (95% CI)	17.70 (7.84, 39.96)	
	p-value	<.0001	
	Peto Odds Ratio (95% CI)	15.50 (7.82, 30.72)	
	p-value	<.0001	
	Risk Difference (95% CI)	0.52 (0.39, 0.65)	
	p-value	<.0001	

RR, OR and RD estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
Stratification factors: Baseline ALP level: < 350 U/L and >= 350 U/L; baseline pruritus NRS: < 4 and >= 4.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Number and Proportion of subjects with ALP reduction of >= 15 % at 6 and 12 months
Intention-to-treat

Timepoint		Seladelpar 10 mg	Placebo
Month 12	Number of subjects with reponse, n/N (%)	107/128 (83.6)	21/ 65 (32.3)
	Number of missing values imputed as Non-Response	14	8
	Stratified Analysis Seladelpar 10 mg vs. Placebo		
	Relative Risk (95% CI)	2.61 (1.81, 3.75)	
	p-value	<.0001	
	Odds Ratio (95% CI)	10.50 (5.18, 21.30)	
	p-value	<.0001	
	Risk Difference (95% CI)	0.52 (0.39, 0.65)	
	p-value	<.0001	
	Unstratified Analysis Seladelpar 10 mg vs. Placebo		
	Relative Risk (95% CI)	2.59 (1.80, 3.71)	
	p-value	<.0001	
	Odds Ratio (95% CI)	10.68 (5.30, 21.48)	
	p-value	<.0001	
	Peto Odds Ratio (95% CI)	9.82 (5.23, 18.43)	
	p-value	<.0001	
	Risk Difference (95% CI)	0.51 (0.38, 0.64)	
	p-value	<.0001	

RR, OR and RD estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
Stratification factors: Baseline ALP level: < 350 U/L and >= 350 U/L; baseline pruritus NRS: < 4 and >= 4.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Number and Proportion of subjects with ALP reduction of >= 15 % at 6 and 12 months - Subgroup analysis
Intention-to-treat

Timepoint	Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	OR (95% CI); p-Value	RD (95% CI); p-Value	Interaction p-Value
Month 6	Age at screening						0.2158
	< 65 years	89/ 99 (89.9)	19/ 53 (35.8)	2.51 (1.74, 3.62); p<.0001	15.93 (6.73, 37.70); p=<.0001	0.54 (0.40, 0.68); p=<.0001	
	>= 65 years	29/ 29 (100.0)	7/ 12 (58.3)	1.71 (1.06, 2.77); p=0.0272	43.27 (2.15, 872.48); p=0.0140	0.42 (0.14, 0.70); p=0.0034	
	Age at PBC diagnosis						0.8134
	< 50 years	55/ 61 (90.2)	13/ 32 (40.6)	2.22 (1.45, 3.40); p=0.0003	13.40 (4.46, 40.21); p=<.0001	0.50 (0.31, 0.68); p=<.0001	
	>= 50 years	63/ 67 (94.0)	13/ 33 (39.4)	2.39 (1.56, 3.66); p<.0001	24.23 (7.09, 82.76); p=<.0001	0.55 (0.37, 0.72); p=<.0001	
	Sex						0.8819
	female	113/ 123 (91.9)	24/ 60 (40.0)	2.30 (1.68, 3.15); p<.0001	16.95 (7.41, 38.78); p=<.0001	0.52 (0.39, 0.65); p=<.0001	
	male	5/ 5 (100.0)	2/ 5 (40.0)	2.50 (0.85, 7.31); p=0.0943	15.40 (0.56, 425.53); p=0.1064	0.60 (0.17, 1.00); p=0.0062	
	Race						
	white	106/ 114 (93.0)	24/ 56 (42.9)				
	black	2/ 2 (100.0)	1/ 2 (50.0)				
	asian	7/ 7 (100.0)	0/ 4 (0.0)				
	other	3/ 5 (60.0)	1/ 3 (33.3)				
	Region						0.9568
	North America	43/ 50 (86.0)	5/ 13 (38.5)	2.24 (1.11, 4.49); p=0.0236	9.83 (2.49, 38.82); p=0.0011	0.48 (0.19, 0.76); p=0.0009	
	Europe	37/ 39 (94.9)	10/ 24 (41.7)	2.28 (1.41, 3.68); p=0.0008	25.90 (5.03, 133.25); p=<.0001	0.53 (0.32, 0.74); p=<.0001	
	Rest-of-World	38/ 39 (97.4)	11/ 28 (39.3)	2.48 (1.56, 3.94); p=0.0001	58.73 (7.01, 491.96); p=0.0002	0.58 (0.39, 0.77); p=<.0001	
	Cirrhosis						0.6369
	yes	17/ 18 (94.4)	3/ 9 (33.3)	2.83 (1.12, 7.19); p=0.0283	34.00 (2.94, 392.85); p=0.0047	0.61 (0.29, 0.94); p=0.0002	
	no	101/ 110 (91.8)	23/ 56 (41.1)	2.24 (1.63, 3.07); p<.0001	16.10 (6.78, 38.24); p=<.0001	0.51 (0.37, 0.65); p=<.0001	
	UDCA						0.4091
	UDCA Use	111/ 120 (92.5)	26/ 62 (41.9)	2.21 (1.64, 2.97); p<.0001	17.08 (7.33, 39.80); p=<.0001	0.51 (0.37, 0.64); p=<.0001	
	UDCA Intolerance	7/ 8 (87.5)	0/ 3 (0.0)	6.67 (0.49, 90.59); p=0.1541	35.00 (1.12, 1094.73); p=0.0430	0.88 (0.65, 1.00); p=<.0001	
	Prior Use of OCA and/or Fibrates						0.4409
	yes	17/ 20 (85.0)	6/ 13 (46.2)	1.84 (1.00, 3.41); p=0.0518	6.61 (1.28, 34.14); p=0.0241	0.39 (0.08, 0.70); p=0.0150	
	no	101/ 108 (93.5)	20/ 52 (38.5)	2.43 (1.72, 3.44); p<.0001	23.09 (8.94, 59.58); p=<.0001	0.55 (0.41, 0.69); p=<.0001	
	Therapy						0.3219
	Monotherapy (SEL)	7/ 8 (87.5)	0/ 4 (0.0)	8.33 (0.59, 117.45); p=0.1163	45.00 (1.49, 1358.27); p=0.0285	0.88 (0.65, 1.00); p=<.0001	
	Combinationtherapy (SEL + UDCA)	111/ 120 (92.5)	26/ 61 (42.6)	2.17 (1.61, 2.92); p<.0001	16.60 (7.11, 38.76); p=<.0001	0.50 (0.37, 0.63); p=<.0001	
	Stratification variable: Baseline Pruritus NRS						0.6256
	< 4	74/ 79 (93.7)	18/ 42 (42.9)	2.19 (1.53, 3.11); p<.0001	19.73 (6.62, 58.84); p=<.0001	0.51 (0.35, 0.67); p=<.0001	
	>= 4	44/ 49 (89.8)	8/ 23 (34.8)	2.58 (1.46, 4.55); p=0.0011	16.50 (4.67, 58.27); p=<.0001	0.55 (0.34, 0.76); p=<.0001	
	Stratification variable: Baseline ALP Level						0.8411
	< 350 U/L	85/ 93 (91.4)	19/ 47 (40.4)	2.26 (1.59, 3.22); p<.0001	15.66 (6.18, 39.68); p=<.0001	0.51 (0.36, 0.66); p=<.0001	
	>= 350 U/L	33/ 35 (94.3)	7/ 18 (38.9)	2.42 (1.35, 4.35); p=0.0030	25.93 (4.67, 143.82); p=0.0002	0.55 (0.32, 0.79); p=<.0001	

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of subjects with event; N=Number of patients included in the analysis; CI=Confidence Interval; OR=Odds Ratio; RR=Relative Risk; RD=Risk Difference; NE=Not estimable

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Number and Proportion of subjects with ALP reduction of >= 15 % at 6 and 12 months - Subgroup analysis
Intention-to-treat

Timepoint	Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	Seladelpar 10 mg vs. Placebo OR (95% CI); p-Value	Seladelpar 10 mg vs. Placebo RD (95% CI); p-Value	Interaction p-Value
Month 6	Gamma-GT (GGT)						0.1291
	<= 3.2 x ULN	36/ 38 (94.7)	10/ 18 (55.6)	1.71 (1.12, 2.60); p=0.0127	14.40 (2.63, 78.87); p=0.0021	0.39 (0.15, 0.63); p=0.0014	
	> 3.2 x ULN	82/ 90 (91.1)	16/ 47 (34.0)	2.68 (1.79, 4.01); p<.0001	19.86 (7.73, 51.04); p=<.0001	0.57 (0.42, 0.72); p=<.0001	
	Total Bilirubin I						0.3600
	<= 1 x ULN	98/ 108 (90.7)	25/ 60 (41.7)	2.18 (1.60, 2.96); p<.0001	13.72 (5.99, 31.42); p=<.0001	0.49 (0.35, 0.63); p=<.0001	
	> 1 x ULN	20/ 20 (100.0)	1/ 5 (20.0)	5.00 (0.87, 28.86); p=0.0720	123.00 (4.28, 3538.61); p=0.0050	0.80 (0.45, 1.00); p=<.0001	
	Total Bilirubin II						0.3621
	< 0.6 x ULN	56/ 59 (94.9)	15/ 32 (46.9)	2.02 (1.39, 2.94); p=0.0002	21.16 (5.47, 81.87); p=<.0001	0.48 (0.30, 0.66); p=<.0001	
	>= 0.6 x ULN	62/ 69 (89.9)	11/ 33 (33.3)	2.70 (1.65, 4.40); p<.0001	17.71 (6.11, 51.39); p=<.0001	0.57 (0.39, 0.74); p=<.0001	

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of subjects with event; N=Number of patients included in the analysis; CI=Confidence Interval; OR=Odds Ratio; RR=Relative Risk; RD=Risk Difference; NE=Not estimable

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Number and Proportion of subjects with ALP reduction of >= 15 % at 6 and 12 months - Subgroup analysis
Intention-to-treat

Timepoint	Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	OR (95% CI); p-Value	RD (95% CI); p-Value	Interaction p-Value
Month 12	Age at screening						0.8202
	< 65 years	84/ 99 (84.8)	17/ 53 (32.1)	2.65 (1.77, 3.95); p<.0001	11.86 (5.35, 26.30); p=<.0001	0.53 (0.38, 0.67); p=<.0001	
	>= 65 years	23/ 29 (79.3)	4/ 12 (33.3)	2.38 (1.05, 5.41); p=0.0386	7.67 (1.71, 34.33); p=0.0077	0.46 (0.16, 0.76); p=0.0031	
	Age at PBC diagnosis						0.5855
	< 50 years	49/ 61 (80.3)	11/ 32 (34.4)	2.34 (1.43, 3.83); p=0.0008	7.80 (2.97, 20.46); p=<.0001	0.46 (0.27, 0.65); p=<.0001	
	>= 50 years	58/ 67 (86.6)	10/ 33 (30.3)	2.86 (1.69, 4.83); p<.0001	14.82 (5.33, 41.18); p=<.0001	0.56 (0.39, 0.74); p=<.0001	
	Sex						0.4449
	female	102/ 123 (82.9)	20/ 60 (33.3)	2.49 (1.72, 3.59); p<.0001	9.71 (4.76, 19.82); p=<.0001	0.50 (0.36, 0.63); p=<.0001	
	male	5/ 5 (100.0)	1/ 5 (20.0)	5.00 (0.87, 28.86); p=0.0720	33.00 (1.06, 1023.56); p=0.0460	0.80 (0.45, 1.00); p=<.0001	
	Race						
	white	95/ 114 (83.3)	19/ 56 (33.9)				
	black	1/ 2 (50.0)	1/ 2 (50.0)				
	asian	7/ 7 (100.0)	1/ 4 (25.0)				
	other	4/ 5 (80.0)	0/ 3 (0.0)				
	Region						0.7960
	North America	39/ 50 (78.0)	3/ 13 (23.1)	3.38 (1.24, 9.22); p=0.0174	11.82 (2.76, 50.55); p=0.0009	0.55 (0.29, 0.81); p=<.0001	
	Europe	34/ 39 (87.2)	9/ 24 (37.5)	2.32 (1.37, 3.95); p=0.0018	11.33 (3.24, 39.58); p=0.0001	0.50 (0.28, 0.72); p=<.0001	
	Rest-of-World	34/ 39 (87.2)	9/ 28 (32.1)	2.71 (1.56, 4.71); p=0.0004	14.36 (4.20, 49.06); p=<.0001	0.55 (0.35, 0.75); p=<.0001	
	Cirrhosis						0.6090
	yes	14/ 18 (77.8)	2/ 9 (22.2)	3.50 (1.01, 12.18); p=0.0489	12.25 (1.79, 83.95); p=0.0107	0.56 (0.22, 0.89); p=0.0011	
	no	93/ 110 (84.5)	19/ 56 (33.9)	2.49 (1.71, 3.62); p<.0001	10.65 (5.00, 22.71); p=<.0001	0.51 (0.36, 0.65); p=<.0001	
	UDCA						0.3975
	UDCA Use	99/ 120 (82.5)	21/ 62 (33.9)	2.44 (1.70, 3.48); p<.0001	9.20 (4.54, 18.65); p=<.0001	0.49 (0.35, 0.62); p=<.0001	
	UDCA Intolerance	8/ 8 (100.0)	0/ 3 (0.0)	7.56 (0.56, 101.48); p=0.1270	119.00 (1.95, 7273.18); p=0.0228	1.00 (1.00, 1.00); p=<.0001	
	Prior Use of OCA and/or Fibrates						0.8896
	yes	15/ 20 (75.0)	4/ 13 (30.8)	2.44 (1.04, 5.72); p=0.0408	6.75 (1.43, 31.90); p=0.0160	0.44 (0.13, 0.76); p=0.0059	
	no	92/ 108 (85.2)	17/ 52 (32.7)	2.61 (1.75, 3.88); p<.0001	11.84 (5.40, 25.98); p=<.0001	0.52 (0.38, 0.67); p=<.0001	
	Therapy						0.6009
	Monotherapy (SEL)	8/ 8 (100.0)	1/ 4 (25.0)	4.00 (0.73, 21.84); p=0.1094	39.67 (1.28, 1229.87); p=0.0357	0.75 (0.33, 1.00); p=0.0005	
	Combinationtherapy (SEL + UDCA)	99/ 120 (82.5)	20/ 61 (32.8)	2.52 (1.74, 3.64); p<.0001	9.66 (4.74, 19.70); p=<.0001	0.50 (0.36, 0.63); p=<.0001	
	Stratification variable: Baseline Pruritus NRS						0.8610
	< 4	70/ 79 (88.6)	14/ 42 (33.3)	2.66 (1.72, 4.11); p<.0001	15.56 (6.05, 40.03); p=<.0001	0.55 (0.39, 0.71); p=<.0001	
	>= 4	37/ 49 (75.5)	7/ 23 (30.4)	2.48 (1.31, 4.70); p=0.0053	7.05 (2.34, 21.20); p=0.0005	0.45 (0.23, 0.67); p=<.0001	
	Stratification variable: Baseline ALP Level						0.3284
	< 350 U/L	80/ 93 (86.0)	14/ 47 (29.8)	2.89 (1.85, 4.51); p<.0001	14.51 (6.16, 34.17); p=<.0001	0.56 (0.41, 0.71); p=<.0001	
	>= 350 U/L	27/ 35 (77.1)	7/ 18 (38.9)	1.98 (1.08, 3.64); p=0.0269	5.30 (1.55, 18.20); p=0.0080	0.38 (0.12, 0.65); p=0.0046	

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of subjects with event; N=Number of patients included in the analysis; CI=Confidence Interval; OR=Odds Ratio; RR=Relative Risk; RD=Risk Difference; NE=Not estimable

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Number and Proportion of subjects with ALP reduction of >= 15 % at 6 and 12 months - Subgroup analysis
Intention-to-treat

Timepoint	Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	Seladelpar 10 mg vs. Placebo OR (95% CI); p-Value	Seladelpar 10 mg vs. Placebo RD (95% CI); p-Value	Interaction p-Value
Month 12	Gamma-GT (GGT)						0.5762
	<= 3.2 x ULN	33/ 38 (86.8)	7/ 18 (38.9)	2.23 (1.24, 4.04); p=0.0078	10.37 (2.73, 39.42); p=0.0006	0.48 (0.23, 0.73); p=0.0002	
	> 3.2 x ULN	74/ 90 (82.2)	14/ 47 (29.8)	2.76 (1.76, 4.33); p<.0001	10.90 (4.77, 24.91); p=<.0001	0.52 (0.37, 0.68); p=<.0001	
	Total Bilirubin I						0.5136
	<= 1 x ULN	89/ 108 (82.4)	20/ 60 (33.3)	2.47 (1.71, 3.57); p<.0001	9.37 (4.51, 19.45); p=<.0001	0.49 (0.35, 0.63); p=<.0001	
	> 1 x ULN	18/ 20 (90.0)	1/ 5 (20.0)	4.50 (0.77, 26.13); p=0.0938	36.00 (2.59, 501.27); p=0.0077	0.70 (0.33, 1.00); p=0.0002	
	Total Bilirubin II						0.6279
	< 0.6 x ULN	53/ 59 (89.8)	12/ 32 (37.5)	2.40 (1.52, 3.78); p=0.0002	14.72 (4.87, 44.53); p=<.0001	0.52 (0.34, 0.71); p=<.0001	
	>= 0.6 x ULN	54/ 69 (78.3)	9/ 33 (27.3)	2.87 (1.62, 5.08); p=0.0003	9.60 (3.69, 24.97); p=<.0001	0.51 (0.33, 0.69); p=<.0001	

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of subjects with event; N=Number of patients included in the analysis; CI=Confidence Interval; OR=Odds Ratio; RR=Relative Risk; RD=Risk Difference; NE=Not estimable

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Number and Proportion of subjects with ALP <1.67× ULN at 6 and 12 months
Intention-to-treat

Timepoint		Seladelpar 10 mg	Placebo
Month 6	Number of subjects with reponse, n/N (%)	89/128 (69.5)	15/ 65 (23.1)
	Number of missing values imputed as Non-Response	6	4
	Stratified Analysis Seladelpar 10 mg vs. Placebo		
	Relative Risk (95% CI)	3.01 (1.93, 4.69)	
	p-value	<.0001	
	Odds Ratio (95% CI)	11.58 (5.10, 26.31)	
	p-value	<.0001	
	Risk Difference (95% CI)	0.46 (0.34, 0.58)	
	p-value	<.0001	
	Unstratified Analysis Seladelpar 10 mg vs. Placebo		
	Relative Risk (95% CI)	3.01 (1.91, 4.77)	
	p-value	<.0001	
	Odds Ratio (95% CI)	7.61 (3.82, 15.15)	
	p-value	<.0001	
	Peto Odds Ratio (95% CI)	6.42 (3.53, 11.67)	
	p-value	<.0001	
	Risk Difference (95% CI)	0.46 (0.33, 0.59)	
	p-value	<.0001	

RR, OR and RD estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
Stratification factors: Baseline ALP level: < 350 U/L and >= 350 U/L; baseline pruritus NRS: < 4 and >= 4.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Number and Proportion of subjects with ALP <1.67× ULN at 6 and 12 months
Intention-to-treat

Timepoint		Seladelpar 10 mg	Placebo
Month 12	Number of subjects with reponse, n/N (%)	84/128 (65.6)	17/ 65 (26.2)
	Number of missing values imputed as Non-Response	14	8
	Stratified Analysis Seladelpar 10 mg vs. Placebo		
	Relative Risk (95% CI)	2.51 (1.65, 3.80)	
	p-value	<.0001	
	Odds Ratio (95% CI)	6.78 (3.22, 14.26)	
	p-value	<.0001	
	Risk Difference (95% CI)	0.39 (0.27, 0.52)	
	p-value	<.0001	
	Unstratified Analysis Seladelpar 10 mg vs. Placebo		
	Relative Risk (95% CI)	2.51 (1.64, 3.85)	
	p-value	<.0001	
	Odds Ratio (95% CI)	5.39 (2.78, 10.46)	
	p-value	<.0001	
	Peto Odds Ratio (95% CI)	4.83 (2.66, 8.76)	
	p-value	<.0001	
	Risk Difference (95% CI)	0.39 (0.26, 0.53)	
	p-value	<.0001	

RR, OR and RD estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
Stratification factors: Baseline ALP level: < 350 U/L and >= 350 U/L; baseline pruritus NRS: < 4 and >= 4.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Number and Proportion of subjects with ALP <1.67× ULN at 6 and 12 months - Subgroup analysis
Intention-to-treat

Timepoint	Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	Seladelpar 10 mg vs. Placebo OR (95% CI); p-Value	Seladelpar 10 mg vs. Placebo RD (95% CI); p-Value	Interaction p-Value
Month 6	Age at screening						0.9791
	< 65 years	67/ 99 (67.7)	12/ 53 (22.6)	2.99 (1.78, 5.01); p<.0001	7.15 (3.32, 15.43); p=<.0001	0.45 (0.30, 0.60); p=<.0001	
	>= 65 years	22/ 29 (75.9)	3/ 12 (25.0)	3.03 (1.11, 8.26); p=0.0298	9.43 (1.98, 44.83); p=0.0048	0.51 (0.22, 0.80); p=0.0006	
	Age at PBC diagnosis						0.3825
	< 50 years	37/ 61 (60.7)	8/ 32 (25.0)	2.43 (1.29, 4.57); p=0.0061	4.63 (1.79, 11.97); p=0.0016	0.36 (0.16, 0.55); p=0.0003	
	>= 50 years	52/ 67 (77.6)	7/ 33 (21.2)	3.66 (1.87, 7.15); p=0.0001	12.88 (4.67, 35.46); p=<.0001	0.56 (0.39, 0.74); p=<.0001	
	Sex						0.7525
	female	85/ 123 (69.1)	14/ 60 (23.3)	2.96 (1.84, 4.76); p<.0001	7.35 (3.61, 14.95); p=<.0001	0.46 (0.32, 0.59); p=<.0001	
	male	4/ 5 (80.0)	1/ 5 (20.0)	4.00 (0.66, 24.37); p=0.1327	16.00 (0.72, 354.80); p=0.0795	0.60 (0.10, 1.00); p=0.0177	
	Race						
	white	79/ 114 (69.3)	15/ 56 (26.8)				
	black	0/ 2 (0.0)	0/ 2 (0.0)				
	asian	7/ 7 (100.0)	0/ 4 (0.0)				
	other	3/ 5 (60.0)	0/ 3 (0.0)				
	Region						0.7937
	North America	34/ 50 (68.0)	2/ 13 (15.4)	4.42 (1.22, 16.04); p=0.0238	11.69 (2.31, 59.03); p=0.0029	0.53 (0.29, 0.76); p=<.0001	
	Europe	29/ 39 (74.4)	6/ 24 (25.0)	2.97 (1.45, 6.09); p=0.0029	8.70 (2.70, 28.05); p=0.0003	0.49 (0.27, 0.71); p=<.0001	
	Rest-of-World	26/ 39 (66.7)	7/ 28 (25.0)	2.67 (1.35, 5.26); p=0.0046	6.00 (2.03, 17.74); p=0.0012	0.42 (0.20, 0.63); p=0.0002	
	Cirrhosis						0.7622
	yes	10/ 18 (55.6)	2/ 9 (22.2)	2.50 (0.69, 9.08); p=0.1639	4.38 (0.70, 27.16); p=0.1131	0.33 (-0.02, 0.69); p=0.0662	
	no	79/ 110 (71.8)	13/ 56 (23.2)	3.09 (1.89, 5.05); p<.0001	8.43 (4.00, 17.78); p=<.0001	0.49 (0.35, 0.62); p=<.0001	
	UDCA						0.7016
	UDCA Use	84/ 120 (70.0)	15/ 62 (24.2)	2.89 (1.83, 4.56); p<.0001	7.31 (3.63, 14.73); p=<.0001	0.46 (0.32, 0.59); p=<.0001	
	UDCA Intolerance	5/ 8 (62.5)	0/ 3 (0.0)	4.89 (0.35, 68.83); p=0.2396	11.00 (0.43, 284.30); p=0.1484	0.63 (0.29, 0.96); p=0.0003	
	Prior Use of OCA and/or Fibrates						0.8857
	yes	10/ 20 (50.0)	2/ 13 (15.4)	3.25 (0.84, 12.51); p=0.0866	5.50 (0.96, 31.43); p=0.0553	0.35 (0.05, 0.64); p=0.0211	
	no	79/ 108 (73.1)	13/ 52 (25.0)	2.93 (1.80, 4.75); p<.0001	8.17 (3.83, 17.45); p=<.0001	0.48 (0.34, 0.63); p=<.0001	
	Therapy						0.5818
	Monotherapy (SEL)	5/ 8 (62.5)	0/ 4 (0.0)	6.11 (0.42, 89.20); p=0.1857	14.14 (0.57, 352.00); p=0.1062	0.63 (0.29, 0.96); p=0.0003	
	Combinationtherapy (SEL + UDCA)	84/ 120 (70.0)	15/ 61 (24.6)	2.85 (1.81, 4.49); p<.0001	7.16 (3.55, 14.43); p=<.0001	0.45 (0.32, 0.59); p=<.0001	
	Stratification variable: Baseline Pruritus NRS						0.6960
	< 4	59/ 79 (74.7)	11/ 42 (26.2)	2.85 (1.69, 4.81); p<.0001	8.31 (3.54, 19.54); p=<.0001	0.48 (0.32, 0.65); p=<.0001	
	>= 4	30/ 49 (61.2)	4/ 23 (17.4)	3.52 (1.41, 8.82); p=0.0072	7.50 (2.21, 25.45); p=0.0012	0.44 (0.23, 0.64); p=<.0001	
	Stratification variable: Baseline ALP Level						0.5683
	< 350 U/L	79/ 93 (84.9)	14/ 47 (29.8)	2.85 (1.82, 4.46); p<.0001	13.30 (5.71, 30.96); p=<.0001	0.55 (0.40, 0.70); p=<.0001	
	>= 350 U/L	10/ 35 (28.6)	1/ 18 (5.6)	5.14 (0.71, 37.08); p=0.1042	6.80 (0.80, 58.14); p=0.0800	0.23 (0.05, 0.41); p=0.0139	

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of subjects with event; N=Number of patients included in the analysis; CI=Confidence Interval; OR=Odds Ratio; RR=Relative Risk; RD=Risk Difference; NE=Not estimable

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Number and Proportion of subjects with ALP <1.67× ULN at 6 and 12 months - Subgroup analysis
Intention-to-treat

Timepoint	Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	Seladelpar 10 mg vs. Placebo OR (95% CI); p-Value	Seladelpar 10 mg vs. Placebo RD (95% CI); p-Value	Interaction p-Value
Month 6	Gamma-GT (GGT)						0.1901
	<= 3.2 x ULN	31/ 38 (81.6)	7/ 18 (38.9)	2.10 (1.15, 3.82); p=0.0153	6.96 (1.99, 24.37); p=0.0024	0.43 (0.17, 0.68); p=0.0011	
	> 3.2 x ULN	58/ 90 (64.4)	8/ 47 (17.0)	3.79 (1.98, 7.25); p<.0001	8.84 (3.68, 21.19); p=<.0001	0.47 (0.33, 0.62); p=<.0001	
	Total Bilirubin I						0.5537
	<= 1 x ULN	78/ 108 (72.2)	15/ 60 (25.0)	2.89 (1.84, 4.55); p<.0001	7.80 (3.80, 16.03); p=<.0001	0.47 (0.33, 0.61); p=<.0001	
	> 1 x ULN	11/ 20 (55.0)	0/ 5 (0.0)	6.57 (0.45, 96.05); p=0.1689	13.32 (0.65, 272.83); p=0.0929	0.55 (0.33, 0.77); p=<.0001	
	Total Bilirubin II						0.1106
	< 0.6 x ULN	45/ 59 (76.3)	11/ 32 (34.4)	2.22 (1.35, 3.66); p=0.0018	6.14 (2.39, 15.78); p=0.0002	0.42 (0.22, 0.62); p=<.0001	
	>= 0.6 x ULN	44/ 69 (63.8)	4/ 33 (12.1)	5.26 (2.06, 13.41); p=0.0005	12.76 (4.02, 40.50); p=<.0001	0.52 (0.36, 0.68); p=<.0001	

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of subjects with event; N=Number of patients included in the analysis; CI=Confidence Interval; OR=Odds Ratio; RR=Relative Risk; RD=Risk Difference; NE=Not estimable

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Number and Proportion of subjects with ALP <1.67× ULN at 6 and 12 months - Subgroup analysis
Intention-to-treat

Timepoint	Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	OR (95% CI); p-Value	RD (95% CI); p-Value	Interaction p-Value
Month 12	Age at screening						0.5353
	< 65 years	65/ 99 (65.7)	13/ 53 (24.5)	2.68 (1.63, 4.38); p<.0001	5.88 (2.78, 12.46); p=<.0001	0.41 (0.26, 0.56); p=<.0001	
	>= 65 years	19/ 29 (65.5)	4/ 12 (33.3)	1.97 (0.85, 4.56); p=0.1160	3.80 (0.92, 15.78); p=0.0661	0.32 (0.00, 0.64); p=0.0472	
	Age at PBC diagnosis						0.4088
	< 50 years	36/ 61 (59.0)	6/ 32 (18.8)	3.15 (1.49, 6.67); p=0.0028	6.24 (2.24, 17.37); p=0.0005	0.40 (0.22, 0.59); p=<.0001	
	>= 50 years	48/ 67 (71.6)	11/ 33 (33.3)	2.15 (1.30, 3.56); p=0.0030	5.05 (2.06, 12.40); p=0.0004	0.38 (0.19, 0.58); p=0.0001	
	Sex						0.4283
	female	79/ 123 (64.2)	16/ 60 (26.7)	2.41 (1.55, 3.74); p<.0001	4.94 (2.50, 9.75); p=<.0001	0.38 (0.24, 0.52); p=<.0001	
	male	5/ 5 (100.0)	1/ 5 (20.0)	5.00 (0.87, 28.86); p=0.0720	33.00 (1.06, 1023.56); p=0.0460	0.80 (0.45, 1.00); p=<.0001	
	Race						
	white	73/ 114 (64.0)	17/ 56 (30.4)				
	black	0/ 2 (0.0)	0/ 2 (0.0)				
	asian	7/ 7 (100.0)	0/ 4 (0.0)				
	other	4/ 5 (80.0)	0/ 3 (0.0)				
	Region						0.2922
	North America	31/ 50 (62.0)	1/ 13 (7.7)	8.06 (1.21, 53.65); p=0.0309	19.58 (2.35, 162.86); p=0.0059	0.54 (0.35, 0.74); p=<.0001	
	Europe	27/ 39 (69.2)	9/ 24 (37.5)	1.85 (1.06, 3.22); p=0.0311	3.75 (1.29, 10.93); p=0.0155	0.32 (0.08, 0.56); p=0.0101	
	Rest-of-World	26/ 39 (66.7)	7/ 28 (25.0)	2.67 (1.35, 5.26); p=0.0046	6.00 (2.03, 17.74); p=0.0012	0.42 (0.20, 0.63); p=0.0002	
	Cirrhosis						0.9947
	yes	10/ 18 (55.6)	2/ 9 (22.2)	2.50 (0.69, 9.08); p=0.1639	4.38 (0.70, 27.16); p=0.1131	0.33 (-0.02, 0.69); p=0.0662	
	no	74/ 110 (67.3)	15/ 56 (26.8)	2.51 (1.60, 3.95); p<.0001	5.62 (2.75, 11.46); p=<.0001	0.40 (0.26, 0.55); p=<.0001	
	UDCA						0.7185
	UDCA Use	80/ 120 (66.7)	17/ 62 (27.4)	2.43 (1.59, 3.72); p<.0001	5.29 (2.70, 10.40); p=<.0001	0.39 (0.25, 0.53); p=<.0001	
	UDCA Intolerance	4/ 8 (50.0)	0/ 3 (0.0)	4.00 (0.28, 57.98); p=0.3095	7.00 (0.27, 178.47); p=0.2389	0.50 (0.15, 0.85); p=0.0047	
	Prior Use of OCA and/or Fibrates						0.6652
	yes	10/ 20 (50.0)	2/ 13 (15.4)	3.25 (0.84, 12.51); p=0.0866	5.50 (0.96, 31.43); p=0.0553	0.35 (0.05, 0.64); p=0.0211	
	no	74/ 108 (68.5)	15/ 52 (28.8)	2.38 (1.52, 3.71); p=0.0001	5.37 (2.60, 11.08); p=<.0001	0.40 (0.25, 0.55); p=<.0001	
	Therapy						0.5983
	Monotherapy (SEL)	4/ 8 (50.0)	0/ 4 (0.0)	5.00 (0.33, 75.11); p=0.2443	9.00 (0.37, 220.93); p=0.1785	0.50 (0.15, 0.85); p=0.0047	
	Combinationtherapy (SEL + UDCA)	80/ 120 (66.7)	17/ 61 (27.9)	2.39 (1.57, 3.65); p<.0001	5.18 (2.63, 10.18); p=<.0001	0.39 (0.25, 0.53); p=<.0001	
	Stratification variable: Baseline Pruritus NRS						0.9054
	< 4	56/ 79 (70.9)	12/ 42 (28.6)	2.48 (1.51, 4.08); p=0.0004	6.09 (2.66, 13.92); p=<.0001	0.42 (0.25, 0.59); p=<.0001	
	>= 4	28/ 49 (57.1)	5/ 23 (21.7)	2.63 (1.17, 5.92); p=0.0197	4.80 (1.53, 15.02); p=0.0070	0.35 (0.14, 0.57); p=0.0015	
	Stratification variable: Baseline ALP Level						0.7754
	< 350 U/L	76/ 93 (81.7)	15/ 47 (31.9)	2.56 (1.67, 3.93); p<.0001	9.54 (4.25, 21.39); p=<.0001	0.50 (0.34, 0.65); p=<.0001	
	>= 350 U/L	8/ 35 (22.9)	2/ 18 (11.1)	2.06 (0.49, 8.70); p=0.3267	2.37 (0.45, 12.57); p=0.3106	0.12 (-0.08, 0.32); p=0.2522	

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RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of subjects with event; N=Number of patients included in the analysis; CI=Confidence Interval; OR=Odds Ratio; RR=Relative Risk; RD=Risk Difference; NE=Not estimable

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Number and Proportion of subjects with ALP <1.67× ULN at 6 and 12 months - Subgroup analysis
Intention-to-treat

Timepoint	Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	Seladelpar 10 mg vs. Placebo OR (95% CI); p-Value	Seladelpar 10 mg vs. Placebo RD (95% CI); p-Value	Interaction p-Value
Month 12	Gamma-GT (GGT)						0.0540
	<= 3.2 x ULN	30/ 38 (78.9)	9/ 18 (50.0)	1.58 (0.97, 2.58); p=0.0679	3.75 (1.12, 12.56); p=0.0321	0.29 (0.02, 0.55); p=0.0322	
	> 3.2 x ULN	54/ 90 (60.0)	8/ 47 (17.0)	3.53 (1.83, 6.78); p=0.0002	7.31 (3.06, 17.45); p=<.0001	0.43 (0.28, 0.58); p=<.0001	
	Total Bilirubin I						0.7680
	<= 1 x ULN	71/ 108 (65.7)	16/ 60 (26.7)	2.47 (1.59, 3.83); p<.0001	5.28 (2.63, 10.59); p=<.0001	0.39 (0.25, 0.53); p=<.0001	
	> 1 x ULN	13/ 20 (65.0)	1/ 5 (20.0)	3.25 (0.55, 19.32); p=0.1949	7.43 (0.69, 79.96); p=0.0981	0.45 (0.04, 0.86); p=0.0307	
	Total Bilirubin II						0.1022
	< 0.6 x ULN	41/ 59 (69.5)	12/ 32 (37.5)	1.85 (1.15, 2.99); p=0.0115	3.80 (1.54, 9.39); p=0.0039	0.32 (0.12, 0.52); p=0.0022	
	>= 0.6 x ULN	43/ 69 (62.3)	5/ 33 (15.2)	4.11 (1.80, 9.41); p=0.0008	9.26 (3.18, 26.97); p=<.0001	0.47 (0.30, 0.64); p=<.0001	

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of subjects with event; N=Number of patients included in the analysis; CI=Confidence Interval; OR=Odds Ratio; RR=Relative Risk; RD=Risk Difference; NE=Not estimable

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Number and Proportion of subjects with ALP <= 1.0× ULN at 6 and 12 months
Intention-to-treat

Timepoint		Seladelpar 10 mg	Placebo
Month 6	Number of subjects with reponse, n/N (%)	34/128 (26.6)	0/ 65 (0.0)
	Number of missing values imputed as Non-Response	6	4
	Stratified Analysis Seladelpar 10 mg vs. Placebo		
	Relative Risk (95% CI)	16.40 (2.32, 116.20)	
	p-value	0.0051	
	Odds Ratio (95% CI)	25.49 (3.34, 194.87)	
	p-value	0.0018	
	Risk Difference (95% CI)	0.27 (0.19, 0.34)	
	p-value	<.0001	
	Unstratified Analysis Seladelpar 10 mg vs. Placebo		
	Relative Risk (95% CI)	35.30 (2.20, 566.78)	
	p-value	0.0119	
	Odds Ratio (95% CI)	47.83 (2.88, 794.02)	
	p-value	0.0070	
	Peto Odds Ratio (95% CI)	6.18 (2.83, 13.49)	
	p-value	<.0001	
	Risk Difference (95% CI)	0.27 (0.19, 0.34)	
	p-value	<.0001	

RR, OR and RD estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
Stratification factors: Baseline ALP level: < 350 U/L and >= 350 U/L; baseline pruritus NRS: < 4 and >= 4.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Number and Proportion of subjects with ALP <= 1.0× ULN at 6 and 12 months
Intention-to-treat

Timepoint		Seladelpar 10 mg	Placebo
Month 12	Number of subjects with reponse, n/N (%)	32/128 (25.0)	0/ 65 (0.0)
	Number of missing values imputed as Non-Response	14	8
	Stratified Analysis Seladelpar 10 mg vs. Placebo		
	Relative Risk (95% CI)	14.80 (2.08, 105.44)	
	p-value	0.0071	
	Odds Ratio (95% CI)	21.99 (2.87, 168.78)	
	p-value	0.0030	
	Risk Difference (95% CI)	0.25 (0.18, 0.33)	
	p-value	<.0001	
	Unstratified Analysis Seladelpar 10 mg vs. Placebo		
	Relative Risk (95% CI)	33.26 (2.07, 534.58)	
	p-value	0.0134	
	Odds Ratio (95% CI)	44.12 (2.65, 733.27)	
	p-value	0.0083	
	Peto Odds Ratio (95% CI)	6.04 (2.71, 13.45)	
	p-value	<.0001	
	Risk Difference (95% CI)	0.25 (0.17, 0.33)	
	p-value	<.0001	

RR, OR and RD estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
Stratification factors: Baseline ALP level: < 350 U/L and >= 350 U/L; baseline pruritus NRS: < 4 and >= 4.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

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Intention-to-treat

Timepoint	Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	Seladelpar 10 mg vs. Placebo OR (95% CI); p-Value	Seladelpar 10 mg vs. Placebo RD (95% CI); p-Value	Interaction p-Value
Month 6	Age at screening						0.4983
	< 65 years	26/ 99 (26.3)	0/ 53 (0.0)	28.62 (1.78, 460.49); p=0.0180	38.58 (2.30, 647.17); p=0.0111	0.26 (0.18, 0.35); p=<.0001	
	>= 65 years	8/ 29 (27.6)	0/ 12 (0.0)	7.37 (0.46, 118.38); p=0.1587	9.88 (0.52, 186.24); p=0.1262	0.28 (0.11, 0.44); p=0.0009	
	Age at PBC diagnosis						0.7456
	< 50 years	11/ 61 (18.0)	0/ 32 (0.0)	12.24 (0.74, 201.26); p=0.0795	14.80 (0.84, 259.90); p=0.0653	0.18 (0.08, 0.28); p=0.0002	
	>= 50 years	23/ 67 (34.3)	0/ 33 (0.0)	23.50 (1.47, 375.30); p=0.0255	35.38 (2.07, 603.65); p=0.0137	0.34 (0.23, 0.46); p=<.0001	
	Sex						0.2499
	female	33/ 123 (26.8)	0/ 60 (0.0)	32.96 (2.05, 528.91); p=0.0136	44.79 (2.69, 744.94); p=0.0080	0.27 (0.19, 0.35); p=<.0001	
	male	1/ 5 (20.0)	0/ 5 (0.0)	3.00 (0.15, 59.89); p=0.4720	3.67 (0.12, 113.73); p=0.4584	0.20 (-0.15, 0.55); p=0.2636	
	Race						
	white	27/ 114 (23.7)	0/ 56 (0.0)				
	black	0/ 2 (0.0)	0/ 2 (0.0)				
	asian	5/ 7 (71.4)	0/ 4 (0.0)				
	other	2/ 5 (40.0)	0/ 3 (0.0)				
	Region						0.8244
	North America	10/ 50 (20.0)	0/ 13 (0.0)	5.76 (0.36, 92.43); p=0.2159	7.00 (0.38, 127.62); p=0.1889	0.20 (0.09, 0.31); p=0.0004	
	Europe	12/ 39 (30.8)	0/ 24 (0.0)	15.63 (0.97, 252.41); p=0.0528	22.27 (1.25, 396.24); p=0.0346	0.31 (0.16, 0.45); p=<.0001	
	Rest-of-World	12/ 39 (30.8)	0/ 28 (0.0)	18.13 (1.12, 293.91); p=0.0415	25.91 (1.46, 459.18); p=0.0265	0.31 (0.16, 0.45); p=<.0001	
	Cirrhosis						0.2179
	yes	2/ 18 (11.1)	0/ 9 (0.0)	2.63 (0.14, 49.69); p=0.5186	2.88 (0.12, 66.48); p=0.5092	0.11 (-0.03, 0.26); p=0.1336	
	no	32/ 110 (29.1)	0/ 56 (0.0)	33.38 (2.08, 535.20); p=0.0132	46.78 (2.81, 780.11); p=0.0074	0.29 (0.21, 0.38); p=<.0001	
	UDCA						0.1758
	UDCA Use	32/ 120 (26.7)	0/ 62 (0.0)	33.84 (2.11, 543.55); p=0.0129	45.90 (2.76, 763.80); p=0.0076	0.27 (0.19, 0.35); p=<.0001	
	UDCA Intolerance	2/ 8 (25.0)	0/ 3 (0.0)	2.22 (0.14, 36.49); p=0.5760	2.69 (0.10, 73.20); p=0.5567	0.25 (-0.05, 0.55); p=0.1025	
	Prior Use of OCA and/or Fibrates						NE
	yes	0/ 20 (0.0)	0/ 13 (0.0)	NE	NE	NE	
	no	34/ 108 (31.5)	0/ 52 (0.0)	33.55 (2.10, 536.74); p=0.0130	48.62 (2.92, 810.94); p=0.0068	0.31 (0.23, 0.40); p=<.0001	
	Therapy						0.2196
	Monotherapy (SEL)	2/ 8 (25.0)	0/ 4 (0.0)	2.78 (0.16, 47.20); p=0.4796	3.46 (0.13, 90.68); p=0.4561	0.25 (-0.05, 0.55); p=0.1025	
	Combinationtherapy (SEL + UDCA)	32/ 120 (26.7)	0/ 61 (0.0)	33.31 (2.07, 534.83); p=0.0133	45.17 (2.71, 751.72); p=0.0079	0.27 (0.19, 0.35); p=<.0001	
	Stratification variable: Baseline Pruritus NRS						0.6327
	< 4	24/ 79 (30.4)	0/ 42 (0.0)	26.34 (1.64, 422.55); p=0.0209	37.52 (2.22, 634.76); p=0.0120	0.30 (0.20, 0.41); p=<.0001	
	>= 4	10/ 49 (20.4)	0/ 23 (0.0)	10.08 (0.62, 164.93); p=0.1052	12.49 (0.70, 223.15); p=0.0860	0.20 (0.09, 0.32); p=0.0004	
	Stratification variable: Baseline ALP Level						NE
	< 350 U/L	34/ 93 (36.6)	0/ 47 (0.0)	35.23 (2.21, 562.33); p=0.0117	55.08 (3.29, 922.06); p=0.0053	0.37 (0.27, 0.46); p=<.0001	
	>= 350 U/L	0/ 35 (0.0)	0/ 18 (0.0)	NE	NE	NE	

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of subjects with event; N=Number of patients included in the analysis; CI=Confidence Interval; OR=Odds Ratio; RR=Relative Risk; RD=Risk Difference; NE=Not estimable

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Number and Proportion of subjects with ALP <= 1.0× ULN at 6 and 12 months - Subgroup analysis
Intention-to-treat

Timepoint	Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	OR (95% CI); p-Value	RD (95% CI); p-Value	Interaction p-Value
Month 6	Gamma-GT (GGT)						0.7391
	<= 3.2 x ULN	12/ 38 (31.6)	0/ 18 (0.0)	12.18 (0.76, 194.95); p=0.0773	17.45 (0.97, 313.53); p=0.0523	0.32 (0.17, 0.46); p=<.0001	
	> 3.2 x ULN	22/ 90 (24.4)	0/ 47 (0.0)	23.74 (1.47, 382.81); p=0.0256	31.20 (1.85, 527.06); p=0.0171	0.24 (0.16, 0.33); p=<.0001	
	Total Bilirubin I						0.1138
	<= 1 x ULN	32/ 108 (29.6)	0/ 60 (0.0)	36.38 (2.27, 583.66); p=0.0111	51.41 (3.08, 856.68); p=0.0061	0.30 (0.21, 0.38); p=<.0001	
	> 1 x ULN	2/ 20 (10.0)	0/ 5 (0.0)	1.43 (0.08, 25.90); p=0.8094	1.49 (0.06, 35.82); p=0.8071	0.10 (-0.03, 0.23); p=0.1360	
	Total Bilirubin II						0.9053
	< 0.6 x ULN	18/ 59 (30.5)	0/ 32 (0.0)	20.35 (1.27, 326.95); p=0.0334	28.98 (1.68, 499.07); p=0.0204	0.31 (0.19, 0.42); p=<.0001	
	>= 0.6 x ULN	16/ 69 (23.2)	0/ 33 (0.0)	16.03 (0.99, 259.27); p=0.0508	20.66 (1.20, 355.96); p=0.0370	0.23 (0.13, 0.33); p=<.0001	

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RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of subjects with event; N=Number of patients included in the analysis; CI=Confidence Interval; OR=Odds Ratio; RR=Relative Risk; RD=Risk Difference; NE=Not estimable

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Number and Proportion of subjects with ALP <= 1.0× ULN at 6 and 12 months - Subgroup analysis
Intention-to-treat

Timepoint	Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	OR (95% CI); p-Value	RD (95% CI); p-Value	Interaction p-Value
Month 12	Age at screening						0.3087
	< 65 years	28/ 99 (28.3)	0/ 53 (0.0)	30.78 (1.92, 494.34); p=0.0156	42.65 (2.55, 714.38); p=0.0091	0.28 (0.19, 0.37); p=<.0001	
	>= 65 years	4/ 29 (13.8)	0/ 12 (0.0)	3.90 (0.23, 67.31); p=0.3490	4.41 (0.22, 88.53); p=0.3320	0.14 (0.01, 0.26); p=0.0312	
	Age at PBC diagnosis						0.8297
	< 50 years	12/ 61 (19.7)	0/ 32 (0.0)	13.31 (0.81, 217.72); p=0.0695	16.41 (0.94, 286.94); p=0.0553	0.20 (0.10, 0.30); p=0.0001	
	>= 50 years	20/ 67 (29.9)	0/ 33 (0.0)	20.50 (1.28, 328.80); p=0.0329	28.92 (1.69, 494.94); p=0.0202	0.30 (0.19, 0.41); p=<.0001	
	Sex						0.2624
	female	31/ 123 (25.2)	0/ 60 (0.0)	30.99 (1.93, 497.99); p=0.0154	41.21 (2.47, 686.10); p=0.0096	0.25 (0.18, 0.33); p=<.0001	
	male	1/ 5 (20.0)	0/ 5 (0.0)	3.00 (0.15, 59.89); p=0.4720	3.67 (0.12, 113.73); p=0.4584	0.20 (-0.15, 0.55); p=0.2636	
	Race						
	white	25/ 114 (21.9)	0/ 56 (0.0)				
	black	0/ 2 (0.0)	0/ 2 (0.0)				
	asian	5/ 7 (71.4)	0/ 4 (0.0)				
	other	2/ 5 (40.0)	0/ 3 (0.0)				
	Region						0.8407
	North America	10/ 50 (20.0)	0/ 13 (0.0)	5.76 (0.36, 92.43); p=0.2159	7.00 (0.38, 127.62); p=0.1889	0.20 (0.09, 0.31); p=0.0004	
	Europe	10/ 39 (25.6)	0/ 24 (0.0)	13.13 (0.80, 214.26); p=0.0708	17.44 (0.97, 312.93); p=0.0523	0.26 (0.12, 0.39); p=0.0002	
	Rest-of-World	12/ 39 (30.8)	0/ 28 (0.0)	18.13 (1.12, 293.91); p=0.0415	25.91 (1.46, 459.18); p=0.0265	0.31 (0.16, 0.45); p=<.0001	
	Cirrhosis						0.1554
	yes	1/ 18 (5.6)	0/ 9 (0.0)	1.58 (0.07, 35.32); p=0.7733	1.63 (0.06, 44.01); p=0.7718	0.06 (-0.05, 0.16); p=0.3035	
	no	31/ 110 (28.2)	0/ 56 (0.0)	32.35 (2.02, 519.08); p=0.0141	44.77 (2.68, 747.01); p=0.0081	0.28 (0.20, 0.37); p=<.0001	
	UDCA						0.1862
	UDCA Use	30/ 120 (25.0)	0/ 62 (0.0)	31.76 (1.97, 510.82); p=0.0147	42.13 (2.53, 701.81); p=0.0092	0.25 (0.17, 0.33); p=<.0001	
	UDCA Intolerance	2/ 8 (25.0)	0/ 3 (0.0)	2.22 (0.14, 36.49); p=0.5760	2.69 (0.10, 73.20); p=0.5567	0.25 (-0.05, 0.55); p=0.1025	
	Prior Use of OCA and/or Fibrates						0.2910
	yes	2/ 20 (10.0)	0/ 13 (0.0)	3.33 (0.17, 64.33); p=0.4253	3.65 (0.16, 82.33); p=0.4156	0.10 (-0.03, 0.23); p=0.1360	
	no	30/ 108 (27.8)	0/ 52 (0.0)	29.66 (1.85, 475.76); p=0.0167	40.80 (2.44, 681.83); p=0.0099	0.28 (0.19, 0.36); p=<.0001	
	Therapy						0.2318
	Monotherapy (SEL)	2/ 8 (25.0)	0/ 4 (0.0)	2.78 (0.16, 47.20); p=0.4796	3.46 (0.13, 90.68); p=0.4561	0.25 (-0.05, 0.55); p=0.1025	
	Combinationtherapy (SEL + UDCA)	30/ 120 (25.0)	0/ 61 (0.0)	31.26 (1.94, 502.62); p=0.0151	41.45 (2.49, 690.70); p=0.0095	0.25 (0.17, 0.33); p=<.0001	
	Stratification variable: Baseline Pruritus NRS						0.5609
	< 4	24/ 79 (30.4)	0/ 42 (0.0)	26.34 (1.64, 422.55); p=0.0209	37.52 (2.22, 634.76); p=0.0120	0.30 (0.20, 0.41); p=<.0001	
	>= 4	8/ 49 (16.3)	0/ 23 (0.0)	8.16 (0.49, 135.58); p=0.1432	9.63 (0.53, 174.38); p=0.1255	0.16 (0.06, 0.27); p=0.0020	
	Stratification variable: Baseline ALP Level						NE
	< 350 U/L	32/ 93 (34.4)	0/ 47 (0.0)	33.19 (2.08, 530.39); p=0.0133	50.20 (3.00, 841.07); p=0.0065	0.34 (0.25, 0.44); p=<.0001	
	>= 350 U/L	0/ 35 (0.0)	0/ 18 (0.0)	NE	NE	NE	

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RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of subjects with event; N=Number of patients included in the analysis; CI=Confidence Interval; OR=Odds Ratio; RR=Relative Risk; RD=Risk Difference; NE=Not estimable

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Number and Proportion of subjects with ALP <= 1.0× ULN at 6 and 12 months - Subgroup analysis
Intention-to-treat

Timepoint	Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	OR (95% CI); p-Value	RD (95% CI); p-Value	Interaction p-Value
Month 12	Gamma-GT (GGT)						0.8719
	<= 3.2 x ULN	14/ 38 (36.8)	0/ 18 (0.0)	14.13 (0.89, 224.42); p=0.0605	21.90 (1.23, 391.31); p=0.0359	0.37 (0.22, 0.52); p=<.0001	
	> 3.2 x ULN	18/ 90 (20.0)	0/ 47 (0.0)	19.52 (1.20, 316.85); p=0.0367	24.24 (1.43, 411.91); p=0.0274	0.20 (0.12, 0.28); p=<.0001	
	Total Bilirubin I						0.1212
	<= 1 x ULN	30/ 108 (27.8)	0/ 60 (0.0)	34.14 (2.12, 548.51); p=0.0127	47.01 (2.82, 784.38); p=0.0073	0.28 (0.19, 0.36); p=<.0001	
	> 1 x ULN	2/ 20 (10.0)	0/ 5 (0.0)	1.43 (0.08, 25.90); p=0.8094	1.49 (0.06, 35.82); p=0.8071	0.10 (-0.03, 0.23); p=0.1360	
	Total Bilirubin II						0.9026
	< 0.6 x ULN	17/ 59 (28.8)	0/ 32 (0.0)	19.25 (1.20, 309.93); p=0.0370	26.76 (1.55, 461.77); p=0.0237	0.29 (0.17, 0.40); p=<.0001	
	>= 0.6 x ULN	15/ 69 (21.7)	0/ 33 (0.0)	15.06 (0.93, 244.22); p=0.0564	19.06 (1.10, 329.04); p=0.0426	0.22 (0.12, 0.31); p=<.0001	

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of subjects with event; N=Number of patients included in the analysis; CI=Confidence Interval; OR=Odds Ratio; RR=Relative Risk; RD=Risk Difference; NE=Not estimable

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Number and Proportion of subjects with ALP <1.5× ULN at 6 and 12 months
Intention-to-treat

Timepoint		Seladelpar 10 mg	Placebo
Month 6	Number of subjects with reponse, n/N (%)	82/128 (64.1)	8/ 65 (12.3)
	Number of missing values imputed as Non-Response	6	4
	Stratified Analysis Seladelpar 10 mg vs. Placebo		
	Relative Risk (95% CI)	5.21 (2.70, 10.05)	
	p-value	<.0001	
	Odds Ratio (95% CI)	15.94 (6.41, 39.64)	
	p-value	<.0001	
	Risk Difference (95% CI)	0.52 (0.40, 0.63)	
	p-value	<.0001	
	Unstratified Analysis Seladelpar 10 mg vs. Placebo		
	Relative Risk (95% CI)	5.21 (2.69, 10.09)	
	p-value	<.0001	
	Odds Ratio (95% CI)	12.70 (5.58, 28.94)	
	p-value	<.0001	
	Peto Odds Ratio (95% CI)	7.92 (4.36, 14.38)	
	p-value	<.0001	
	Risk Difference (95% CI)	0.52 (0.40, 0.63)	
	p-value	<.0001	

RR, OR and RD estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
Stratification factors: Baseline ALP level: < 350 U/L and >= 350 U/L; baseline pruritus NRS: < 4 and >= 4.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Number and Proportion of subjects with ALP <1.5× ULN at 6 and 12 months
Intention-to-treat

Timepoint		Seladelpar 10 mg	Placebo
Month 12	Number of subjects with reponse, n/N (%)	75/128 (58.6)	8/ 65 (12.3)
	Number of missing values imputed as Non-Response	14	8
	Stratified Analysis Seladelpar 10 mg vs. Placebo		
	Relative Risk (95% CI)	4.79 (2.45, 9.37)	
	p-value	<.0001	
	Odds Ratio (95% CI)	9.87 (4.28, 22.73)	
	p-value	<.0001	
	Risk Difference (95% CI)	0.46 (0.35, 0.58)	
	p-value	<.0001	
	Unstratified Analysis Seladelpar 10 mg vs. Placebo		
	Relative Risk (95% CI)	4.76 (2.45, 9.26)	
	p-value	<.0001	
	Odds Ratio (95% CI)	10.08 (4.44, 22.88)	
	p-value	<.0001	
	Peto Odds Ratio (95% CI)	6.54 (3.59, 11.94)	
	p-value	<.0001	
	Risk Difference (95% CI)	0.46 (0.35, 0.58)	
	p-value	<.0001	

RR, OR and RD estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
Stratification factors: Baseline ALP level: < 350 U/L and >= 350 U/L; baseline pruritus NRS: < 4 and >= 4.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

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RESPONSE - Seladelpar 10 mg vs Placebo
Number and Proportion of subjects with ALP <1.5× ULN at 6 and 12 months - Subgroup analysis
Intention-to-treat

Timepoint	Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	Seladelpar 10 mg vs. Placebo OR (95% CI); p-Value	Seladelpar 10 mg vs. Placebo RD (95% CI); p-Value	Interaction p-Value
Month 6	Age at screening						0.7681
	< 65 years	61/ 99 (61.6)	6/ 53 (11.3)	5.44 (2.52, 11.75); p<.0001	12.57 (4.91, 32.23); p=<.0001	0.50 (0.37, 0.63); p=<.0001	
	>= 65 years	21/ 29 (72.4)	2/ 12 (16.7)	4.34 (1.20, 15.70); p=0.0250	13.13 (2.34, 73.50); p=0.0034	0.56 (0.29, 0.82); p=<.0001	
	Age at PBC diagnosis						0.2290
	< 50 years	33/ 61 (54.1)	5/ 32 (15.6)	3.46 (1.50, 8.00); p=0.0037	6.36 (2.16, 18.72); p=0.0008	0.38 (0.21, 0.56); p=<.0001	
	>= 50 years	49/ 67 (73.1)	3/ 33 (9.1)	8.04 (2.71, 23.89); p=0.0002	27.22 (7.39, 100.28); p=<.0001	0.64 (0.50, 0.78); p=<.0001	
	Sex						0.7568
	female	78/ 123 (63.4)	7/ 60 (11.7)	5.44 (2.67, 11.05); p<.0001	13.12 (5.50, 31.31); p=<.0001	0.52 (0.40, 0.64); p=<.0001	
	male	4/ 5 (80.0)	1/ 5 (20.0)	4.00 (0.66, 24.37); p=0.1327	16.00 (0.72, 354.80); p=0.0795	0.60 (0.10, 1.00); p=0.0177	
	Race						
	white	72/ 114 (63.2)	8/ 56 (14.3)				
	black	0/ 2 (0.0)	0/ 2 (0.0)				
	asian	7/ 7 (100.0)	0/ 4 (0.0)				
	other	3/ 5 (60.0)	0/ 3 (0.0)				
	Region						0.3742
	North America	31/ 50 (62.0)	2/ 13 (15.4)	4.03 (1.11, 14.69); p=0.0347	8.97 (1.79, 44.95); p=0.0076	0.47 (0.23, 0.70); p=0.0001	
	Europe	26/ 39 (66.7)	1/ 24 (4.2)	16.00 (2.32, 110.40); p=0.0049	46.00 (5.58, 379.39); p=0.0004	0.63 (0.46, 0.79); p=<.0001	
	Rest-of-World	25/ 39 (64.1)	5/ 28 (17.9)	3.59 (1.57, 8.22); p=0.0025	8.21 (2.56, 26.40); p=0.0004	0.46 (0.26, 0.67); p=<.0001	
	Cirrhosis						0.1435
	yes	8/ 18 (44.4)	2/ 9 (22.2)	2.00 (0.53, 7.54); p=0.3059	2.80 (0.45, 17.38); p=0.2691	0.22 (-0.13, 0.58); p=0.2207	
	no	74/ 110 (67.3)	6/ 56 (10.7)	6.28 (2.92, 13.52); p<.0001	17.13 (6.72, 43.67); p=<.0001	0.57 (0.45, 0.68); p=<.0001	
	UDCA						0.9902
	UDCA Use	77/ 120 (64.2)	8/ 62 (12.9)	4.97 (2.57, 9.63); p<.0001	12.09 (5.27, 27.75); p=<.0001	0.51 (0.39, 0.63); p=<.0001	
	UDCA Intolerance	5/ 8 (62.5)	0/ 3 (0.0)	4.89 (0.35, 68.83); p=0.2396	11.00 (0.43, 284.30); p=0.1484	0.63 (0.29, 0.96); p=0.0003	
	Prior Use of OCA and/or Fibrates						0.5201
	yes	8/ 20 (40.0)	0/ 13 (0.0)	11.33 (0.71, 181.02); p=0.0859	18.36 (0.96, 352.23); p=0.0535	0.40 (0.19, 0.61); p=0.0003	
	no	74/ 108 (68.5)	8/ 52 (15.4)	4.45 (2.32, 8.53); p<.0001	11.97 (5.09, 28.17); p=<.0001	0.53 (0.40, 0.66); p=<.0001	
	Therapy						0.8746
	Monotherapy (SEL)	5/ 8 (62.5)	0/ 4 (0.0)	6.11 (0.42, 89.20); p=0.1857	14.14 (0.57, 352.00); p=0.1062	0.63 (0.29, 0.96); p=0.0003	
	Combinationtherapy (SEL + UDCA)	77/ 120 (64.2)	8/ 61 (13.1)	4.89 (2.53, 9.46); p<.0001	11.86 (5.16, 27.26); p=<.0001	0.51 (0.39, 0.63); p=<.0001	
	Stratification variable: Baseline Pruritus NRS						0.6871
	< 4	54/ 79 (68.4)	6/ 42 (14.3)	4.78 (2.25, 10.19); p<.0001	12.96 (4.84, 34.73); p=<.0001	0.54 (0.39, 0.69); p=<.0001	
	>= 4	28/ 49 (57.1)	2/ 23 (8.7)	6.57 (1.71, 25.26); p=0.0061	14.00 (2.95, 66.41); p=0.0009	0.48 (0.30, 0.66); p=<.0001	
	Stratification variable: Baseline ALP Level						0.8088
	< 350 U/L	74/ 93 (79.6)	7/ 47 (14.9)	5.34 (2.68, 10.66); p<.0001	22.26 (8.62, 57.44); p=<.0001	0.65 (0.52, 0.78); p=<.0001	
	>= 350 U/L	8/ 35 (22.9)	1/ 18 (5.6)	4.11 (0.56, 30.39); p=0.1656	5.04 (0.58, 43.92); p=0.1434	0.17 (-0.00, 0.35); p=0.0524	

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of subjects with event; N=Number of patients included in the analysis; CI=Confidence Interval; OR=Odds Ratio; RR=Relative Risk; RD=Risk Difference; NE=Not estimable

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Number and Proportion of subjects with ALP <1.5× ULN at 6 and 12 months - Subgroup analysis
Intention-to-treat

Timepoint	Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	Seladelpar 10 mg vs. Placebo OR (95% CI); p-Value	Seladelpar 10 mg vs. Placebo RD (95% CI); p-Value	Interaction p-Value
Month 6	Gamma-GT (GGT)						0.8421
	<= 3.2 x ULN	30/ 38 (78.9)	3/ 18 (16.7)	4.74 (1.66, 13.48); p=0.0036	18.75 (4.33, 81.10); p=<.0001	0.62 (0.41, 0.84); p=<.0001	
	> 3.2 x ULN	52/ 90 (57.8)	5/ 47 (10.6)	5.43 (2.33, 12.67); p<.0001	11.49 (4.16, 31.79); p=<.0001	0.47 (0.34, 0.61); p=<.0001	
	Total Bilirubin I						0.8385
	<= 1 x ULN	71/ 108 (65.7)	8/ 60 (13.3)	4.93 (2.55, 9.53); p<.0001	12.47 (5.36, 29.00); p=<.0001	0.52 (0.40, 0.65); p=<.0001	
	> 1 x ULN	11/ 20 (55.0)	0/ 5 (0.0)	6.57 (0.45, 96.05); p=0.1689	13.32 (0.65, 272.83); p=0.0929	0.55 (0.33, 0.77); p=<.0001	
	Total Bilirubin II						0.0825
	< 0.6 x ULN	41/ 59 (69.5)	7/ 32 (21.9)	3.18 (1.62, 6.25); p=0.0008	8.13 (2.98, 22.22); p=<.0001	0.48 (0.29, 0.66); p=<.0001	
	>= 0.6 x ULN	41/ 69 (59.4)	1/ 33 (3.0)	19.61 (2.82, 136.43); p=0.0026	46.86 (6.05, 363.09); p=0.0002	0.56 (0.43, 0.69); p=<.0001	

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of subjects with event; N=Number of patients included in the analysis; CI=Confidence Interval; OR=Odds Ratio; RR=Relative Risk; RD=Risk Difference; NE=Not estimable

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Number and Proportion of subjects with ALP <1.5× ULN at 6 and 12 months - Subgroup analysis
Intention-to-treat

Timepoint	Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	OR (95% CI); p-Value	RD (95% CI); p-Value	Interaction p-Value
Month 12	Age at screening						0.7116
	< 65 years	59/ 99 (59.6)	7/ 53 (13.2)	4.51 (2.22, 9.17); p<.0001	9.69 (3.98, 23.62); p=<.0001	0.46 (0.33, 0.60); p=<.0001	
	>= 65 years	16/ 29 (55.2)	1/ 12 (8.3)	6.62 (0.99, 44.49); p=0.0518	13.54 (1.54, 119.05); p=0.0188	0.47 (0.23, 0.71); p=0.0001	
	Age at PBC diagnosis						0.3405
	< 50 years	30/ 61 (49.2)	2/ 32 (6.3)	7.87 (2.01, 30.84); p=0.0031	14.52 (3.18, 66.16); p=0.0005	0.43 (0.28, 0.58); p=<.0001	
	>= 50 years	45/ 67 (67.2)	6/ 33 (18.2)	3.69 (1.76, 7.76); p=0.0006	9.20 (3.32, 25.55); p=<.0001	0.49 (0.32, 0.66); p=<.0001	
	Sex						0.6183
	female	72/ 123 (58.5)	7/ 60 (11.7)	5.02 (2.46, 10.23); p<.0001	10.69 (4.50, 25.41); p=<.0001	0.47 (0.35, 0.59); p=<.0001	
	male	3/ 5 (60.0)	1/ 5 (20.0)	3.00 (0.45, 19.93); p=0.2555	6.00 (0.35, 101.57); p=0.2145	0.40 (-0.15, 0.95); p=0.1573	
	Race						
	white	65/ 114 (57.0)	8/ 56 (14.3)				
	black	0/ 2 (0.0)	0/ 2 (0.0)				
	asian	7/ 7 (100.0)	0/ 4 (0.0)				
	other	3/ 5 (60.0)	0/ 3 (0.0)				
	Region						0.6173
	North America	28/ 50 (56.0)	0/ 13 (0.0)	15.65 (1.02, 240.58); p=0.0485	34.20 (1.93, 606.99); p=0.0161	0.56 (0.42, 0.70); p=<.0001	
	Europe	24/ 39 (61.5)	4/ 24 (16.7)	3.69 (1.46, 9.34); p=0.0058	8.00 (2.29, 27.99); p=0.0011	0.45 (0.24, 0.66); p=<.0001	
	Rest-of-World	23/ 39 (59.0)	4/ 28 (14.3)	4.13 (1.61, 10.61); p=0.0033	8.63 (2.51, 29.68); p=0.0006	0.45 (0.25, 0.65); p=<.0001	
	Cirrhosis						0.9504
	yes	9/ 18 (50.0)	1/ 9 (11.1)	4.50 (0.67, 30.23); p=0.1217	8.00 (0.82, 77.82); p=0.0732	0.39 (0.08, 0.70); p=0.0137	
	no	66/ 110 (60.0)	7/ 56 (12.5)	4.80 (2.36, 9.76); p<.0001	10.50 (4.36, 25.29); p=<.0001	0.48 (0.35, 0.60); p=<.0001	
	UDCA						0.9226
	UDCA Use	71/ 120 (59.2)	8/ 62 (12.9)	4.59 (2.36, 8.90); p<.0001	9.78 (4.28, 22.36); p=<.0001	0.46 (0.34, 0.58); p=<.0001	
	UDCA Intolerance	4/ 8 (50.0)	0/ 3 (0.0)	4.00 (0.28, 57.98); p=0.3095	7.00 (0.27, 178.47); p=0.2389	0.50 (0.15, 0.85); p=0.0047	
	Prior Use of OCA and/or Fibrates						0.8101
	yes	9/ 20 (45.0)	1/ 13 (7.7)	5.85 (0.84, 40.89); p=0.0750	9.82 (1.06, 90.59); p=0.0439	0.37 (0.11, 0.63); p=0.0052	
	no	66/ 108 (61.1)	7/ 52 (13.5)	4.54 (2.24, 9.19); p<.0001	10.10 (4.17, 24.49); p=<.0001	0.48 (0.35, 0.61); p=<.0001	
	Therapy						0.9424
	Monotherapy (SEL)	4/ 8 (50.0)	0/ 4 (0.0)	5.00 (0.33, 75.11); p=0.2443	9.00 (0.37, 220.93); p=0.1785	0.50 (0.15, 0.85); p=0.0047	
	Combinationtherapy (SEL + UDCA)	71/ 120 (59.2)	8/ 61 (13.1)	4.51 (2.33, 8.75); p<.0001	9.60 (4.20, 21.97); p=<.0001	0.46 (0.34, 0.58); p=<.0001	
	Stratification variable: Baseline Pruritus NRS						0.6012
	< 4	51/ 79 (64.6)	5/ 42 (11.9)	5.42 (2.34, 12.55); p<.0001	13.48 (4.76, 38.19); p=<.0001	0.53 (0.38, 0.67); p=<.0001	
	>= 4	24/ 49 (49.0)	3/ 23 (13.0)	3.76 (1.26, 11.20); p=0.0177	6.40 (1.68, 24.36); p=0.0065	0.36 (0.16, 0.56); p=0.0003	
	Stratification variable: Baseline ALP Level						0.1690
	< 350 U/L	68/ 93 (73.1)	6/ 47 (12.8)	5.73 (2.69, 12.22); p<.0001	18.59 (7.03, 49.11); p=<.0001	0.60 (0.47, 0.73); p=<.0001	
	>= 350 U/L	7/ 35 (20.0)	2/ 18 (11.1)	1.80 (0.42, 7.79); p=0.4317	2.00 (0.37, 10.81); p=0.4207	0.09 (-0.11, 0.29); p=0.3755	

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of subjects with event; N=Number of patients included in the analysis; CI=Confidence Interval; OR=Odds Ratio; RR=Relative Risk; RD=Risk Difference; NE=Not estimable

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Number and Proportion of subjects with ALP <1.5× ULN at 6 and 12 months - Subgroup analysis
Intention-to-treat

Timepoint	Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	Seladelpar 10 mg vs. Placebo OR (95% CI); p-Value	Seladelpar 10 mg vs. Placebo RD (95% CI); p-Value	Interaction p-Value
Month 12	Gamma-GT (GGT)						0.8794
	<= 3.2 x ULN	28/ 38 (73.7)	3/ 18 (16.7)	4.42 (1.55, 12.64); p=0.0055	14.00 (3.34, 58.77); p=0.0003	0.57 (0.35, 0.79); p=<.0001	
	> 3.2 x ULN	47/ 90 (52.2)	5/ 47 (10.6)	4.91 (2.09, 11.51); p=0.0003	9.18 (3.33, 25.34); p=<.0001	0.42 (0.28, 0.55); p=<.0001	
	Total Bilirubin I						0.5340
	<= 1 x ULN	64/ 108 (59.3)	7/ 60 (11.7)	5.08 (2.49, 10.37); p<.0001	11.01 (4.58, 26.46); p=<.0001	0.48 (0.35, 0.60); p=<.0001	
	> 1 x ULN	11/ 20 (55.0)	1/ 5 (20.0)	2.75 (0.46, 16.59); p=0.2700	4.89 (0.46, 51.87); p=0.1878	0.35 (-0.06, 0.76); p=0.0966	
	Total Bilirubin II						0.6100
	< 0.6 x ULN	38/ 59 (64.4)	5/ 32 (15.6)	4.12 (1.80, 9.43); p=0.0008	9.77 (3.28, 29.15); p=<.0001	0.49 (0.31, 0.66); p=<.0001	
	>= 0.6 x ULN	37/ 69 (53.6)	3/ 33 (9.1)	5.90 (1.96, 17.74); p=0.0016	11.56 (3.22, 41.49); p=0.0002	0.45 (0.29, 0.60); p=<.0001	

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of subjects with event; N=Number of patients included in the analysis; CI=Confidence Interval; OR=Odds Ratio; RR=Relative Risk; RD=Risk Difference; NE=Not estimable

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Summary of mean values, absolute and relative changes from baseline of ALP by visit
Intention-to-treat

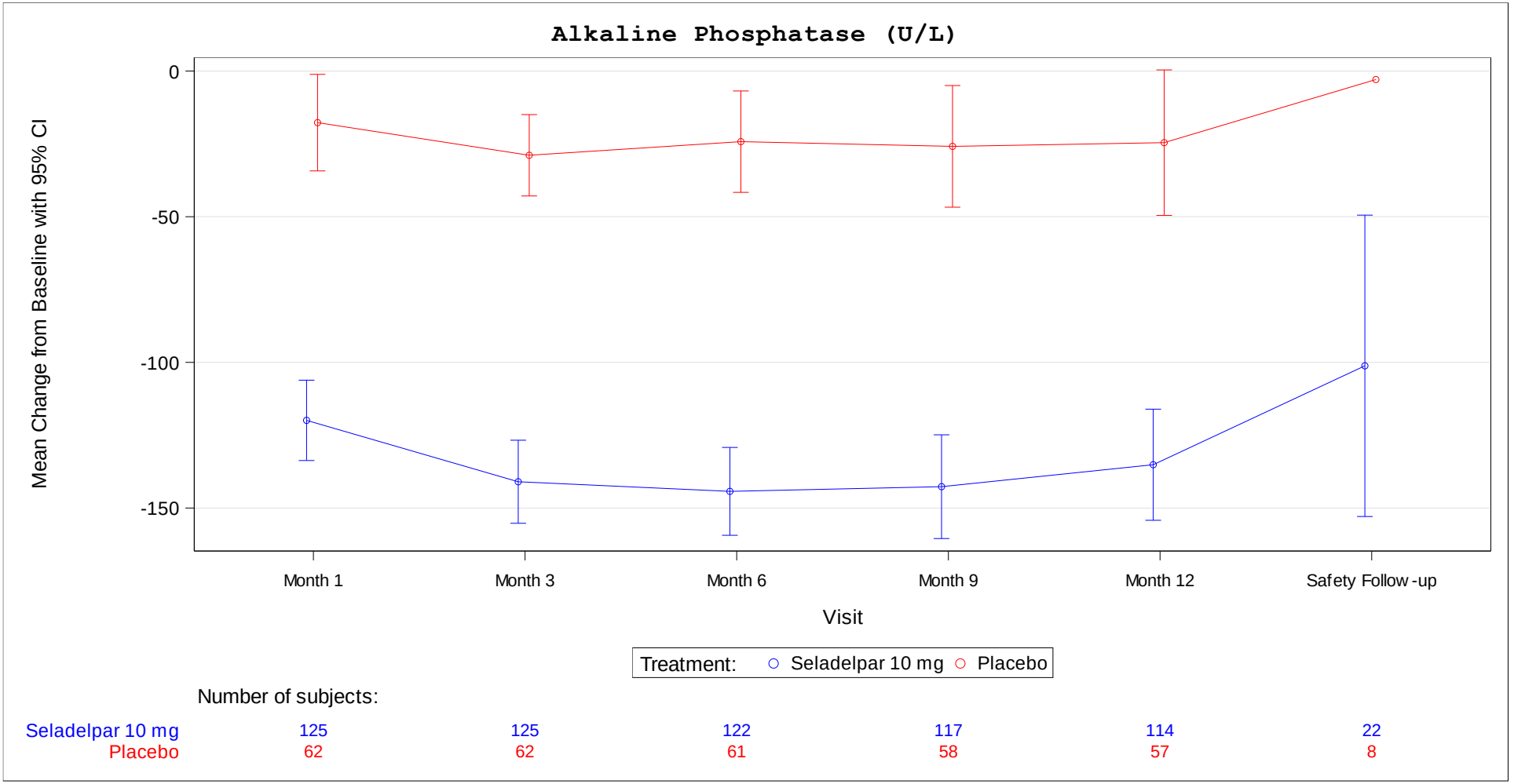
		Seladelpar 10 mg (N=128)				Placebo (N=65)			
		Value at Timepoint		Change from Baseline		Value at Timepoint		Change from Baseline	
Variable	Timepoint	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Change from baseline	Baseline	128	314.55 (122.96)	0	-	65	313.83 (117.68)	0	-
	Month 1	125	193.75 (84.42)	125	-119.90 (77.90)	62	295.73 (132.77)	62	-17.71 (65.25)
	Month 3	125	172.67 (74.37)	125	-140.98 (80.53)	62	282.21 (112.29)	62	-28.91 (54.99)
	Month 6	122	170.57 (87.93)	122	-144.28 (84.12)	61	287.36 (113.92)	61	-24.24 (67.96)
	Month 9	117	169.46 (88.00)	117	-142.67 (97.24)	58	286.29 (111.02)	58	-25.85 (79.41)
	Month 12	114	175.45 (101.59)	114	-135.14 (102.80)	57	289.23 (120.55)	57	-24.58 (94.11)
	Safety Follow-up	22	255.09 (158.55)	22	-101.19 (116.65)	8	310.75 (176.05)	8	-2.92 (63.24)

N describes number of patients with non-missing value at the respective timepoint.
N=Number of subjects included in the analysis, SD: Standard Deviation; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Summary of mean values, absolute and relative changes from baseline of ALP by visit
Intention-to-treat

		Seladelpar 10 mg (N=128)				Placebo (N=65)			
		Value at Timepoint		Change from Baseline		Value at Timepoint		Change from Baseline	
Variable	Timepoint	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Percent change from baseline	Baseline	128	314.55 (122.96)	0	-	65	313.83 (117.68)	0	-
	Month 1	125	193.75 (84.42)	125	-36.89 (22.41)	62	295.73 (132.77)	62	-5.63 (15.85)
	Month 3	125	172.67 (74.37)	125	-44.09 (14.38)	62	282.21 (112.29)	62	-9.12 (16.13)
	Month 6	122	170.57 (87.93)	122	-45.79 (16.78)	61	287.36 (113.92)	61	-7.02 (21.08)
	Month 9	117	169.46 (88.00)	117	-44.94 (21.92)	58	286.29 (111.02)	58	-6.82 (22.76)
	Month 12	114	175.45 (101.59)	114	-43.11 (24.92)	57	289.23 (120.55)	57	-6.06 (27.03)
	Safety Follow-up	22	255.09 (158.55)	22	-29.02 (27.22)	8	310.75 (176.05)	8	-4.38 (28.19)

N describes number of patients with non-missing value at the respective timepoint.
N=Number of subjects included in the analysis, SD: Standard Deviation; CI=Confidence Interval



Number of subjects:

	Month 1	Month 3	Month 6	Month 9	Month 12	Safety Follow-up
Seladelpar 10 mg	125	125	122	117	114	22
Placebo	62	62	61	58	57	8

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of absolute and relative changes from baseline of ALP by visit
Intention-to-treat

		Seladelpar 10 mg (N=128)		Placebo (N=65)		Difference of		
Score	Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)
Change from baseline	Month 1	126	-117.46 (5.96)	63	-15.64 (7.84)	-101.82 (-119.20, -84.45)	<.0001	-1.55 (-1.89, -1.21)
	Month 3	126	-138.45 (5.51)	63	-23.36 (7.12)	-115.10 (-130.64, -99.55)	<.0001	-1.91 (-2.27, -1.55)
	Month 6	126	-140.59 (6.52)	63	-18.03 (8.66)	-122.56 (-142.15, -102.98)	<.0001	-1.70 (-2.05, -1.35)
	Month 9	126	-136.15 (7.89)	63	-17.38 (10.75)	-118.78 (-143.67, -93.88)	<.0001	-1.35 (-1.68, -1.02)
	Month 12	126	-133.93 (8.51)	63	-16.91 (11.67)	-117.02 (-144.20, -89.84)	<.0001	-1.23 (-1.56, -0.90)

(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
N=Number of subjects included in the analysis, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of absolute and relative changes from baseline of ALP by visit
Intention-to-treat

		Seladelpar 10 mg (N=128)		Placebo (N=65)		Difference of		
Score	Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)
Percent change from baseline	Month 1	126	-36.20 (2.03)	63	-4.83 (2.72)	-31.36 (-37.57, -25.16)	<.0001	-1.39 (-1.73, -1.06)
	Month 3	126	-43.38 (1.62)	63	-8.03 (2.09)	-35.35 (-39.93, -30.78)	<.0001	-1.99 (-2.36, -1.63)
	Month 6	126	-44.82 (1.89)	63	-5.91 (2.51)	-38.91 (-44.59, -33.22)	<.0001	-1.86 (-2.22, -1.50)
	Month 9	126	-42.79 (2.40)	63	-4.52 (3.29)	-38.27 (-45.91, -30.63)	<.0001	-1.43 (-1.77, -1.09)
	Month 12	126	-42.44 (2.54)	63	-4.25 (3.48)	-38.19 (-46.31, -30.06)	<.0001	-1.35 (-1.68, -1.02)

(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
N=Number of subjects included in the analysis, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of absolute and relative changes from baseline of ALP at month 6 and 12 - Subgroup analysis
Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
			Baseline		Change from BL		Baseline		Change from BL					
Variable	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
Change from baseline	Month 6	Age at screening												0.1210
		< 65 years	99	311.78 (118.36)	97	-137.29 (7.90)	53	319.27 (122.81)	51	-10.85 (10.35)	-126.43 (-150.30, -102.57)	<.0001	-1.64 (-2.03, -1.26)	
		>= 65 years	29	324.03 (139.36)	29	-147.46 (9.75)	12	289.83 (92.22)	12	-48.89 (13.27)	-98.57 (-125.62, -71.53)	<.0001	-1.91 (-2.71, -1.10)	
		Age at PBC diagnosis												0.9948
		< 50 years	61	324.68 (119.38)	59	-136.99 (10.51)	32	322.56 (116.29)	30	-12.94 (14.43)	-124.06 (-157.68, -90.44)	<.0001	-1.53 (-2.03, -1.04)	
		>= 50 years	67	305.33 (126.31)	67	-146.66 (8.09)	33	305.37 (120.19)	33	-22.74 (10.35)	-123.93 (-147.01, -100.85)	<.0001	-1.92 (-2.42, -1.42)	
		Sex												NE
		female	123	317.95 (124.10)	121	-142.30 (6.71)	60	312.49 (119.98)	58	-16.69 (9.17)	-125.61 (-146.33, -104.89)	<.0001	-1.72 (-2.09, -1.36)	
		male	5	230.97 (34.03)	5	NE	5	329.93 (94.28)	5	NE	NE		NE	
		Race												
		white	114	316.39 (120.09)	113		56	304.35 (110.31)	54					
		black	2	583.67 (182.43)	2		2	452.00 (347.43)	2					
		asian	7	241.29 (53.00)	7		4	323.75 (81.33)	4					
		other	5	267.48 (107.58)	4		3	385.53 (93.38)	3					
		Region												0.8784
		North America	50	308.53 (125.03)	49	-134.36 (13.45)	13	293.40 (133.65)	12	-8.21 (23.15)	-126.15 (-174.62, -77.69)	<.0001	-1.36 (-2.04, -0.68)	
		Europe	39	325.24 (144.17)	39	-162.39 (9.74)	24	324.07 (127.64)	23	-30.98 (12.19)	-131.41 (-159.36, -103.46)	<.0001	-2.16 (-2.81, -1.52)	
		Rest-of-World	39	311.58 (97.01)	38	-132.38 (10.08)	28	314.54 (103.50)	28	-11.25 (11.75)	-121.13 (-150.56, -91.69)	<.0001	-1.93 (-2.52, -1.33)	
		Cirrhosis												0.1769
		yes	18	344.01 (143.51)	18	-138.51 (19.94)	9	349.31 (159.95)	9	26.63 (27.80)	-165.13 (-234.59, -95.67)	<.0001	-1.90 (-2.87, -0.93)	
		no	110	309.73 (119.31)	108	-139.96 (6.79)	56	308.13 (110.24)	54	-21.81 (9.01)	-118.16 (-138.62, -97.70)	<.0001	-1.70 (-2.08, -1.32)	
		UDCA												NE
		UDCA Use	120	307.35 (114.91)	118	-138.39 (6.41)	62	316.90 (119.64)	60	-21.83 (8.45)	-116.56 (-135.57, -97.55)	<.0001	-1.70 (-2.06, -1.34)	
		UDCA Intolerance	8	422.50 (188.69)	8	NE	3	250.39 (15.06)	3	NE	NE		NE	
		Prior Use of OCA and/or Fibrates												0.4172
		yes	20	370.95 (144.98)	18	-148.12 (18.73)	13	348.62 (141.91)	12	-46.17 (22.58)	-101.95 (-161.51, -42.39)	0.0016	-1.26 (-2.06, -0.45)	
		no	108	304.11 (116.22)	108	-140.34 (6.77)	52	305.13 (110.69)	51	-13.45 (9.14)	-126.88 (-147.00, -106.76)	<.0001	-1.84 (-2.23, -1.44)	
		Therapy												NE
		Monotherapy (SEL)	8	422.50 (188.69)	8	NE	4	323.29 (146.32)	4	NE	NE		NE	
		Combinationtherapy (SEL + UDCA)	120	307.35 (114.91)	118	-137.52 (6.42)	61	313.21 (117.02)	59	-22.74 (8.50)	-114.79 (-133.85, -95.72)	<.0001	-1.67 (-2.03, -1.31)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of absolute and relative changes from baseline of ALP at month 6 and 12 - Subgroup analysis
Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
			Baseline		Change from BL		Baseline		Change from BL					
Variable	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
Change from baseline	Month 6	Stratification variable: Baseline Pruritus NRS												0.2246
		< 4	79	299.94 (112.09)	79	-134.69 (8.29)	42	299.22 (111.09)	41	-22.44 (10.26)	-112.25 (-134.84, -89.66)	<.0001	-1.57 (-2.00, -1.14)	
		>= 4	49	338.10 (136.62)	47	-149.32 (10.76)	23	340.52 (127.01)	22	-10.19 (15.91)	-139.13 (-177.17, -101.10)	<.0001	-1.86 (-2.46, -1.26)	
		Stratification variable: Baseline ALP Level												0.0017
		< 350 U/L	93	254.17 (47.01)	92	-113.66 (5.74)	47	253.63 (44.61)	45	-13.25 (8.05)	-100.41 (-119.53, -81.29)	<.0001	-1.82 (-2.24, -1.41)	
		>= 350 U/L	35	475.00 (118.40)	34	-219.72 (15.97)	18	471.04 (102.75)	18	-28.57 (22.17)	-191.15 (-246.47, -135.82)	<.0001	-2.02 (-2.71, -1.32)	
		Gamma-GT (GGT)												0.0561
		<= 3 x ULN	33	258.55 (81.31)	32	-102.34 (16.36)	14	258.29 (53.23)	13	-6.99 (19.95)	-95.35 (-127.77, -62.92)	<.0001	-1.07 (-1.76, -0.39)	
		> 3 x ULN	95	334.00 (129.20)	94	-151.26 (7.94)	51	329.08 (126.05)	50	-16.90 (10.51)	-134.36 (-159.37, -109.35)	<.0001	-1.76 (-2.16, -1.36)	
		Total Bilirubin I												0.0246
		<= 1 x ULN	108	301.65 (114.03)	106	-130.98 (7.24)	60	306.77 (109.72)	59	-17.48 (9.09)	-113.50 (-134.04, -92.96)	<.0001	-1.55 (-1.91, -1.19)	
		> 1 x ULN	20	384.24 (147.54)	20	-187.06 (14.61)	5	398.58 (185.12)	4	15.65 (35.48)	-202.71 (-282.83, -122.58)	<.0001	-2.96 (-4.37, -1.55)	
		Total Bilirubin II												0.0529
		< 0.6 x ULN	59	289.19 (100.38)	58	-128.51 (9.39)	32	287.50 (102.63)	31	-23.44 (11.33)	-105.07 (-129.13, -81.01)	<.0001	-1.52 (-2.01, -1.02)	
		>= 0.6 x ULN	69	336.24 (136.40)	68	-150.70 (9.85)	33	339.37 (126.99)	32	-5.57 (14.18)	-145.12 (-178.54, -111.71)	<.0001	-1.78 (-2.27, -1.29)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of absolute and relative changes from baseline of ALP at month 6 and 12 - Subgroup analysis
Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
			Baseline		Change from BL		Baseline		Change from BL					
Variable	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
Change from baseline	Month 12	Age at screening												0.6726
		< 65 years	99	311.78 (118.36)	97	-131.68 (10.50)	53	319.27 (122.81)	51	-14.15 (14.26)	-117.53 (-151.20, -83.85)	<.0001	-1.14 (-1.50, -0.77)	
		>= 65 years	29	324.03 (139.36)	29	-138.12 (11.69)	12	289.83 (92.22)	12	-30.89 (16.12)	-107.23 (-142.54, -71.93)	<.0001	-1.72 (-2.50, -0.94)	
		Age at PBC diagnosis												0.6680
		< 50 years	61	324.68 (119.38)	59	-127.21 (12.66)	32	322.56 (116.29)	30	-14.40 (17.78)	-112.81 (-154.75, -70.86)	<.0001	-1.15 (-1.62, -0.68)	
		>= 50 years	67	305.33 (126.31)	67	-143.75 (11.65)	33	305.37 (120.19)	33	-18.89 (15.75)	-124.86 (-161.83, -87.89)	<.0001	-1.32 (-1.78, -0.86)	
		Sex												NE
		female	123	317.95 (124.10)	121	-135.34 (8.42)	60	312.49 (119.98)	58	-17.64 (11.76)	-117.69 (-144.92, -90.46)	<.0001	-1.28 (-1.62, -0.94)	
		male	5	230.97 (34.03)	5	NE	5	329.93 (94.28)	5	NE	NE		NE	
		Race												
		white	114	316.39 (120.09)	113		56	304.35 (110.31)	54					
		black	2	583.67 (182.43)	2		2	452.00 (347.43)	2					
		asian	7	241.29 (53.00)	7		4	323.75 (81.33)	4					
		other	5	267.48 (107.58)	4		3	385.53 (93.38)	3					
		Region												0.8345
		North America	50	308.53 (125.03)	49	-118.08 (19.06)	13	293.40 (133.65)	12	26.68 (36.85)	-144.76 (-224.63, -64.89)	0.0006	-1.08 (-1.74, -0.42)	
		Europe	39	325.24 (144.17)	39	-161.49 (10.69)	24	324.07 (127.64)	23	-42.45 (13.35)	-119.04 (-150.28, -87.81)	<.0001	-1.79 (-2.40, -1.18)	
		Rest-of-World	39	311.58 (97.01)	38	-132.16 (12.31)	28	314.54 (103.50)	28	-10.11 (14.05)	-122.05 (-158.15, -85.94)	<.0001	-1.60 (-2.17, -1.04)	
		Cirrhosis												0.6002
		yes	18	344.01 (143.51)	18	-121.44 (28.88)	9	349.31 (159.95)	9	23.17 (43.09)	-144.61 (-252.31, -36.91)	0.0114	-1.12 (-1.99, -0.26)	
		no	110	309.73 (119.31)	108	-134.77 (8.80)	56	308.13 (110.24)	54	-17.97 (11.91)	-116.80 (-144.70, -88.90)	<.0001	-1.29 (-1.65, -0.93)	
		UDCA												NE
		UDCA Use	120	307.35 (114.91)	118	-130.69 (8.87)	62	316.90 (119.64)	60	-20.44 (12.05)	-110.26 (-138.48, -82.04)	<.0001	-1.15 (-1.48, -0.82)	
		UDCA Intolerance	8	422.50 (188.69)	8	NE	3	250.39 (15.06)	3	NE	NE		NE	
		Prior Use of OCA and/or Fibrates												0.7901
		yes	20	370.95 (144.98)	18	-130.79 (33.84)	13	348.62 (141.91)	12	-25.34 (41.59)	-105.45 (-215.34, 4.45)	0.0593	-0.71 (-1.47, 0.04)	
		no	108	304.11 (116.22)	108	-135.72 (7.94)	52	305.13 (110.69)	51	-15.66 (10.97)	-120.06 (-144.90, -95.22)	<.0001	-1.47 (-1.84, -1.10)	
		Therapy												NE
		Monotherapy (SEL)	8	422.50 (188.69)	8	NE	4	323.29 (146.32)	4	NE	NE		NE	
		Combinationtherapy (SEL + UDCA)	120	307.35 (114.91)	118	-129.69 (8.75)	61	313.21 (117.02)	59	-15.66 (11.95)	-114.03 (-141.89, -86.17)	<.0001	-1.21 (-1.55, -0.87)	

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p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
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RESPONSE - Seladelpar 10 mg vs Placebo
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Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
			Baseline		Change from BL		Baseline		Change from BL					
Variable	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
Change from baseline	Month 12	Stratification variable: Baseline Pruritus NRS												0.2223
		< 4	79	299.94 (112.09)	79	-129.49 (11.34)	42	299.22 (111.09)	41	-24.83 (14.92)	-104.66 (-139.41, -69.91)	<.0001	-1.05 (-1.45, -0.65)	
		>= 4	49	338.10 (136.62)	47	-142.53 (12.01)	23	340.52 (127.01)	22	-4.28 (17.74)	-138.25 (-180.70, -95.81)	<.0001	-1.65 (-2.24, -1.07)	
		Stratification variable: Baseline ALP Level												0.1209
		< 350 U/L	93	254.17 (47.01)	92	-106.06 (8.80)	47	253.63 (44.61)	45	0.24 (12.60)	-106.30 (-136.46, -76.14)	<.0001	-1.25 (-1.64, -0.87)	
		>= 350 U/L	35	475.00 (118.40)	34	-216.06 (18.45)	18	471.04 (102.75)	18	-56.38 (24.73)	-159.69 (-222.10, -97.28)	<.0001	-1.47 (-2.12, -0.83)	
		Gamma-GT (GGT)												0.1201
		<= 3 x ULN	33	258.55 (81.31)	32	-99.50 (16.83)	14	258.29 (53.23)	13	-9.39 (20.89)	-90.11 (-126.07, -54.15)	<.0001	-0.98 (-1.66, -0.30)	
		> 3 x ULN	95	334.00 (129.20)	94	-143.05 (10.77)	51	329.08 (126.05)	50	-14.03 (14.53)	-129.02 (-164.07, -93.96)	<.0001	-1.24 (-1.61, -0.86)	
		Total Bilirubin I												0.3538
		<= 1 x ULN	108	301.65 (114.03)	106	-122.47 (9.45)	60	306.77 (109.72)	59	-13.62 (12.21)	-108.86 (-137.58, -80.13)	<.0001	-1.13 (-1.47, -0.79)	
		> 1 x ULN	20	384.24 (147.54)	20	-185.14 (19.39)	5	398.58 (185.12)	4	-25.98 (48.64)	-159.16 (-268.23, -50.08)	0.0064	-1.74 (-2.94, -0.54)	
		Total Bilirubin II												0.1387
		< 0.6 x ULN	59	289.19 (100.38)	58	-121.62 (10.97)	32	287.50 (102.63)	31	-22.39 (14.04)	-99.23 (-130.55, -67.90)	<.0001	-1.20 (-1.68, -0.73)	
		>= 0.6 x ULN	69	336.24 (136.40)	68	-143.87 (13.50)	33	339.37 (126.99)	32	-2.91 (19.51)	-140.96 (-187.48, -94.44)	<.0001	-1.26 (-1.72, -0.80)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
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p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

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Intention-to-treat

Variable	Timepoint	Subgroup Level	Seladelpar 10 mg (N=128) Baseline N	Seladelpar 10 mg (N=128) Baseline Mean (SD)	Seladelpar 10 mg (N=128) Change from BL N	Seladelpar 10 mg (N=128) Change from BL LSMean (SE)	Placebo (N=65) Baseline N	Placebo (N=65) Baseline Mean (SD)	Placebo (N=65) Change from BL N	Placebo (N=65) Change from BL LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
Percent change from baseline	Month 6	Age at screening												0.0752
		< 65 years	99	311.78 (118.36)	97	-44.31 (2.28)	53	319.27 (122.81)	51	-3.72 (2.98)	-40.59 (-47.46, -33.71)	<.0001	-1.83 (-2.23, -1.43)	
		>= 65 years	29	324.03 (139.36)	29	-45.32 (2.83)	12	289.83 (92.22)	12	-14.05 (3.90)	-31.27 (-39.20, -23.34)	<.0001	-2.07 (-2.90, -1.25)	
		Age at PBC diagnosis												0.5990
		< 50 years	61	324.68 (119.38)	59	-42.78 (2.82)	32	322.56 (116.29)	30	-4.86 (3.88)	-37.92 (-47.00, -28.84)	<.0001	-1.75 (-2.26, -1.24)	
		>= 50 years	67	305.33 (126.31)	67	-47.22 (2.63)	33	305.37 (120.19)	33	-6.20 (3.34)	-41.02 (-48.44, -33.60)	<.0001	-1.96 (-2.46, -1.46)	
		Sex												NE
		female	123	317.95 (124.10)	121	-45.17 (1.94)	60	312.49 (119.98)	58	-5.55 (2.65)	-39.62 (-45.60, -33.64)	<.0001	-1.88 (-2.25, -1.51)	
		male	5	230.97 (34.03)	5	NE	5	329.93 (94.28)	5	NE	NE		NE	
		Race												
		white	114	316.39 (120.09)	113		56	304.35 (110.31)	54					
		black	2	583.67 (182.43)	2		2	452.00 (347.43)	2					
		asian	7	241.29 (53.00)	7		4	323.75 (81.33)	4					
		other	5	267.48 (107.58)	4		3	385.53 (93.38)	3					
		Region												0.8375
		North America	50	308.53 (125.03)	49	-42.95 (3.95)	13	293.40 (133.65)	12	0.81 (6.81)	-43.76 (-58.08, -29.43)	<.0001	-1.60 (-2.30, -0.91)	
		Europe	39	325.24 (144.17)	39	-50.22 (2.67)	24	324.07 (127.64)	23	-9.75 (3.35)	-40.47 (-48.11, -32.84)	<.0001	-2.43 (-3.11, -1.75)	
		Rest-of-World	39	311.58 (97.01)	38	-43.68 (2.97)	28	314.54 (103.50)	28	-4.87 (3.46)	-38.81 (-47.46, -30.15)	<.0001	-2.09 (-2.70, -1.48)	
		Cirrhosis												0.5565
		yes	18	344.01 (143.51)	18	-38.37 (6.24)	9	349.31 (159.95)	9	6.99 (8.68)	-45.36 (-67.15, -23.57)	0.0004	-1.67 (-2.61, -0.74)	
		no	110	309.73 (119.31)	108	-45.54 (2.04)	56	308.13 (110.24)	54	-6.52 (2.69)	-39.02 (-45.09, -32.95)	<.0001	-1.87 (-2.26, -1.49)	
		UDCA												0.0046
		UDCA Use	120	307.35 (114.91)	118	-44.51 (1.91)	62	316.90 (119.64)	60	-7.42 (2.51)	-37.09 (-42.73, -31.45)	<.0001	-1.82 (-2.18, -1.45)	
		UDCA Intolerance	8	422.50 (188.69)	8	-52.07 (7.25)	3	250.39 (15.06)	3	25.11 (11.92)	-77.18 (-108.76, -45.59)	0.0004	-3.44 (-5.67, -1.21)	
		Prior Use of OCA and/or Fibrates												0.2855
		yes	20	370.95 (144.98)	18	-39.31 (5.49)	13	348.62 (141.91)	12	-8.62 (6.62)	-30.69 (-48.15, -13.24)	0.0012	-1.29 (-2.10, -0.48)	
		no	108	304.11 (116.22)	108	-45.90 (1.99)	52	305.13 (110.69)	51	-5.57 (2.68)	-40.33 (-46.23, -34.44)	<.0001	-1.99 (-2.39, -1.59)	
		Therapy												0.0064
		Monotherapy (SEL)	8	422.50 (188.69)	8	-49.57 (7.04)	4	323.29 (146.32)	4	21.32 (10.05)	-70.90 (-98.34, -43.45)	0.0002	-3.28 (-5.28, -1.28)	
		Combinationtherapy (SEL + UDCA)	120	307.35 (114.91)	118	-44.47 (1.92)	61	313.21 (117.02)	59	-7.68 (2.53)	-36.79 (-42.45, -31.12)	<.0001	-1.80 (-2.16, -1.43)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of absolute and relative changes from baseline of ALP at month 6 and 12 - Subgroup analysis
Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
			Baseline		Change from BL		Baseline		Change from BL					
Variable	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
Percent change from baseline	Month 6	Stratification variable: Baseline Pruritus NRS												0.6813
		< 4	79	299.94 (112.09)	79	-44.81 (2.60)	42	299.22 (111.09)	41	-6.93 (3.21)	-37.88 (-44.93, -30.82)	<.0001	-1.69 (-2.13, -1.26)	
		>= 4	49	338.10 (136.62)	47	-44.57 (2.81)	23	340.52 (127.01)	22	-4.18 (4.18)	-40.39 (-50.34, -30.45)	<.0001	-2.06 (-2.68, -1.44)	
		Stratification variable: Baseline ALP Level												0.9669
		< 350 U/L	93	254.17 (47.01)	92	-45.21 (2.06)	47	253.63 (44.61)	45	-5.46 (2.87)	-39.75 (-46.56, -32.94)	<.0001	-2.02 (-2.45, -1.59)	
		>= 350 U/L	35	475.00 (118.40)	34	-46.16 (3.28)	18	471.04 (102.75)	18	-6.68 (4.57)	-39.48 (-50.83, -28.13)	<.0001	-2.02 (-2.72, -1.32)	
		Gamma-GT (GGT)												0.5808
		<= 3 x ULN	33	258.55 (81.31)	32	-40.50 (5.90)	14	258.29 (53.23)	13	-3.76 (7.21)	-36.74 (-48.33, -25.15)	<.0001	-1.15 (-1.84, -0.46)	
		> 3 x ULN	95	334.00 (129.20)	94	-45.68 (2.14)	51	329.08 (126.05)	50	-5.25 (2.84)	-40.43 (-47.22, -33.64)	<.0001	-1.96 (-2.37, -1.55)	
		Total Bilirubin I												0.1330
		<= 1 x ULN	108	301.65 (114.03)	106	-43.79 (2.24)	60	306.77 (109.72)	59	-5.47 (2.79)	-38.32 (-44.55, -32.08)	<.0001	-1.70 (-2.06, -1.33)	
		> 1 x ULN	20	384.24 (147.54)	20	-48.22 (3.34)	5	398.58 (185.12)	4	4.13 (8.15)	-52.35 (-70.97, -33.74)	<.0001	-3.34 (-4.83, -1.85)	
		Total Bilirubin II												0.3558
		< 0.6 x ULN	59	289.19 (100.38)	58	-44.13 (3.21)	32	287.50 (102.63)	31	-7.12 (3.83)	-37.01 (-45.00, -29.01)	<.0001	-1.57 (-2.06, -1.07)	
		>= 0.6 x ULN	69	336.24 (136.40)	68	-44.81 (2.50)	33	339.37 (126.99)	32	-2.37 (3.62)	-42.44 (-50.96, -33.91)	<.0001	-2.05 (-2.56, -1.54)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of absolute and relative changes from baseline of ALP at month 6 and 12 - Subgroup analysis
Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
			Baseline		Change from BL		Baseline		Change from BL					
Variable	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
Percent change from baseline	Month 12	Age at screening												0.5592
		< 65 years	99	311.78 (118.36)	97	-42.00 (3.12)	53	319.27 (122.81)	51	-3.12 (4.24)	-38.87 (-48.91, -28.84)	<.0001	-1.26 (-1.63, -0.90)	
		>= 65 years	29	324.03 (139.36)	29	-42.78 (3.49)	12	289.83 (92.22)	12	-8.17 (4.82)	-34.61 (-45.26, -23.95)	<.0001	-1.86 (-2.66, -1.07)	
		Age at PBC diagnosis												0.3700
		< 50 years	61	324.68 (119.38)	59	-38.60 (3.57)	32	322.56 (116.29)	30	-3.46 (5.04)	-35.14 (-47.09, -23.19)	<.0001	-1.27 (-1.75, -0.79)	
		>= 50 years	67	305.33 (126.31)	67	-46.78 (3.64)	33	305.37 (120.19)	33	-4.18 (4.89)	-42.59 (-54.02, -31.16)	<.0001	-1.44 (-1.91, -0.98)	
		Sex												NE
		female	123	317.95 (124.10)	121	-42.68 (2.46)	60	312.49 (119.98)	58	-5.00 (3.44)	-37.68 (-45.66, -29.71)	<.0001	-1.40 (-1.75, -1.05)	
		male	5	230.97 (34.03)	5	NE	5	329.93 (94.28)	5	NE	NE		NE	
		Race												
		white	114	316.39 (120.09)	113		56	304.35 (110.31)	54					
		black	2	583.67 (182.43)	2		2	452.00 (347.43)	2					
		asian	7	241.29 (53.00)	7		4	323.75 (81.33)	4					
		other	5	267.48 (107.58)	4		3	385.53 (93.38)	3					
		Region												0.3335
		North America	50	308.53 (125.03)	49	-37.45 (5.88)	13	293.40 (133.65)	12	18.16 (11.40)	-55.61 (-80.44, -30.77)	<.0001	-1.34 (-2.02, -0.67)	
		Europe	39	325.24 (144.17)	39	-49.15 (3.11)	24	324.07 (127.64)	23	-12.92 (3.90)	-36.23 (-45.43, -27.03)	<.0001	-1.87 (-2.48, -1.25)	
		Rest-of-World	39	311.58 (97.01)	38	-43.83 (3.51)	28	314.54 (103.50)	28	-3.86 (4.00)	-39.97 (-50.21, -29.73)	<.0001	-1.84 (-2.43, -1.26)	
		Cirrhosis												0.9802
		yes	18	344.01 (143.51)	18	-32.61 (8.99)	9	349.31 (159.95)	9	7.26 (13.34)	-39.87 (-73.79, -5.95)	0.0245	-1.00 (-1.85, -0.15)	
		no	110	309.73 (119.31)	108	-43.63 (2.70)	56	308.13 (110.24)	54	-4.17 (3.65)	-39.46 (-47.99, -30.93)	<.0001	-1.42 (-1.78, -1.06)	
		UDCA												0.0005
		UDCA Use	120	307.35 (114.91)	118	-42.06 (2.64)	62	316.90 (119.64)	60	-5.83 (3.58)	-36.23 (-44.60, -27.87)	<.0001	-1.27 (-1.61, -0.93)	
		UDCA Intolerance	8	422.50 (188.69)	8	-50.67 (7.12)	3	250.39 (15.06)	3	39.13 (13.06)	-89.80 (-127.66, -51.95)	0.0017	-3.96 (-6.42, -1.51)	
		Prior Use of OCA and/or Fibrates												0.8087
		yes	20	370.95 (144.98)	18	-33.97 (10.28)	13	348.62 (141.91)	12	1.09 (12.63)	-35.06 (-68.67, -1.45)	0.0416	-0.78 (-1.54, -0.02)	
		no	108	304.11 (116.22)	108	-44.09 (2.42)	52	305.13 (110.69)	51	-4.98 (3.35)	-39.10 (-46.72, -31.48)	<.0001	-1.57 (-1.95, -1.20)	
		Therapy												0.1292
		Monotherapy (SEL)	8	422.50 (188.69)	8	-48.17 (12.97)	4	323.29 (146.32)	4	25.18 (19.81)	-73.35 (-135.16, -11.53)	0.0289	-1.80 (-3.29, -0.31)	
		Combinationtherapy (SEL + UDCA)	120	307.35 (114.91)	118	-42.00 (2.64)	61	313.21 (117.02)	59	-5.03 (3.60)	-36.98 (-45.37, -28.59)	<.0001	-1.30 (-1.64, -0.96)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of absolute and relative changes from baseline of ALP at month 6 and 12 - Subgroup analysis
Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
			Baseline		Change from BL		Baseline		Change from BL					
Variable	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
Percent change from baseline	Month 12	Stratification variable: Baseline Pruritus NRS												0.9988
		< 4	79	299.94 (112.09)	79	-43.39 (3.47)	42	299.22 (111.09)	41	-5.46 (4.55)	-37.93 (-48.48, -27.38)	<.0001	-1.24 (-1.65, -0.83)	
		>= 4	49	338.10 (136.62)	47	-41.12 (3.64)	23	340.52 (127.01)	22	-3.20 (5.39)	-37.92 (-50.84, -25.00)	<.0001	-1.50 (-2.06, -0.93)	
		Stratification variable: Baseline ALP Level												0.3214
		< 350 U/L	93	254.17 (47.01)	92	-42.51 (3.01)	47	253.63 (44.61)	45	-0.88 (4.31)	-41.63 (-51.91, -31.34)	<.0001	-1.43 (-1.83, -1.04)	
		>= 350 U/L	35	475.00 (118.40)	34	-44.82 (3.98)	18	471.04 (102.75)	18	-11.58 (5.35)	-33.24 (-46.69, -19.79)	<.0001	-1.42 (-2.06, -0.78)	
		Gamma-GT (GGT)												0.4745
		<= 3 x ULN	33	258.55 (81.31)	32	-40.13 (6.07)	14	258.29 (53.23)	13	-5.73 (7.53)	-34.40 (-47.21, -21.58)	<.0001	-1.04 (-1.72, -0.36)	
		> 3 x ULN	95	334.00 (129.20)	94	-42.56 (3.09)	51	329.08 (126.05)	50	-2.34 (4.19)	-40.22 (-50.36, -30.08)	<.0001	-1.34 (-1.72, -0.96)	
		Total Bilirubin I												0.7695
		<= 1 x ULN	108	301.65 (114.03)	106	-40.85 (2.94)	60	306.77 (109.72)	59	-3.30 (3.79)	-37.56 (-46.42, -28.69)	<.0001	-1.25 (-1.60, -0.91)	
		> 1 x ULN	20	384.24 (147.54)	20	-48.26 (4.33)	5	398.58 (185.12)	4	-7.00 (11.05)	-41.27 (-66.10, -16.43)	0.0026	-2.02 (-3.26, -0.78)	
		Total Bilirubin II												0.2898
		< 0.6 x ULN	59	289.19 (100.38)	58	-41.41 (3.64)	32	287.50 (102.63)	31	-6.71 (4.58)	-34.70 (-44.75, -24.65)	<.0001	-1.27 (-1.75, -0.80)	
		>= 0.6 x ULN	69	336.24 (136.40)	68	-42.63 (3.79)	33	339.37 (126.99)	32	0.87 (5.49)	-43.50 (-56.63, -30.38)	<.0001	-1.38 (-1.85, -0.92)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Number and Proportion of subjects with total bilirubin <= ULN at 6 and 12 months
Intention-to-treat

Timepoint		Seladelpar 10 mg	Placebo
Month 6	Number of subjects with reponse, n/N (%)	111/128 (86.7)	54/ 65 (83.1)
	Number of missing values imputed as Non-Response	6	4
	Stratified Analysis Seladelpar 10 mg vs. Placebo		
	Relative Risk (95% CI)	1.05 (0.93, 1.19)	
	p-value	0.4456	
	Odds Ratio (95% CI)	1.41 (0.60, 3.27)	
	p-value	0.4284	
	Risk Difference (95% CI)	0.04 (-0.06, 0.15)	
	p-value	0.4417	
	Unstratified Analysis Seladelpar 10 mg vs. Placebo		
	Relative Risk (95% CI)	1.04 (0.92, 1.19)	
	p-value	0.5144	
	Odds Ratio (95% CI)	1.33 (0.58, 3.04)	
	p-value	0.4981	
	Peto Odds Ratio (95% CI)	1.34 (0.58, 3.12)	
	p-value	0.4983	
	Risk Difference (95% CI)	0.04 (-0.07, 0.14)	
	p-value	0.5105	

RR, OR and RD estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
Stratification factors: Baseline ALP level: < 350 U/L and >= 350 U/L; baseline pruritus NRS: < 4 and >= 4.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Number and Proportion of subjects with total bilirubin <= ULN at 6 and 12 months
Intention-to-treat

Timepoint		Seladelpar 10 mg	Placebo
Month 12	Number of subjects with reponse, n/N (%)	104/128 (81.3)	50/ 65 (76.9)
	Number of missing values imputed as Non-Response	14	8
	Stratified Analysis Seladelpar 10 mg vs. Placebo		
	Relative Risk (95% CI)	1.06 (0.91, 1.24)	
	p-value	0.4511	
	Odds Ratio (95% CI)	1.34 (0.64, 2.79)	
	p-value	0.4335	
	Risk Difference (95% CI)	0.05 (-0.07, 0.17)	
	p-value	0.4441	
	Unstratified Analysis Seladelpar 10 mg vs. Placebo		
	Relative Risk (95% CI)	1.06 (0.90, 1.24)	
	p-value	0.4946	
	Odds Ratio (95% CI)	1.30 (0.63, 2.69)	
	p-value	0.4799	
	Peto Odds Ratio (95% CI)	1.31 (0.62, 2.74)	
	p-value	0.4804	
	Risk Difference (95% CI)	0.04 (-0.08, 0.17)	
	p-value	0.4896	

RR, OR and RD estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
Stratification factors: Baseline ALP level: < 350 U/L and >= 350 U/L; baseline pruritus NRS: < 4 and >= 4.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Number and Proportion of subjects with total bilirubin <= ULN at 6 and 12 months - Subgroup analysis
Intention-to-treat

Timepoint	Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	Seladelpar 10 mg vs. Placebo OR (95% CI); p-Value	Seladelpar 10 mg vs. Placebo RD (95% CI); p-Value	Interaction p-Value
Month 6	Age at screening						0.5723
	< 65 years	84/ 99 (84.8)	44/ 53 (83.0)	1.02 (0.88, 1.18); p=0.7721	1.15 (0.46, 2.83); p=0.7683	0.02 (-0.11, 0.14); p=0.7712	
	>= 65 years	27/ 29 (93.1)	10/ 12 (83.3)	1.12 (0.85, 1.47); p=0.4239	2.70 (0.33, 21.83); p=0.3516	0.10 (-0.13, 0.33); p=0.4054	
	Age at PBC diagnosis						0.0651
	< 50 years	49/ 61 (80.3)	28/ 32 (87.5)	0.92 (0.77, 1.10); p=0.3530	0.58 (0.17, 1.98); p=0.3878	-0.07 (-0.22, 0.08); p=0.3548	
	>= 50 years	62/ 67 (92.5)	26/ 33 (78.8)	1.17 (0.97, 1.42); p=0.0964	3.34 (0.97, 11.49); p=0.0559	0.14 (-0.02, 0.29); p=0.0782	
	Sex						0.8943
	female	107/ 123 (87.0)	50/ 60 (83.3)	1.04 (0.91, 1.19); p=0.5241	1.34 (0.57, 3.16); p=0.5067	0.04 (-0.07, 0.15); p=0.5201	
	male	4/ 5 (80.0)	4/ 5 (80.0)	1.00 (0.54, 1.86); p=1.0000	1.00 (0.05, 22.18); p=1.0000	0.00 (-0.50, 0.50); p=1.0000	
	Race						
	white	99/ 114 (86.8)	45/ 56 (80.4)				
	black	2/ 2 (100.0)	2/ 2 (100.0)				
	asian	7/ 7 (100.0)	4/ 4 (100.0)				
	other	3/ 5 (60.0)	3/ 3 (100.0)				
	Region						0.0291
	North America	44/ 50 (88.0)	9/ 13 (69.2)	1.27 (0.87, 1.85); p=0.2118	3.26 (0.76, 13.95); p=0.1113	0.19 (-0.08, 0.45); p=0.1676	
	Europe	35/ 39 (89.7)	18/ 24 (75.0)	1.20 (0.93, 1.54); p=0.1664	2.92 (0.73, 11.67); p=0.1304	0.15 (-0.05, 0.35); p=0.1438	
	Rest-of-World	32/ 39 (82.1)	27/ 28 (96.4)	0.85 (0.72, 1.00); p=0.0525	0.17 (0.02, 1.46); p=0.1066	-0.14 (-0.28, -0.01); p=0.0422	
	Cirrhosis						0.1092
	yes	13/ 18 (72.2)	3/ 9 (33.3)	2.17 (0.82, 5.70); p=0.1172	5.20 (0.92, 29.26); p=0.0614	0.39 (0.02, 0.76); p=0.0399	
	no	98/ 110 (89.1)	51/ 56 (91.1)	0.98 (0.88, 1.09); p=0.6812	0.80 (0.27, 2.40); p=0.6911	-0.02 (-0.11, 0.07); p=0.6819	
	UDCA						0.5822
	UDCA Use	104/ 120 (86.7)	52/ 62 (83.9)	1.03 (0.91, 1.18); p=0.6204	1.25 (0.53, 2.95); p=0.6100	0.03 (-0.08, 0.14); p=0.6181	
	UDCA Intolerance	7/ 8 (87.5)	2/ 3 (66.7)	1.31 (0.57, 3.05); p=0.5267	3.50 (0.14, 84.69); p=0.4409	0.21 (-0.37, 0.79); p=0.4819	
	Prior Use of OCA and/or Fibrates						0.2802
	yes	17/ 20 (85.0)	12/ 13 (92.3)	0.92 (0.72, 1.17); p=0.5040	0.47 (0.04, 5.11); p=0.5368	-0.07 (-0.29, 0.14); p=0.5018	
	no	94/ 108 (87.0)	42/ 52 (80.8)	1.08 (0.93, 1.25); p=0.3329	1.60 (0.66, 3.89); p=0.3011	0.06 (-0.06, 0.19); p=0.3236	
	Therapy						0.7162
	Monotherapy (SEL)	7/ 8 (87.5)	3/ 4 (75.0)	1.17 (0.63, 2.18); p=0.6280	2.33 (0.11, 50.98); p=0.5903	0.13 (-0.36, 0.61); p=0.6115	
	Combinationtherapy (SEL + UDCA)	104/ 120 (86.7)	51/ 61 (83.6)	1.04 (0.91, 1.18); p=0.5919	1.27 (0.54, 3.01); p=0.5796	0.03 (-0.08, 0.14); p=0.5891	
	Stratification variable: Baseline Pruritus NRS						0.4167
	< 4	74/ 79 (93.7)	36/ 42 (85.7)	1.09 (0.95, 1.25); p=0.2012	2.47 (0.71, 8.63); p=0.1575	0.08 (-0.04, 0.20); p=0.1888	
	>= 4	37/ 49 (75.5)	18/ 23 (78.3)	0.96 (0.74, 1.26); p=0.7936	0.86 (0.26, 2.80); p=0.7979	-0.03 (-0.23, 0.18); p=0.7947	
	Stratification variable: Baseline ALP Level						0.1927
	< 350 U/L	85/ 93 (91.4)	39/ 47 (83.0)	1.10 (0.95, 1.27); p=0.1875	2.18 (0.76, 6.23); p=0.1462	0.08 (-0.04, 0.21); p=0.1749	
	>= 350 U/L	26/ 35 (74.3)	15/ 18 (83.3)	0.89 (0.67, 1.18); p=0.4277	0.58 (0.14, 2.47); p=0.4593	-0.09 (-0.32, 0.13); p=0.4305	

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of subjects with event; N=Number of patients included in the analysis; CI=Confidence Interval; OR=Odds Ratio; RR=Relative Risk; RD=Risk Difference; NE=Not estimable

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Number and Proportion of subjects with total bilirubin <= ULN at 6 and 12 months - Subgroup analysis
Intention-to-treat

Timepoint	Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	OR (95% CI); p-Value	RD (95% CI); p-Value	Interaction p-Value
Month 6	Gamma-GT (GGT)						0.9504
	<= 3.2 x ULN	35/ 38 (92.1)	16/ 18 (88.9)	1.04 (0.86, 1.25); p=0.7110	1.46 (0.22, 9.60); p=0.6947	0.03 (-0.14, 0.20); p=0.7085	
	> 3.2 x ULN	76/ 90 (84.4)	38/ 47 (80.9)	1.04 (0.89, 1.23); p=0.6054	1.29 (0.51, 3.24); p=0.5938	0.04 (-0.10, 0.17); p=0.6022	
	Total Bilirubin I						0.2062
	<= 1 x ULN	98/ 108 (90.7)	53/ 60 (88.3)	1.03 (0.92, 1.15); p=0.6317	1.29 (0.47, 3.60); p=0.6208	0.02 (-0.07, 0.12); p=0.6299	
	> 1 x ULN	13/ 20 (65.0)	1/ 5 (20.0)	3.25 (0.55, 19.32); p=0.1949	7.43 (0.69, 79.96); p=0.0981	0.45 (0.04, 0.86); p=0.0307	
	Total Bilirubin II						0.3870
	< 0.6 x ULN	57/ 59 (96.6)	31/ 32 (96.9)	1.00 (0.92, 1.08); p=0.9455	0.92 (0.08, 10.55); p=0.9462	-0.00 (-0.08, 0.07); p=0.9455	
	>= 0.6 x ULN	54/ 69 (78.3)	23/ 33 (69.7)	1.12 (0.87, 1.45); p=0.3769	1.57 (0.61, 4.00); p=0.3488	0.09 (-0.10, 0.27); p=0.3631	

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of subjects with event; N=Number of patients included in the analysis; CI=Confidence Interval; OR=Odds Ratio; RR=Relative Risk; RD=Risk Difference; NE=Not estimable

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Number and Proportion of subjects with total bilirubin <= ULN at 6 and 12 months - Subgroup analysis
Intention-to-treat

Timepoint	Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	Seladelpar 10 mg vs. Placebo OR (95% CI); p-Value	Seladelpar 10 mg vs. Placebo RD (95% CI); p-Value	Interaction p-Value
Month 12	Age at screening						0.7916
	< 65 years	82/ 99 (82.8)	41/ 53 (77.4)	1.07 (0.90, 1.27); p=0.4337	1.41 (0.62, 3.23); p=0.4147	0.05 (-0.08, 0.19); p=0.4270	
	>= 65 years	22/ 29 (75.9)	9/ 12 (75.0)	1.01 (0.69, 1.49); p=0.9537	1.05 (0.22, 4.98); p=0.9534	0.01 (-0.28, 0.30); p=0.9536	
	Age at PBC diagnosis						0.7577
	< 50 years	47/ 61 (77.0)	24/ 32 (75.0)	1.03 (0.81, 1.31); p=0.8275	1.12 (0.41, 3.04); p=0.8252	0.02 (-0.16, 0.20); p=0.8267	
	>= 50 years	57/ 67 (85.1)	26/ 33 (78.8)	1.08 (0.88, 1.32); p=0.4596	1.53 (0.53, 4.48); p=0.4334	0.06 (-0.10, 0.23); p=0.4511	
	Sex						0.9281
	female	101/ 123 (82.1)	47/ 60 (78.3)	1.05 (0.90, 1.23); p=0.5552	1.27 (0.59, 2.74); p=0.5421	0.04 (-0.09, 0.16); p=0.5511	
	male	3/ 5 (60.0)	3/ 5 (60.0)	1.00 (0.36, 2.75); p=1.0000	1.00 (0.08, 12.56); p=1.0000	0.00 (-0.61, 0.61); p=1.0000	
	Race						
	white	91/ 114 (79.8)	41/ 56 (73.2)				
	black	2/ 2 (100.0)	2/ 2 (100.0)				
	asian	7/ 7 (100.0)	4/ 4 (100.0)				
	other	4/ 5 (80.0)	3/ 3 (100.0)				
	Region						0.0202
	North America	41/ 50 (82.0)	5/ 13 (38.5)	2.13 (1.06, 4.29); p=0.0340	7.29 (1.93, 27.56); p=0.0034	0.44 (0.15, 0.72); p=0.0028	
	Europe	33/ 39 (84.6)	19/ 24 (79.2)	1.07 (0.84, 1.37); p=0.5944	1.45 (0.39, 5.39); p=0.5813	0.05 (-0.14, 0.25); p=0.5897	
	Rest-of-World	30/ 39 (76.9)	26/ 28 (92.9)	0.83 (0.68, 1.01); p=0.0654	0.26 (0.05, 1.30); p=0.0996	-0.16 (-0.32, 0.00); p=0.0554	
	Cirrhosis						0.2426
	yes	11/ 18 (61.1)	3/ 9 (33.3)	1.83 (0.68, 4.96); p=0.2324	3.14 (0.59, 16.84); p=0.1813	0.28 (-0.10, 0.66); p=0.1536	
	no	93/ 110 (84.5)	47/ 56 (83.9)	1.01 (0.88, 1.16); p=0.9182	1.05 (0.43, 2.53); p=0.9177	0.01 (-0.11, 0.12); p=0.9181	
	UDCA						0.1553
	UDCA Use	97/ 120 (80.8)	50/ 62 (80.6)	1.00 (0.86, 1.16); p=0.9757	1.01 (0.47, 2.20); p=0.9756	0.00 (-0.12, 0.12); p=0.9757	
	UDCA Intolerance	7/ 8 (87.5)	0/ 3 (0.0)	6.67 (0.49, 90.59); p=0.1541	35.00 (1.12, 1094.73); p=0.0430	0.88 (0.65, 1.00); p=<.0001	
	Prior Use of OCA and/or Fibrates						0.2769
	yes	15/ 20 (75.0)	11/ 13 (84.6)	0.89 (0.63, 1.25); p=0.4908	0.55 (0.09, 3.35); p=0.5128	-0.10 (-0.37, 0.18); p=0.4899	
	no	89/ 108 (82.4)	39/ 52 (75.0)	1.10 (0.92, 1.31); p=0.3037	1.56 (0.70, 3.47); p=0.2747	0.07 (-0.06, 0.21); p=0.2923	
	Therapy						0.1565
	Monotherapy (SEL)	7/ 8 (87.5)	1/ 4 (25.0)	3.50 (0.63, 19.50); p=0.1528	21.00 (0.96, 458.84); p=0.0530	0.63 (0.14, 1.00); p=0.0111	
	Combinationtherapy (SEL + UDCA)	97/ 120 (80.8)	49/ 61 (80.3)	1.01 (0.86, 1.17); p=0.9354	1.03 (0.47, 2.25); p=0.9351	0.01 (-0.12, 0.13); p=0.9353	
	Stratification variable: Baseline Pruritus NRS						0.7901
	< 4	69/ 79 (87.3)	34/ 42 (81.0)	1.08 (0.91, 1.28); p=0.3784	1.62 (0.59, 4.49); p=0.3500	0.06 (-0.08, 0.20); p=0.3696	
	>= 4	35/ 49 (71.4)	16/ 23 (69.6)	1.03 (0.74, 1.42); p=0.8726	1.09 (0.37, 3.23); p=0.8712	0.02 (-0.21, 0.25); p=0.8720	
	Stratification variable: Baseline ALP Level						0.0465
	< 350 U/L	78/ 93 (83.9)	34/ 47 (72.3)	1.16 (0.95, 1.41); p=0.1431	1.99 (0.85, 4.63); p=0.1109	0.12 (-0.03, 0.26); p=0.1271	
	>= 350 U/L	26/ 35 (74.3)	16/ 18 (88.9)	0.84 (0.65, 1.08); p=0.1666	0.36 (0.07, 1.89); p=0.2274	-0.15 (-0.35, 0.06); p=0.1628	

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of subjects with event; N=Number of patients included in the analysis; CI=Confidence Interval; OR=Odds Ratio; RR=Relative Risk; RD=Risk Difference; NE=Not estimable

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Number and Proportion of subjects with total bilirubin <= ULN at 6 and 12 months - Subgroup analysis
Intention-to-treat

Timepoint	Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	Seladelpar 10 mg vs. Placebo OR (95% CI); p-Value	Seladelpar 10 mg vs. Placebo RD (95% CI); p-Value	Interaction p-Value
Month 12	Gamma-GT (GGT)						0.6519
	<= 3.2 x ULN	34/ 38 (89.5)	16/ 18 (88.9)	1.01 (0.83, 1.23); p=0.9478	1.06 (0.18, 6.42); p=0.9473	0.01 (-0.17, 0.18); p=0.9478	
	> 3.2 x ULN	70/ 90 (77.8)	34/ 47 (72.3)	1.08 (0.87, 1.32); p=0.4956	1.34 (0.60, 3.01); p=0.4806	0.05 (-0.10, 0.21); p=0.4891	
	Total Bilirubin I						0.3646
	<= 1 x ULN	90/ 108 (83.3)	48/ 60 (80.0)	1.04 (0.89, 1.21); p=0.5988	1.25 (0.56, 2.81); p=0.5893	0.03 (-0.09, 0.16); p=0.5960	
	> 1 x ULN	14/ 20 (70.0)	2/ 5 (40.0)	1.75 (0.58, 5.32); p=0.3236	3.50 (0.46, 26.62); p=0.2262	0.30 (-0.17, 0.77); p=0.2148	
	Total Bilirubin II						0.8129
	< 0.6 x ULN	56/ 59 (94.9)	28/ 32 (87.5)	1.08 (0.94, 1.25); p=0.2671	2.67 (0.56, 12.74); p=0.2191	0.07 (-0.05, 0.20); p=0.2546	
	>= 0.6 x ULN	48/ 69 (69.6)	22/ 33 (66.7)	1.04 (0.78, 1.39); p=0.7716	1.14 (0.47, 2.77); p=0.7680	0.03 (-0.17, 0.22); p=0.7697	

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of subjects with event; N=Number of patients included in the analysis; CI=Confidence Interval; OR=Odds Ratio; RR=Relative Risk; RD=Risk Difference; NE=Not estimable

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Summary of mean values, absolute and relative changes from baseline of total bilirubin by visit
Intention-to-treat

		Seladelpar 10 mg (N=128)				Placebo (N=65)			
		Value at Timepoint		Change from Baseline		Value at Timepoint		Change from Baseline	
Variable	Timepoint	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Change from baseline	Baseline	128	0.77 (0.31)	0	-	65	0.74 (0.31)	0	-
	Month 1	125	0.71 (0.28)	125	-0.07 (0.18)	62	0.71 (0.30)	62	-0.01 (0.14)
	Month 3	125	0.69 (0.29)	125	-0.08 (0.16)	62	0.67 (0.26)	62	-0.04 (0.15)
	Month 6	122	0.70 (0.36)	122	-0.07 (0.27)	61	0.71 (0.34)	61	0.00 (0.24)
	Month 9	117	0.69 (0.34)	117	-0.08 (0.24)	58	0.69 (0.24)	58	-0.02 (0.19)
	Month 12	114	0.73 (0.48)	114	-0.03 (0.42)	57	0.71 (0.29)	57	-0.00 (0.19)
	Safety Follow-up	22	0.84 (0.40)	22	-0.05 (0.35)	8	1.24 (0.92)	8	0.30 (0.81)

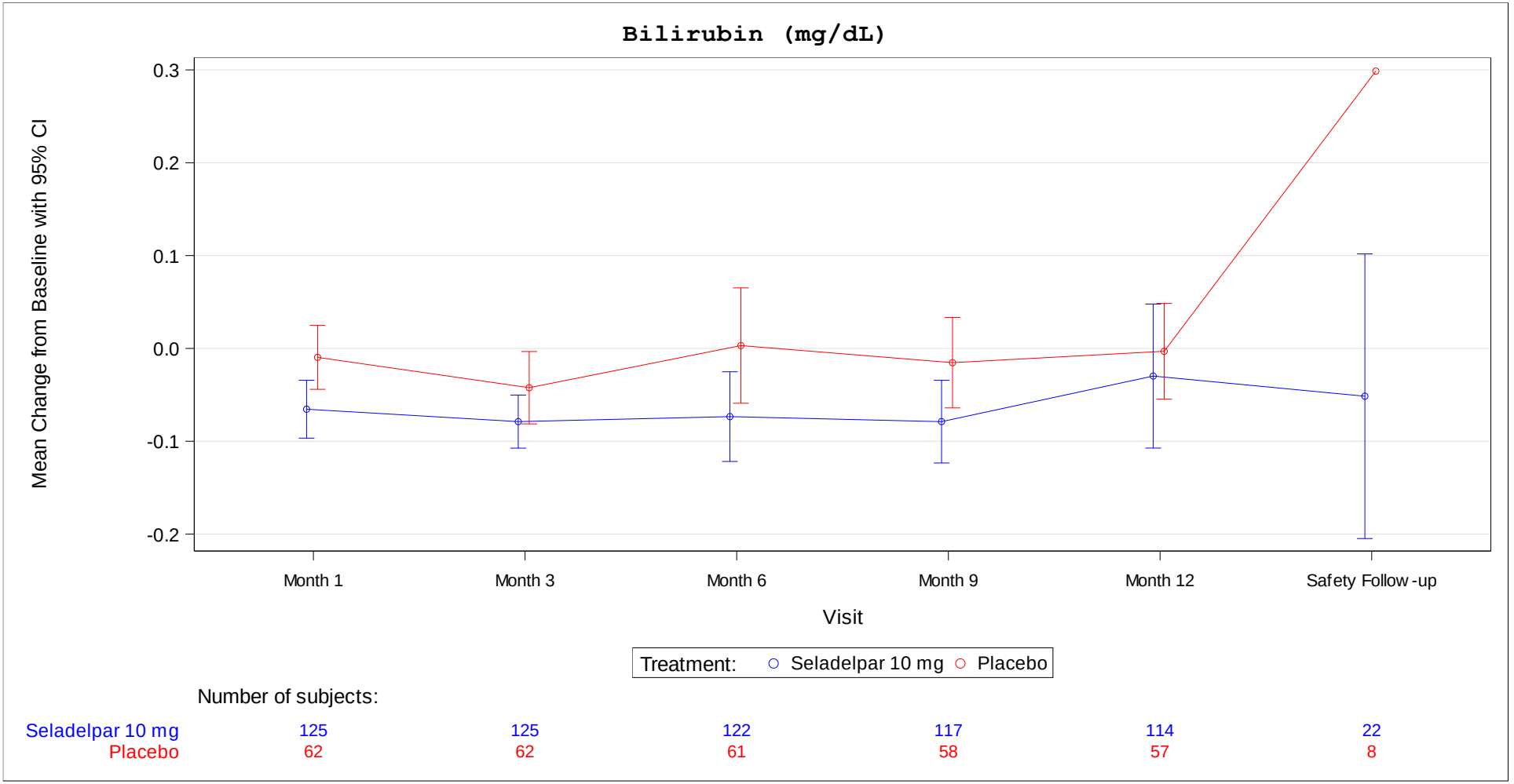
N describes number of patients with non-missing value at the respective timepoint.
N=Number of subjects included in the analysis, SD: Standard Deviation; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Summary of mean values, absolute and relative changes from baseline of total bilirubin by visit
Intention-to-treat

		Seladelpar 10 mg (N=128)				Placebo (N=65)			
		Value at Timepoint		Change from Baseline		Value at Timepoint		Change from Baseline	
Variable	Timepoint	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Percent change from baseline	Baseline	128	0.77 (0.31)	0	-	65	0.74 (0.31)	0	-
	Month 1	125	0.71 (0.28)	125	-6.38 (22.53)	62	0.71 (0.30)	62	-0.58 (19.25)
	Month 3	125	0.69 (0.29)	125	-9.07 (17.99)	62	0.67 (0.26)	62	-5.56 (18.98)
	Month 6	122	0.70 (0.36)	122	-8.62 (27.05)	61	0.71 (0.34)	61	1.25 (30.74)
	Month 9	117	0.69 (0.34)	117	-8.76 (29.71)	58	0.69 (0.24)	58	1.14 (24.57)
	Month 12	114	0.73 (0.48)	114	-2.59 (49.56)	57	0.71 (0.29)	57	2.10 (30.72)
	Safety Follow-up	22	0.84 (0.40)	22	-4.20 (32.63)	8	1.24 (0.92)	8	31.52 (79.68)

N describes number of patients with non-missing value at the respective timepoint.
N=Number of subjects included in the analysis, SD: Standard Deviation; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Graphical summary of change from baseline of total bilirubin by visit
Intention-to-treat



Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of absolute and relative changes from baseline of total bilirubin by visit
Intention-to-treat

		Seladelpar 10 mg (N=128)		Placebo (N=65)				
Score	Visit	N	LSMean (SE)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)
Change from baseline	Month 1	126	-0.06 (0.01)	63	-0.01 (0.02)	-0.05 (-0.09, 0.00)	0.0513	-0.29 (-0.59, 0.02)
	Month 3	126	-0.07 (0.01)	63	-0.05 (0.02)	-0.03 (-0.07, 0.02)	0.2464	-0.17 (-0.47, 0.13)
	Month 6	126	-0.07 (0.02)	63	0.00 (0.03)	-0.07 (-0.15, 0.01)	0.0896	-0.26 (-0.56, 0.05)
	Month 9	126	-0.06 (0.02)	63	-0.00 (0.03)	-0.05 (-0.13, 0.02)	0.1800	-0.20 (-0.51, 0.10)
	Month 12	126	-0.00 (0.04)	63	0.02 (0.05)	-0.02 (-0.14, 0.11)	0.7777	-0.04 (-0.35, 0.26)

(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
N=Number of subjects included in the analysis, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of absolute and relative changes from baseline of total bilirubin by visit
Intention-to-treat

		Seladelpar 10 mg (N=128)		Placebo (N=65)		Difference of		
Score	Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)
Percent change from baseline	Month 1	126	-6.07 (1.99)	63	-0.75 (2.75)	-5.33 (-11.82, 1.16)	0.1069	-0.24 (-0.54, 0.06)
	Month 3	126	-8.80 (1.75)	63	-5.77 (2.40)	-3.03 (-8.65, 2.59)	0.2889	-0.16 (-0.46, 0.15)
	Month 6	126	-8.25 (2.63)	63	1.20 (3.66)	-9.45 (-18.19, -0.70)	0.0344	-0.32 (-0.62, -0.02)
	Month 9	126	-6.75 (2.82)	63	2.52 (3.96)	-9.27 (-18.74, 0.20)	0.0550	-0.29 (-0.60, 0.01)
	Month 12	126	-0.38 (4.24)	63	3.55 (6.00)	-3.93 (-18.36, 10.50)	0.5914	-0.08 (-0.38, 0.22)

(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
N=Number of subjects included in the analysis, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of absolute and relative changes from baseline of total bilirubin at month 6 and 12 - Subgroup analysis
Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
			Baseline		Change from BL		Baseline		Change from BL					
Variable	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
Change from baseline	Month 6	Age at screening												0.5197
		< 65 years	99	0.78 (0.33)	97	-0.06 (0.03)	53	0.72 (0.33)	51	-0.01 (0.04)	-0.06 (-0.16, 0.04)	0.2397	-0.20 (-0.54, 0.14)	
		>= 65 years	29	0.74 (0.24)	29	-0.08 (0.03)	12	0.79 (0.23)	12	0.03 (0.05)	-0.11 (-0.22, 0.01)	0.0683	-0.61 (-1.30, 0.08)	
		Age at PBC diagnosis												0.7953
		< 50 years	61	0.82 (0.33)	59	-0.05 (0.04)	32	0.72 (0.34)	30	0.01 (0.06)	-0.06 (-0.21, 0.09)	0.4152	-0.18 (-0.62, 0.26)	
		>= 50 years	67	0.73 (0.30)	67	-0.09 (0.02)	33	0.76 (0.28)	33	-0.00 (0.03)	-0.08 (-0.15, -0.02)	0.0175	-0.48 (-0.90, -0.06)	
		Sex												0.1824
		female	123	0.76 (0.31)	121	-0.07 (0.02)	60	0.72 (0.29)	58	0.01 (0.04)	-0.08 (-0.17, 0.00)	0.0502	-0.31 (-0.62, 0.00)	
		male	5	0.94 (0.47)	5	-0.08 (0.08)	5	0.99 (0.42)	5	-0.15 (0.07)	0.07 (-0.18, 0.31)	0.5359	0.37 (-0.89, 1.62)	
		Race												
		white	114	0.77 (0.32)	113		56	0.74 (0.32)	54					
		black	2	0.88 (0.07)	2		2	0.50 (0.34)	2					
		asian	7	0.84 (0.26)	7		4	0.77 (0.08)	4					
		other	5	0.62 (0.14)	4		3	0.76 (0.34)	3					
		Region												0.3878
		North America	50	0.73 (0.26)	49	-0.08 (0.04)	13	0.83 (0.44)	12	0.09 (0.07)	-0.17 (-0.32, -0.01)	0.0333	-0.64 (-1.29, -0.00)	
		Europe	39	0.77 (0.34)	39	-0.04 (0.04)	24	0.76 (0.32)	23	-0.01 (0.06)	-0.03 (-0.18, 0.11)	0.6378	-0.12 (-0.64, 0.39)	
		Rest-of-World	39	0.82 (0.35)	38	-0.08 (0.04)	28	0.67 (0.22)	28	-0.03 (0.05)	-0.05 (-0.18, 0.08)	0.4633	-0.18 (-0.67, 0.31)	
		Cirrhosis												0.1706
		yes	18	0.97 (0.34)	18	-0.10 (0.09)	9	0.98 (0.39)	9	0.15 (0.13)	-0.25 (-0.57, 0.07)	0.1190	-0.64 (-1.46, 0.18)	
		no	110	0.74 (0.30)	108	-0.06 (0.02)	56	0.70 (0.28)	54	-0.03 (0.03)	-0.03 (-0.11, 0.05)	0.4200	-0.13 (-0.46, 0.20)	
		UDCA												0.2756
		UDCA Use	120	0.77 (0.32)	118	-0.07 (0.03)	62	0.73 (0.31)	60	0.00 (0.03)	-0.07 (-0.15, 0.02)	0.1162	-0.25 (-0.56, 0.07)	
		UDCA Intolerance	8	0.78 (0.21)	8	-0.09 (0.05)	3	0.85 (0.31)	3	0.11 (0.10)	-0.20 (-0.49, 0.09)	0.1387	-1.26 (-2.74, 0.22)	
		Prior Use of OCA and/or Fibrates												0.0880
		yes	20	0.77 (0.24)	18	0.04 (0.07)	13	0.61 (0.19)	12	-0.06 (0.09)	0.10 (-0.13, 0.33)	0.3711	0.33 (-0.41, 1.07)	
		no	108	0.77 (0.33)	108	-0.09 (0.02)	52	0.77 (0.33)	51	0.02 (0.04)	-0.10 (-0.19, -0.02)	0.0167	-0.40 (-0.74, -0.06)	
		Therapy												0.3411
		Monotherapy (SEL)	8	0.78 (0.21)	8	-0.08 (0.04)	4	0.80 (0.27)	4	0.07 (0.07)	-0.15 (-0.38, 0.08)	0.1369	-1.12 (-2.43, 0.20)	
		Combinationtherapy (SEL + UDCA)	120	0.77 (0.32)	118	-0.07 (0.03)	61	0.73 (0.31)	59	-0.00 (0.04)	-0.07 (-0.15, 0.02)	0.1267	-0.24 (-0.55, 0.07)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of absolute and relative changes from baseline of total bilirubin at month 6 and 12 - Subgroup analysis
Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
			Baseline		Change from BL		Baseline		Change from BL					
Variable	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
Change from baseline	Month 6	Stratification variable: Baseline Pruritus NRS												0.3782
		< 4	79	0.74 (0.31)	79	-0.10 (0.02)	42	0.75 (0.33)	41	-0.00 (0.03)	-0.10 (-0.18, -0.03)	0.0068	-0.50 (-0.89, -0.12)	
		>= 4	49	0.82 (0.32)	47	-0.02 (0.05)	23	0.71 (0.27)	22	-0.00 (0.08)	-0.02 (-0.20, 0.17)	0.8524	-0.05 (-0.55, 0.46)	
		Stratification variable: Baseline ALP Level												0.0737
		< 350 U/L	93	0.73 (0.31)	92	-0.10 (0.02)	47	0.70 (0.30)	45	0.02 (0.03)	-0.13 (-0.20, -0.06)	0.0005	-0.63 (-0.99, -0.26)	
		>= 350 U/L	35	0.87 (0.31)	34	0.02 (0.06)	18	0.84 (0.33)	18	-0.05 (0.09)	0.08 (-0.14, 0.29)	0.4843	0.20 (-0.37, 0.78)	
		Gamma-GT (GGT)												0.8233
		<= 3 x ULN	33	0.76 (0.33)	32	-0.10 (0.03)	14	0.54 (0.17)	13	-0.03 (0.04)	-0.07 (-0.16, 0.02)	0.1229	-0.42 (-1.07, 0.23)	
		> 3 x ULN	95	0.77 (0.31)	94	-0.05 (0.03)	51	0.79 (0.32)	50	0.00 (0.04)	-0.06 (-0.16, 0.04)	0.2741	-0.19 (-0.53, 0.15)	
		Total Bilirubin I												0.4772
		<= 1 x ULN	108	0.66 (0.18)	106	-0.03 (0.03)	60	0.68 (0.21)	59	0.01 (0.03)	-0.05 (-0.13, 0.03)	0.2451	-0.18 (-0.50, 0.13)	
		> 1 x ULN	20	1.35 (0.24)	20	-0.27 (0.06)	5	1.48 (0.34)	4	-0.11 (0.14)	-0.16 (-0.48, 0.16)	0.3085	-0.61 (-1.70, 0.48)	
		Total Bilirubin II												0.4178
		< 0.6 x ULN	59	0.53 (0.09)	58	-0.05 (0.02)	32	0.51 (0.10)	31	-0.01 (0.02)	-0.04 (-0.08, 0.01)	0.1053	-0.33 (-0.77, 0.11)	
		>= 0.6 x ULN	69	0.98 (0.29)	68	-0.09 (0.04)	33	0.96 (0.28)	32	0.01 (0.06)	-0.10 (-0.25, 0.05)	0.1774	-0.29 (-0.71, 0.13)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of absolute and relative changes from baseline of total bilirubin at month 6 and 12 - Subgroup analysis
Intention-to-treat

Variable	Timepoint	Subgroup Level	Seladelpar 10 mg (N=128) Baseline N	Seladelpar 10 mg (N=128) Baseline Mean (SD)	Seladelpar 10 mg (N=128) Change from BL N	Seladelpar 10 mg (N=128) Change from BL LSMean (SE)	Placebo (N=65) Baseline N	Placebo (N=65) Baseline Mean (SD)	Placebo (N=65) Change from BL N	Placebo (N=65) Change from BL LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
Change from baseline	Month 12	Age at screening												0.8116
		< 65 years	99	0.78 (0.33)	97	-0.03 (0.03)	53	0.72 (0.33)	51	0.00 (0.04)	-0.03 (-0.13, 0.07)	0.5309	-0.11 (-0.45, 0.23)	
		>= 65 years	29	0.74 (0.24)	29	0.03 (0.11)	12	0.79 (0.23)	12	0.01 (0.16)	0.02 (-0.38, 0.41)	0.9335	0.03 (-0.64, 0.70)	
		Age at PBC diagnosis												0.6851
		< 50 years	61	0.82 (0.33)	59	-0.02 (0.04)	32	0.72 (0.34)	30	0.03 (0.05)	-0.05 (-0.18, 0.09)	0.4739	-0.16 (-0.60, 0.28)	
		>= 50 years	67	0.73 (0.30)	67	-0.02 (0.05)	33	0.76 (0.28)	33	-0.01 (0.08)	-0.00 (-0.18, 0.18)	0.9842	-0.00 (-0.42, 0.41)	
		Sex												0.1632
		female	123	0.76 (0.31)	121	-0.01 (0.04)	60	0.72 (0.29)	58	0.03 (0.05)	-0.04 (-0.17, 0.09)	0.5241	-0.10 (-0.41, 0.21)	
		male	5	0.94 (0.47)	5	0.12 (0.14)	5	0.99 (0.42)	5	-0.12 (0.14)	0.24 (-0.20, 0.68)	0.2444	0.71 (-0.59, 2.02)	
		Race												
		white	114	0.77 (0.32)	113		56	0.74 (0.32)	54					
		black	2	0.88 (0.07)	2		2	0.50 (0.34)	2					
		asian	7	0.84 (0.26)	7		4	0.77 (0.08)	4					
		other	5	0.62 (0.14)	4		3	0.76 (0.34)	3					
		Region												0.1141
		North America	50	0.73 (0.26)	49	-0.02 (0.04)	13	0.83 (0.44)	12	0.20 (0.09)	-0.21 (-0.41, -0.01)	0.0363	-0.69 (-1.33, -0.04)	
		Europe	39	0.77 (0.34)	39	-0.07 (0.04)	24	0.76 (0.32)	23	-0.01 (0.06)	-0.06 (-0.20, 0.09)	0.4293	-0.20 (-0.72, 0.31)	
		Rest-of-World	39	0.82 (0.35)	38	0.09 (0.09)	28	0.67 (0.22)	28	-0.05 (0.11)	0.14 (-0.15, 0.43)	0.3281	0.24 (-0.25, 0.73)	
		Cirrhosis												0.6138
		yes	18	0.97 (0.34)	18	0.17 (0.25)	9	0.98 (0.39)	9	0.43 (0.37)	-0.26 (-1.21, 0.69)	0.5676	-0.24 (-1.04, 0.57)	
		no	110	0.74 (0.30)	108	-0.05 (0.02)	56	0.70 (0.28)	54	-0.01 (0.03)	-0.03 (-0.12, 0.05)	0.3920	-0.14 (-0.47, 0.19)	
		UDCA												0.0004
		UDCA Use	120	0.77 (0.32)	118	0.00 (0.04)	62	0.73 (0.31)	60	0.01 (0.05)	-0.00 (-0.13, 0.13)	0.9658	-0.01 (-0.32, 0.30)	
		UDCA Intolerance	8	0.78 (0.21)	8	-0.09 (0.04)	3	0.85 (0.31)	3	0.38 (0.10)	-0.47 (-0.73, -0.20)	0.0036	-3.21 (-5.34, -1.07)	
		Prior Use of OCA and/or Fibrates												0.1497
		yes	20	0.77 (0.24)	18	0.18 (0.10)	13	0.61 (0.19)	12	-0.02 (0.13)	0.20 (-0.19, 0.59)	0.2627	0.45 (-0.29, 1.19)	
		no	108	0.77 (0.33)	108	-0.03 (0.04)	52	0.77 (0.33)	51	0.02 (0.06)	-0.06 (-0.19, 0.08)	0.4273	-0.13 (-0.47, 0.20)	
		Therapy												0.0645
		Monotherapy (SEL)	8	0.78 (0.21)	8	-0.09 (0.07)	4	0.80 (0.27)	4	0.20 (0.12)	-0.29 (-0.65, 0.07)	0.0910	-1.24 (-2.59, 0.10)	
		Combinationtherapy (SEL + UDCA)	120	0.77 (0.32)	118	0.00 (0.04)	61	0.73 (0.31)	59	0.01 (0.05)	-0.01 (-0.14, 0.13)	0.9350	-0.01 (-0.33, 0.30)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of absolute and relative changes from baseline of total bilirubin at month 6 and 12 - Subgroup analysis
Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
			Baseline		Change from BL		Baseline		Change from BL					
Variable	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
Change from baseline	Month 12	Stratification variable: Baseline Pruritus NRS												0.3599
		< 4	79	0.74 (0.31)	79	-0.05 (0.03)	42	0.75 (0.33)	41	0.01 (0.04)	-0.06 (-0.16, 0.04)	0.2119	-0.23 (-0.61, 0.14)	
		>= 4	49	0.82 (0.32)	47	0.10 (0.09)	23	0.71 (0.27)	22	0.01 (0.13)	0.09 (-0.24, 0.42)	0.5750	0.15 (-0.36, 0.65)	
		Stratification variable: Baseline ALP Level												0.1935
		< 350 U/L	93	0.73 (0.31)	92	-0.04 (0.03)	47	0.70 (0.30)	45	0.04 (0.04)	-0.08 (-0.17, 0.02)	0.1202	-0.28 (-0.64, 0.08)	
		>= 350 U/L	35	0.87 (0.31)	34	0.14 (0.12)	18	0.84 (0.33)	18	-0.07 (0.17)	0.21 (-0.24, 0.65)	0.3447	0.28 (-0.29, 0.85)	
		Gamma-GT (GGT)												0.5584
		<= 3 x ULN	33	0.76 (0.33)	32	-0.07 (0.03)	14	0.54 (0.17)	13	-0.01 (0.05)	-0.05 (-0.15, 0.05)	0.3041	-0.29 (-0.93, 0.36)	
		> 3 x ULN	95	0.77 (0.31)	94	0.03 (0.05)	51	0.79 (0.32)	50	0.02 (0.07)	0.00 (-0.16, 0.17)	0.9638	0.01 (-0.34, 0.35)	
		Total Bilirubin I												0.9829
		<= 1 x ULN	108	0.66 (0.18)	106	0.05 (0.04)	60	0.68 (0.21)	59	0.04 (0.06)	0.01 (-0.13, 0.15)	0.8975	0.02 (-0.30, 0.34)	
		> 1 x ULN	20	1.35 (0.24)	20	-0.26 (0.07)	5	1.48 (0.34)	4	-0.26 (0.17)	0.00 (-0.38, 0.39)	0.9799	0.01 (-1.06, 1.09)	
		Total Bilirubin II												0.6966
		< 0.6 x ULN	59	0.53 (0.09)	58	-0.04 (0.02)	32	0.51 (0.10)	31	0.01 (0.02)	-0.05 (-0.11, 0.01)	0.0865	-0.36 (-0.80, 0.08)	
		>= 0.6 x ULN	69	0.98 (0.29)	68	0.04 (0.07)	33	0.96 (0.28)	32	0.04 (0.10)	-0.00 (-0.25, 0.25)	0.9976	-0.00 (-0.42, 0.42)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
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N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of absolute and relative changes from baseline of total bilirubin at month 6 and 12 - Subgroup analysis
Intention-to-treat

Variable	Timepoint	Subgroup Level	Seladelpar 10 mg (N=128) Baseline N	Seladelpar 10 mg (N=128) Baseline Mean (SD)	Seladelpar 10 mg (N=128) Change from BL N	Seladelpar 10 mg (N=128) Change from BL LSMean (SE)	Placebo (N=65) Baseline N	Placebo (N=65) Baseline Mean (SD)	Placebo (N=65) Change from BL N	Placebo (N=65) Change from BL LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
Percent change from baseline	Month 6	Age at screening												0.7208
		< 65 years	99	0.78 (0.33)	97	-7.89 (3.22)	53	0.72 (0.33)	51	0.84 (4.37)	-8.74 (-19.33, 1.86)	0.1053	-0.28 (-0.62, 0.07)	
		>= 65 years	29	0.74 (0.24)	29	-9.66 (3.91)	12	0.79 (0.23)	12	2.23 (6.12)	-11.88 (-26.03, 2.26)	0.0971	-0.55 (-1.24, 0.13)	
		Age at PBC diagnosis												0.9341
		< 50 years	61	0.82 (0.33)	59	-7.76 (4.71)	32	0.72 (0.34)	30	2.34 (6.59)	-10.11 (-26.15, 5.94)	0.2139	-0.28 (-0.72, 0.16)	
		>= 50 years	67	0.73 (0.30)	67	-9.52 (2.76)	33	0.76 (0.28)	33	-0.17 (3.79)	-9.34 (-18.21, -0.48)	0.0391	-0.41 (-0.84, 0.01)	
		Sex												0.0014
		female	123	0.76 (0.31)	121	-8.69 (2.72)	60	0.72 (0.29)	58	2.37 (3.89)	-11.06 (-20.31, -1.81)	0.0194	-0.37 (-0.68, -0.05)	
		male	5	0.94 (0.47)	5	4.23 (5.06)	5	0.99 (0.42)	5	-10.79 (4.74)	15.02 (-0.58, 30.62)	0.0571	1.24 (-0.18, 2.66)	
		Race												
		white	114	0.77 (0.32)	113		56	0.74 (0.32)	54					
		black	2	0.88 (0.07)	2		2	0.50 (0.34)	2					
		asian	7	0.84 (0.26)	7		4	0.77 (0.08)	4					
		other	5	0.62 (0.14)	4		3	0.76 (0.34)	3					
		Region												0.3144
		North America	50	0.73 (0.26)	49	-11.33 (4.36)	13	0.83 (0.44)	12	9.45 (8.02)	-20.77 (-38.22, -3.32)	0.0206	-0.68 (-1.33, -0.04)	
		Europe	39	0.77 (0.34)	39	-4.04 (4.53)	24	0.76 (0.32)	23	-0.61 (6.05)	-3.43 (-18.39, 11.54)	0.6481	-0.12 (-0.63, 0.40)	
		Rest-of-World	39	0.82 (0.35)	38	-10.01 (5.07)	28	0.67 (0.22)	28	-0.85 (5.88)	-9.17 (-24.56, 6.22)	0.2384	-0.29 (-0.78, 0.20)	
		Cirrhosis												0.2430
		yes	18	0.97 (0.34)	18	-8.27 (9.04)	9	0.98 (0.39)	9	17.23 (13.12)	-25.50 (-58.32, 7.31)	0.1215	-0.64 (-1.46, 0.18)	
		no	110	0.74 (0.30)	108	-8.03 (2.69)	56	0.70 (0.28)	54	-1.77 (3.73)	-6.26 (-15.17, 2.65)	0.1673	-0.22 (-0.55, 0.10)	
		UDCA												0.1799
		UDCA Use	120	0.77 (0.32)	118	-8.02 (2.78)	62	0.73 (0.31)	60	1.16 (3.83)	-9.17 (-18.38, 0.03)	0.0507	-0.30 (-0.62, 0.01)	
		UDCA Intolerance	8	0.78 (0.21)	8	-13.58 (5.18)	3	0.85 (0.31)	3	14.18 (11.62)	-27.76 (-65.82, 10.29)	0.1090	-1.58 (-3.15, -0.02)	
		Prior Use of OCA and/or Fibrates												0.0403
		yes	20	0.77 (0.24)	18	3.84 (7.00)	13	0.61 (0.19)	12	-7.36 (8.55)	11.20 (-11.58, 33.98)	0.3225	0.37 (-0.37, 1.10)	
		no	108	0.77 (0.33)	108	-10.74 (2.82)	52	0.77 (0.33)	51	2.91 (4.04)	-13.65 (-23.18, -4.13)	0.0053	-0.47 (-0.80, -0.13)	
		Therapy												0.1593
		Monotherapy (SEL)	8	0.78 (0.21)	8	-13.01 (3.93)	4	0.80 (0.27)	4	8.98 (6.94)	-21.99 (-41.97, -2.01)	0.0363	-1.69 (-3.15, -0.23)	
		Combinationtherapy (SEL + UDCA)	120	0.77 (0.32)	118	-8.08 (2.79)	61	0.73 (0.31)	59	0.88 (3.88)	-8.96 (-18.23, 0.32)	0.0583	-0.30 (-0.61, 0.02)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of absolute and relative changes from baseline of total bilirubin at month 6 and 12 - Subgroup analysis
Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
			Baseline		Change from BL		Baseline		Change from BL					
Variable	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
Percent change from baseline	Month 6	Stratification variable: Baseline Pruritus NRS												0.2855
		< 4	79	0.74 (0.31)	79	-11.74 (3.02)	42	0.75 (0.33)	41	1.79 (4.00)	-13.54 (-23.07, -4.00)	0.0058	-0.51 (-0.89, -0.13)	
		>= 4	49	0.82 (0.32)	47	-3.10 (4.99)	23	0.71 (0.27)	22	-0.46 (7.47)	-2.64 (-20.61, 15.33)	0.7700	-0.08 (-0.58, 0.43)	
		Stratification variable: Baseline ALP Level												0.0541
		< 350 U/L	93	0.73 (0.31)	92	-11.68 (2.61)	47	0.70 (0.30)	45	4.15 (3.66)	-15.83 (-24.58, -7.08)	0.0005	-0.63 (-1.00, -0.27)	
		>= 350 U/L	35	0.87 (0.31)	34	0.23 (6.22)	18	0.84 (0.33)	18	-6.33 (8.76)	6.55 (-15.06, 28.16)	0.5448	0.18 (-0.40, 0.75)	
		Gamma-GT (GGT)												0.3796
		<= 3 x ULN	33	0.76 (0.33)	32	-7.35 (5.39)	14	0.54 (0.17)	13	7.89 (7.52)	-15.24 (-30.96, 0.49)	0.0572	-0.51 (-1.16, 0.15)	
		> 3 x ULN	95	0.77 (0.31)	94	-7.22 (3.19)	51	0.79 (0.32)	50	-0.30 (4.36)	-6.92 (-17.52, 3.69)	0.1993	-0.22 (-0.57, 0.12)	
		Total Bilirubin I												0.7059
		<= 1 x ULN	108	0.66 (0.18)	106	-6.33 (3.01)	60	0.68 (0.21)	59	2.13 (3.93)	-8.46 (-17.98, 1.07)	0.0816	-0.27 (-0.59, 0.05)	
		> 1 x ULN	20	1.35 (0.24)	20	-19.39 (4.14)	5	1.48 (0.34)	4	-6.28 (10.60)	-13.11 (-36.82, 10.60)	0.2622	-0.67 (-1.76, 0.42)	
		Total Bilirubin II												0.8297
		< 0.6 x ULN	59	0.53 (0.09)	58	-8.38 (3.16)	32	0.51 (0.10)	31	0.05 (4.00)	-8.43 (-17.81, 0.96)	0.0778	-0.36 (-0.80, 0.08)	
		>= 0.6 x ULN	69	0.98 (0.29)	68	-8.52 (4.14)	33	0.96 (0.28)	32	1.79 (6.10)	-10.31 (-24.90, 4.29)	0.1643	-0.30 (-0.72, 0.12)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of absolute and relative changes from baseline of total bilirubin at month 6 and 12 - Subgroup analysis
Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
			Baseline		Change from BL		Baseline		Change from BL					
Variable	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
Percent change from baseline	Month 12	Age at screening												0.7085
		< 65 years	99	0.78 (0.33)	97	-2.89 (3.52)	53	0.72 (0.33)	51	3.58 (4.87)	-6.47 (-18.24, 5.30)	0.2783	-0.19 (-0.53, 0.15)	
		>= 65 years	29	0.74 (0.24)	29	3.23 (13.35)	12	0.79 (0.23)	12	0.34 (20.42)	2.89 (-46.30, 52.07)	0.9061	0.04 (-0.63, 0.71)	
		Age at PBC diagnosis												0.4271
		< 50 years	61	0.82 (0.33)	59	-1.82 (4.98)	32	0.72 (0.34)	30	8.33 (7.09)	-10.14 (-27.49, 7.21)	0.2459	-0.26 (-0.70, 0.18)	
		>= 50 years	67	0.73 (0.30)	67	-0.36 (6.56)	33	0.76 (0.28)	33	-1.49 (9.27)	1.13 (-21.23, 23.50)	0.9202	0.02 (-0.40, 0.44)	
		Sex												0.0540
		female	123	0.76 (0.31)	121	-1.44 (4.37)	60	0.72 (0.29)	58	5.01 (6.32)	-6.45 (-21.55, 8.66)	0.4002	-0.13 (-0.45, 0.18)	
		male	5	0.94 (0.47)	5	24.80 (13.30)	5	0.99 (0.42)	5	-8.45 (13.87)	33.25 (-10.62, 77.12)	0.1192	0.99 (-0.37, 2.35)	
		Race												
		white	114	0.77 (0.32)	113		56	0.74 (0.32)	54					
		black	2	0.88 (0.07)	2		2	0.50 (0.34)	2					
		asian	7	0.84 (0.26)	7		4	0.77 (0.08)	4					
		other	5	0.62 (0.14)	4		3	0.76 (0.34)	3					
		Region												0.0500
		North America	50	0.73 (0.26)	49	-4.18 (5.71)	13	0.83 (0.44)	12	30.34 (11.65)	-34.51 (-60.03, -9.00)	0.0091	-0.85 (-1.50, -0.20)	
		Europe	39	0.77 (0.34)	39	-3.52 (5.14)	24	0.76 (0.32)	23	0.68 (6.52)	-4.20 (-20.67, 12.27)	0.6113	-0.13 (-0.65, 0.39)	
		Rest-of-World	39	0.82 (0.35)	38	6.49 (10.26)	28	0.67 (0.22)	28	-4.42 (11.95)	10.91 (-20.70, 42.51)	0.4913	0.17 (-0.32, 0.66)	
		Cirrhosis												0.5729
		yes	18	0.97 (0.34)	18	22.19 (32.09)	9	0.98 (0.39)	9	61.52 (47.50)	-39.33 (-161.37, 82.72)	0.5029	-0.28 (-1.08, 0.53)	
		no	110	0.74 (0.30)	108	-5.60 (3.08)	56	0.70 (0.28)	54	1.29 (4.25)	-6.89 (-17.11, 3.33)	0.1848	-0.22 (-0.54, 0.11)	
		UDCA												0.0009
		UDCA Use	120	0.77 (0.32)	118	0.35 (4.51)	62	0.73 (0.31)	60	2.37 (6.28)	-2.03 (-17.24, 13.18)	0.7923	-0.04 (-0.35, 0.27)	
		UDCA Intolerance	8	0.78 (0.21)	8	-12.63 (5.08)	3	0.85 (0.31)	3	45.07 (13.57)	-57.70 (-92.87, -22.54)	0.0062	-3.14 (-5.24, -1.03)	
		Prior Use of OCA and/or Fibrates												0.2479
		yes	20	0.77 (0.24)	18	17.42 (10.60)	13	0.61 (0.19)	12	1.92 (13.14)	15.51 (-23.64, 54.65)	0.3869	0.33 (-0.40, 1.07)	
		no	108	0.77 (0.33)	108	-3.27 (4.72)	52	0.77 (0.33)	51	2.99 (6.87)	-6.27 (-22.64, 10.10)	0.4501	-0.13 (-0.46, 0.21)	
		Therapy												0.0810
		Monotherapy (SEL)	8	0.78 (0.21)	8	-12.06 (9.60)	4	0.80 (0.27)	4	25.34 (15.81)	-37.40 (-89.01, 14.21)	0.1140	-1.21 (-2.55, 0.13)	
		Combinationtherapy (SEL + UDCA)	120	0.77 (0.32)	118	0.31 (4.52)	61	0.73 (0.31)	59	2.74 (6.36)	-2.43 (-17.78, 12.92)	0.7545	-0.05 (-0.36, 0.26)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of absolute and relative changes from baseline of total bilirubin at month 6 and 12 - Subgroup analysis
Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
			Baseline		Change from BL		Baseline		Change from BL					
Variable	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
Percent change from baseline	Month 12	Stratification variable: Baseline Pruritus NRS												0.3314
		< 4	79	0.74 (0.31)	79	-5.46 (3.88)	42	0.75 (0.33)	41	2.69 (5.26)	-8.15 (-20.81, 4.51)	0.2045	-0.24 (-0.62, 0.14)	
		>= 4	49	0.82 (0.32)	47	12.18 (10.62)	23	0.71 (0.27)	22	0.80 (15.84)	11.38 (-27.39, 50.14)	0.5548	0.15 (-0.35, 0.66)	
		Stratification variable: Baseline ALP Level												0.1571
		< 350 U/L	93	0.73 (0.31)	92	-4.14 (3.58)	47	0.70 (0.30)	45	7.47 (5.16)	-11.61 (-23.94, 0.72)	0.0646	-0.34 (-0.69, 0.02)	
		>= 350 U/L	35	0.87 (0.31)	34	15.43 (13.42)	18	0.84 (0.33)	18	-6.38 (18.42)	21.81 (-25.37, 68.99)	0.3486	0.27 (-0.30, 0.85)	
		Gamma-GT (GGT)												0.2382
		<= 3 x ULN	33	0.76 (0.33)	32	-2.89 (6.45)	14	0.54 (0.17)	13	13.21 (9.44)	-16.10 (-36.87, 4.66)	0.1251	-0.44 (-1.09, 0.21)	
		> 3 x ULN	95	0.77 (0.31)	94	2.35 (5.46)	51	0.79 (0.32)	50	2.12 (7.51)	0.23 (-18.16, 18.63)	0.9800	0.00 (-0.34, 0.35)	
		Total Bilirubin I												0.8882
		<= 1 x ULN	108	0.66 (0.18)	106	3.03 (4.90)	60	0.68 (0.21)	59	5.08 (6.53)	-2.06 (-18.06, 13.95)	0.7999	-0.04 (-0.36, 0.28)	
		> 1 x ULN	20	1.35 (0.24)	20	-18.18 (4.57)	5	1.48 (0.34)	4	-18.19 (11.40)	0.01 (-25.59, 25.61)	0.9994	0.00 (-1.07, 1.07)	
		Total Bilirubin II												0.3863
		< 0.6 x ULN	59	0.53 (0.09)	58	-6.62 (3.88)	32	0.51 (0.10)	31	4.95 (5.21)	-11.58 (-23.92, 0.76)	0.0655	-0.39 (-0.83, 0.05)	
		>= 0.6 x ULN	69	0.98 (0.29)	68	7.20 (7.97)	33	0.96 (0.28)	32	5.42 (11.66)	1.78 (-26.66, 30.21)	0.9003	0.03 (-0.39, 0.45)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Summary of mean values, absolute and relative changes from baseline of enhanced liver fibrosis (ELF) by visit
Intention-to-treat

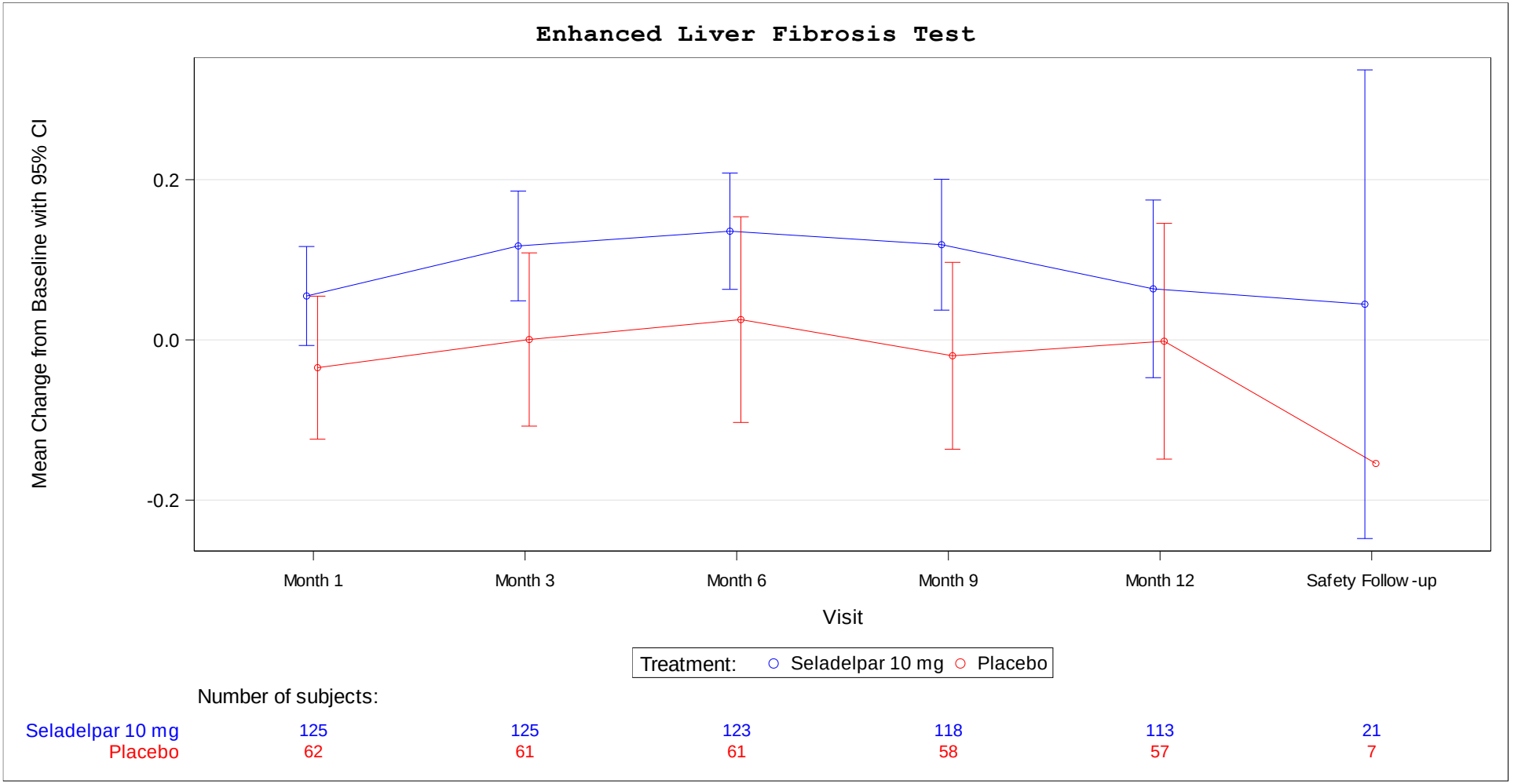
		Seladelpar 10 mg (N=128)				Placebo (N=65)			
		Value at Timepoint		Change from Baseline		Value at Timepoint		Change from Baseline	
Variable	Timepoint	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Change from baseline	Baseline	128	10.16 (1.03)	0	-	65	10.23 (0.85)	0	-
	Month 1	125	10.22 (1.08)	125	0.05 (0.35)	62	10.18 (0.95)	62	-0.03 (0.35)
	Month 3	125	10.27 (1.06)	125	0.12 (0.39)	61	10.20 (0.97)	61	0.00 (0.42)
	Month 6	123	10.27 (1.05)	123	0.14 (0.41)	61	10.22 (0.92)	61	0.03 (0.50)
	Month 9	118	10.25 (1.07)	118	0.12 (0.45)	58	10.20 (0.94)	58	-0.02 (0.44)
	Month 12	113	10.14 (1.07)	113	0.06 (0.59)	57	10.20 (0.99)	57	-0.00 (0.55)
	Safety Follow-up	21	10.65 (1.29)	21	0.04 (0.64)	7	9.92 (0.78)	7	-0.15 (0.48)

N describes number of patients with non-missing value at the respective timepoint.
N=Number of subjects included in the analysis, SD: Standard Deviation; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Summary of mean values, absolute and relative changes from baseline of enhanced liver fibrosis (ELF) by visit
Intention-to-treat

		Seladelpar 10 mg (N=128)				Placebo (N=65)			
		Value at Timepoint		Change from Baseline		Value at Timepoint		Change from Baseline	
Variable	Timepoint	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Percent change from baseline	Baseline	128	10.16 (1.03)	0	-	65	10.23 (0.85)	0	-
	Month 1	125	10.22 (1.08)	125	0.56 (3.42)	62	10.18 (0.95)	62	-0.36 (3.49)
	Month 3	125	10.27 (1.06)	125	1.21 (3.96)	61	10.20 (0.97)	61	-0.01 (4.16)
	Month 6	123	10.27 (1.05)	123	1.41 (4.00)	61	10.22 (0.92)	61	0.31 (4.96)
	Month 9	118	10.25 (1.07)	118	1.25 (4.45)	58	10.20 (0.94)	58	-0.17 (4.31)
	Month 12	113	10.14 (1.07)	113	0.74 (6.00)	57	10.20 (0.99)	57	0.01 (5.35)
	Safety Follow-up	21	10.65 (1.29)	21	0.40 (5.92)	7	9.92 (0.78)	7	-1.26 (4.46)

N describes number of patients with non-missing value at the respective timepoint.
N=Number of subjects included in the analysis, SD: Standard Deviation; CI=Confidence Interval


Enhanced Liver Fibrosis Test
Mean Change from Baseline with 95% CI
0.2
0.0
-0.2
Month 1
Month 3
Month 6
Month 9
Month 12
Safety Follow-up
Visit
Treatment: Seladelpar 10 mg Placebo
Number of subjects:
Seladelpar 10 mg 125 125 123 118 113 21
Placebo 62 61 61 58 57 7

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of absolute and relative changes from baseline of enhanced liver fibrosis (ELF) by visit
Intention-to-treat

		Seladelpar 10 mg (N=128)		Placebo (N=65)				
Score	Visit	N	LSMean (SE)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)
Change from baseline	Month 1	126	0.08 (0.03)	63	-0.01 (0.05)	0.09 (-0.01, 0.20)	0.0888	0.25 (-0.06, 0.55)
	Month 3	126	0.14 (0.04)	63	0.04 (0.05)	0.10 (-0.02, 0.23)	0.0967	0.25 (-0.06, 0.55)
	Month 6	126	0.16 (0.04)	63	0.06 (0.06)	0.10 (-0.03, 0.24)	0.1264	0.23 (-0.08, 0.53)
	Month 9	126	0.15 (0.04)	63	0.01 (0.06)	0.14 (0.00, 0.28)	0.0473	0.30 (-0.01, 0.60)
	Month 12	126	0.10 (0.06)	63	0.02 (0.08)	0.08 (-0.11, 0.26)	0.4215	0.12 (-0.18, 0.42)

(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
N=Number of subjects included in the analysis, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of absolute and relative changes from baseline of enhanced liver fibrosis (ELF) by visit
Intention-to-treat

		Seladelpar 10 mg (N=128)		Placebo (N=65)				
Score	Visit	N	LSMean (SE)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)
Percent change from baseline	Month 1	126	0.82 (0.33)	63	-0.13 (0.46)	0.95 (-0.11, 2.00)	0.0787	0.26 (-0.05, 0.56)
	Month 3	126	1.44 (0.38)	63	0.32 (0.53)	1.12 (-0.12, 2.36)	0.0767	0.26 (-0.04, 0.57)
	Month 6	126	1.66 (0.40)	63	0.63 (0.56)	1.04 (-0.28, 2.35)	0.1215	0.23 (-0.07, 0.53)
	Month 9	126	1.55 (0.41)	63	0.11 (0.58)	1.43 (0.07, 2.79)	0.0394	0.31 (0.00, 0.61)
	Month 12	126	1.08 (0.55)	63	0.25 (0.77)	0.83 (-1.00, 2.66)	0.3719	0.13 (-0.17, 0.44)

(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
N=Number of subjects included in the analysis, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Summary of mean values, absolute and relative changes from baseline of liver stiffness by visit
Intention-to-treat

		Seladelpar 10 mg (N=128)				Placebo (N=65)			
		Value at Timepoint		Change from Baseline		Value at Timepoint		Change from Baseline	
Variable	Timepoint	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Change from baseline	Baseline	115	9.84 (6.16)	0	-	62	8.74 (4.18)	0	-
	Month 1	1	13.90 (-)	1	-2.30 (-)	0	-	0	-
	Month 6	110	10.05 (8.09)	108	0.44 (4.32)	58	9.89 (8.41)	58	1.32 (5.97)
	Month 12	99	9.76 (7.98)	96	0.24 (4.39)	55	9.84 (10.00)	55	1.34 (7.56)
	Safety Follow-up	6	13.43 (9.38)	6	0.33 (4.80)	2	6.00 (0.14)	2	0.50 (0.71)

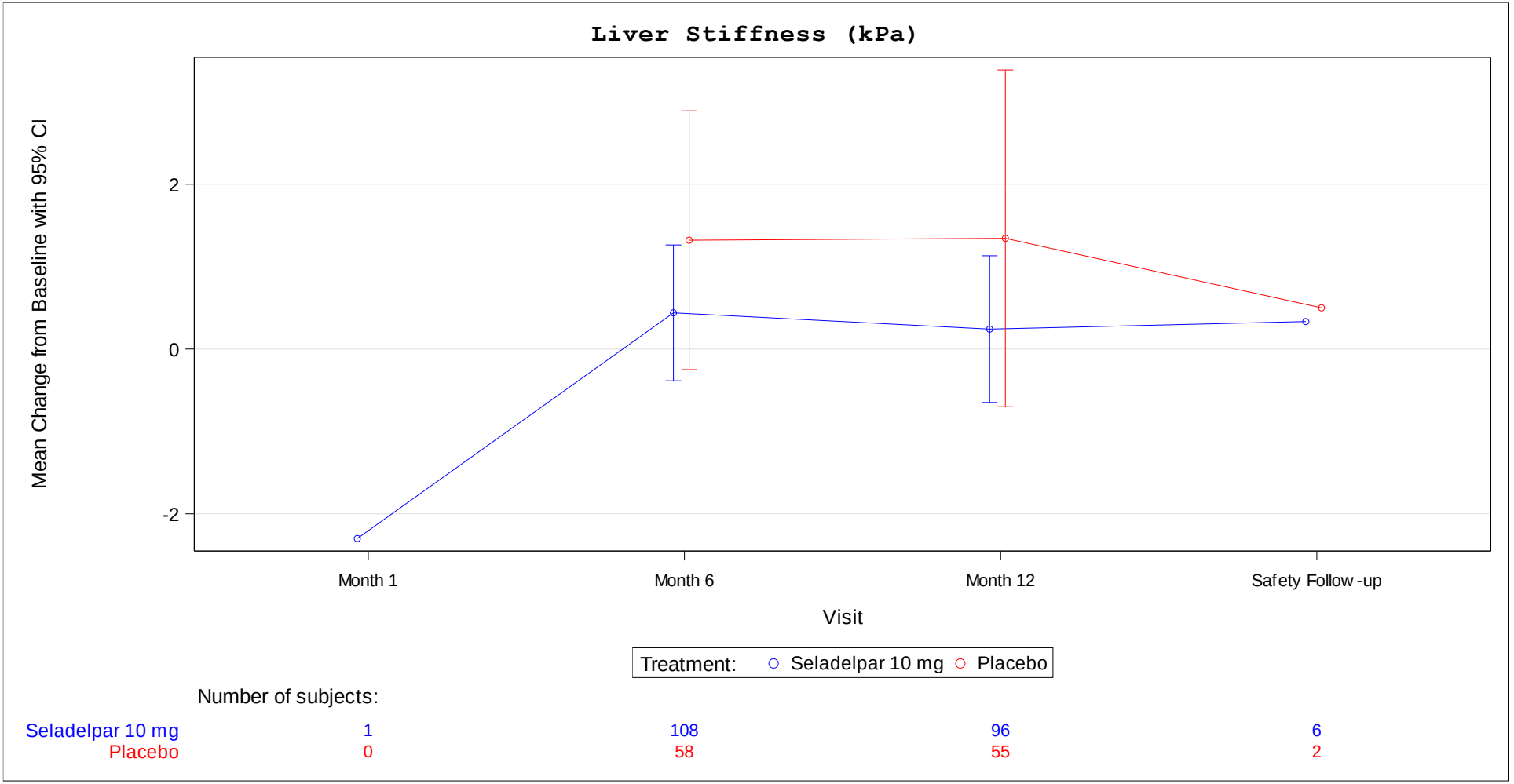
N describes number of patients with non-missing value at the respective timepoint.
N=Number of subjects included in the analysis, SD: Standard Deviation; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Summary of mean values, absolute and relative changes from baseline of liver stiffness by visit
Intention-to-treat

		Seladelpar 10 mg (N=128)				Placebo (N=65)			
		Value at Timepoint		Change from Baseline		Value at Timepoint		Change from Baseline	
Variable	Timepoint	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Percent change from baseline	Baseline	115	9.84 (6.16)	0	-	62	8.74 (4.18)	0	-
	Month 1	1	13.90 (-)	1	-14.20 (-)	0	-	0	-
	Month 6	110	10.05 (8.09)	108	7.29 (40.71)	58	9.89 (8.41)	58	13.52 (40.63)
	Month 12	99	9.76 (7.98)	96	4.58 (37.56)	55	9.84 (10.00)	55	9.88 (42.93)
	Safety Follow-up	6	13.43 (9.38)	6	4.73 (40.59)	2	6.00 (0.14)	2	10.20 (14.43)

N describes number of patients with non-missing value at the respective timepoint.
N=Number of subjects included in the analysis, SD: Standard Deviation; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Graphical summary of change from baseline of liver stiffness by visit
Intention-to-treat



Number of subjects:

Seladelpar 10 mg	1	108	96	6
Placebo	0	58	55	2

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of absolute and relative changes from baseline of liver stiffness by visit
Intention-to-treat

		Seladelpar 10 mg (N=128)		Placebo (N=65)				
Score	Visit	N	LSMean (SE)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)
Change from baseline	Month 1	109	NE	59	NE	NE		NE
	Month 6	109	0.84 (0.50)	59	2.00 (0.65)	-1.15 (-2.67, 0.36)	0.1354	-0.22 (-0.54, 0.09)
	Month 12	109	0.56 (0.56)	59	1.92 (0.72)	-1.37 (-3.09, 0.35)	0.1174	-0.24 (-0.55, 0.08)

(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
N=Number of subjects included in the analysis, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of absolute and relative changes from baseline of liver stiffness by visit
Intention-to-treat

		Seladelpar 10 mg (N=128)		Placebo (N=65)				
Score	Visit	N	LSMean (SE)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)
Percent change from baseline	Month 1	109	NE	59	NE	NE		NE
	Month 6	109	12.44 (4.19)	59	17.38 (5.44)	-4.94 (-17.80, 7.92)	0.4494	-0.11 (-0.43, 0.20)
	Month 12	109	9.56 (4.21)	59	13.02 (5.32)	-3.46 (-16.17, 9.25)	0.5913	-0.08 (-0.40, 0.24)

(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
N=Number of subjects included in the analysis, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Summary of mean values, absolute and relative changes from baseline of ALT by visit
Intention-to-treat

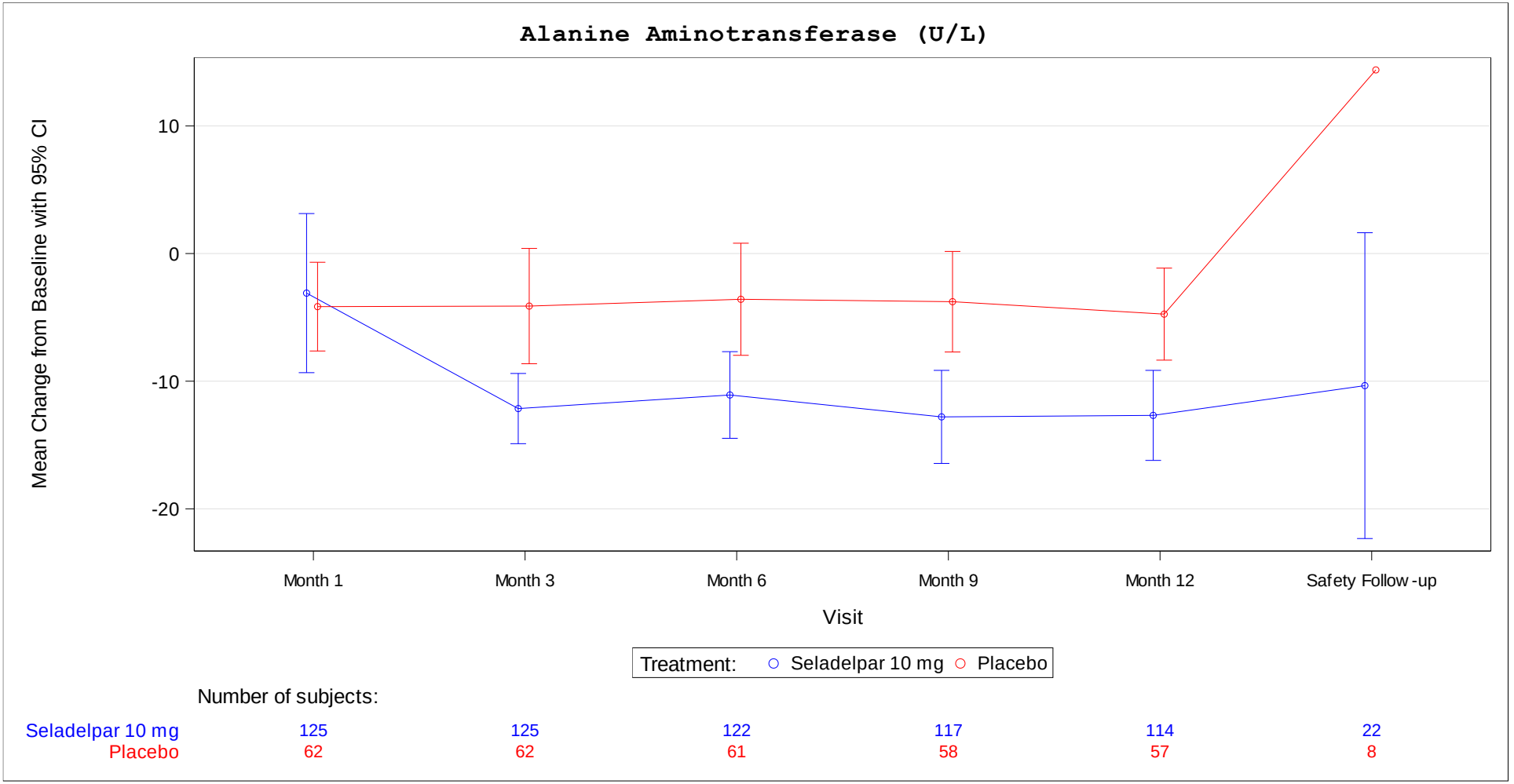
		Seladelpar 10 mg (N=128)				Placebo (N=65)			
		Value at Timepoint		Change from Baseline		Value at Timepoint		Change from Baseline	
Variable	Timepoint	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Change from baseline	Baseline	128	47.45 (23.47)	0	-	65	48.25 (22.83)	0	-
	Month 1	125	44.26 (41.43)	125	-3.10 (35.21)	62	43.35 (23.94)	62	-4.16 (13.68)
	Month 3	125	35.42 (19.50)	125	-12.15 (15.53)	62	43.44 (23.87)	62	-4.12 (17.78)
	Month 6	122	36.65 (25.16)	122	-11.08 (18.93)	61	44.15 (29.66)	61	-3.58 (17.15)
	Month 9	117	34.38 (23.30)	117	-12.80 (19.90)	58	42.36 (25.98)	58	-3.77 (14.97)
	Month 12	114	34.80 (23.55)	114	-12.68 (19.00)	57	41.42 (21.21)	57	-4.75 (13.59)
	Safety Follow-up	22	42.41 (33.23)	22	-10.35 (27.02)	8	74.75 (42.48)	8	14.39 (28.06)

N describes number of patients with non-missing value at the respective timepoint.
N=Number of subjects included in the analysis, SD: Standard Deviation; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Summary of mean values, absolute and relative changes from baseline of ALT by visit
Intention-to-treat

		Seladelpar 10 mg (N=128)				Placebo (N=65)			
		Value at Timepoint		Change from Baseline		Value at Timepoint		Change from Baseline	
Variable	Timepoint	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Percent change from baseline	Baseline	128	47.45 (23.47)	0	-	65	48.25 (22.83)	0	-
	Month 1	125	44.26 (41.43)	125	-3.61 (82.56)	62	43.35 (23.94)	62	-8.14 (25.25)
	Month 3	125	35.42 (19.50)	125	-22.66 (25.38)	62	43.44 (23.87)	62	-6.04 (33.72)
	Month 6	122	36.65 (25.16)	122	-21.24 (37.93)	61	44.15 (29.66)	61	-8.84 (34.95)
	Month 9	117	34.38 (23.30)	117	-24.58 (42.88)	58	42.36 (25.98)	58	-8.85 (32.28)
	Month 12	114	34.80 (23.55)	114	-24.62 (38.54)	57	41.42 (21.21)	57	-8.10 (26.83)
	Safety Follow-up	22	42.41 (33.23)	22	-19.84 (41.16)	8	74.75 (42.48)	8	23.58 (45.78)

N describes number of patients with non-missing value at the respective timepoint.
N=Number of subjects included in the analysis, SD: Standard Deviation; CI=Confidence Interval



Number of subjects:

Seladelpar 10 mg	125	125	122	117	114	22
Placebo	62	62	61	58	57	8

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of absolute and relative changes from baseline of ALT by visit
Intention-to-treat

		Seladelpar 10 mg (N=128)		Placebo (N=65)				
Score	Visit	N	LSMean (SE)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)
Change from baseline	Month 1	126	-2.89 (2.75)	63	-4.20 (3.87)	1.31 (-7.97, 10.58)	0.7812	0.04 (-0.26, 0.34)
	Month 3	126	-11.73 (1.40)	63	-3.52 (1.92)	-8.21 (-12.68, -3.75)	0.0004	-0.53 (-0.83, -0.22)
	Month 6	126	-10.67 (1.69)	63	-2.69 (2.34)	-7.98 (-13.49, -2.47)	0.0048	-0.42 (-0.73, -0.12)
	Month 9	126	-12.26 (1.69)	63	-2.97 (2.34)	-9.29 (-14.80, -3.78)	0.0011	-0.49 (-0.80, -0.19)
	Month 12	126	-12.20 (1.62)	63	-3.88 (2.22)	-8.32 (-13.55, -3.09)	0.0020	-0.46 (-0.77, -0.16)

(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
N=Number of subjects included in the analysis, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of absolute and relative changes from baseline of ALT by visit
Intention-to-treat

		Seladelpar 10 mg (N=128)		Placebo (N=65)				
Score	Visit	N	LSMean (SE)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)
Percent change from baseline	Month 1	126	-2.99 (6.23)	63	-7.62 (8.79)	4.63 (-16.43, 25.69)	0.6652	0.07 (-0.24, 0.37)
	Month 3	126	-21.84 (2.72)	63	-4.90 (3.73)	-16.94 (-25.59, -8.30)	0.0002	-0.56 (-0.87, -0.25)
	Month 6	126	-20.56 (3.46)	63	-7.41 (4.80)	-13.16 (-24.46, -1.86)	0.0228	-0.34 (-0.64, -0.04)
	Month 9	126	-23.22 (3.81)	63	-7.24 (5.30)	-15.98 (-28.54, -3.42)	0.0130	-0.37 (-0.68, -0.07)
	Month 12	126	-23.55 (3.42)	63	-6.54 (4.71)	-17.01 (-28.14, -5.88)	0.0030	-0.44 (-0.75, -0.14)

(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
N=Number of subjects included in the analysis, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of absolute and relative changes from baseline of ALT at month 6 and 12 - Subgroup analysis
Intention-to-treat

Variable	Timepoint	Subgroup Level	Seladelpar 10 mg (N=128) Baseline N	Seladelpar 10 mg (N=128) Baseline Mean (SD)	Seladelpar 10 mg (N=128) Change from BL N	Seladelpar 10 mg (N=128) Change from BL LSMean (SE)	Placebo (N=65) Baseline N	Placebo (N=65) Baseline Mean (SD)	Placebo (N=65) Change from BL N	Placebo (N=65) Change from BL LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
Change from baseline	Month 6	Age at screening												0.1678
		< 65 years	99	50.64 (23.44)	97	-10.12 (2.08)	53	50.72 (23.37)	51	-0.89 (2.80)	-9.23 (-15.97, -2.49)	0.0077	-0.45 (-0.79, -0.11)	
		>= 65 years	29	36.56 (20.42)	29	-10.58 (1.86)	12	37.31 (16.98)	12	-7.78 (2.89)	-2.80 (-9.26, 3.67)	0.3855	-0.27 (-0.95, 0.40)	
		Age at PBC diagnosis												0.2885
		< 50 years	61	54.36 (24.06)	59	-8.54 (2.85)	32	52.53 (20.32)	30	-3.67 (3.96)	-4.87 (-14.40, 4.66)	0.3119	-0.22 (-0.66, 0.22)	
		>= 50 years	67	41.16 (21.20)	67	-12.70 (1.95)	33	44.10 (24.62)	33	-1.73 (2.70)	-10.97 (-17.30, -4.65)	0.0009	-0.69 (-1.12, -0.26)	
		Sex												NE
		female	123	47.50 (23.27)	121	-10.50 (1.76)	60	47.08 (22.67)	58	-2.22 (2.50)	-8.28 (-14.15, -2.41)	0.0060	-0.43 (-0.74, -0.11)	
		male	5	46.13 (31.23)	5	NE	5	62.33 (22.11)	5	NE	NE		NE	
		Race												
		white	114	47.01 (23.15)	113		56	47.34 (22.28)	54					
		black	2	98.67 (8.49)	2		2	33.50 (12.02)	2					
		asian	7	42.67 (14.57)	7		4	54.33 (20.86)	4					
		other	5	43.55 (25.32)	4		3	66.92 (38.25)	3					
		Region												0.4553
		North America	50	46.39 (25.22)	49	-14.39 (3.31)	13	58.19 (28.65)	12	0.61 (6.34)	-15.00 (-28.94, -1.06)	0.0354	-0.65 (-1.29, -0.00)	
		Europe	39	49.93 (22.05)	39	-12.36 (2.32)	24	43.27 (17.14)	23	-5.52 (3.05)	-6.84 (-14.31, 0.62)	0.0716	-0.47 (-0.99, 0.06)	
		Rest-of-World	39	46.33 (22.92)	38	-6.01 (2.93)	28	47.90 (23.46)	28	-1.24 (3.43)	-4.77 (-13.56, 4.03)	0.2827	-0.26 (-0.75, 0.23)	
		Cirrhosis												0.7941
		yes	18	45.55 (18.93)	18	-8.43 (4.46)	9	52.64 (12.98)	9	1.26 (6.54)	-9.69 (-26.15, 6.76)	0.2333	-0.49 (-1.30, 0.32)	
		no	110	47.76 (24.19)	108	-10.62 (1.86)	56	47.54 (24.04)	54	-3.14 (2.57)	-7.49 (-13.55, -1.42)	0.0160	-0.39 (-0.72, -0.06)	
		UDCA												0.3824
		UDCA Use	120	46.33 (23.15)	118	-10.37 (1.70)	62	46.23 (20.20)	60	-3.51 (2.30)	-6.86 (-12.30, -1.43)	0.0136	-0.38 (-0.69, -0.06)	
		UDCA Intolerance	8	64.25 (23.25)	8	-13.46 (10.95)	3	90.03 (38.48)	3	12.54 (18.74)	-26.00 (-75.68, 23.69)	0.2642	-0.76 (-2.14, 0.63)	
		Prior Use of OCA and/or Fibrates												0.3858
		yes	20	60.40 (31.12)	18	-9.91 (6.12)	13	54.85 (27.39)	12	-9.18 (7.47)	-0.73 (-20.55, 19.08)	0.9401	-0.03 (-0.76, 0.70)	
		no	108	45.05 (21.09)	108	-10.41 (1.66)	52	46.60 (21.53)	51	-0.99 (2.36)	-9.42 (-14.89, -3.95)	0.0009	-0.55 (-0.88, -0.21)	
		Therapy												0.2704
		Monotherapy (SEL)	8	64.25 (23.25)	8	-13.21 (10.74)	4	84.10 (33.58)	4	14.30 (15.59)	-27.51 (-70.29, 15.27)	0.1799	-0.83 (-2.10, 0.44)	
		Combinationtherapy (SEL + UDCA)	120	46.33 (23.15)	118	-10.33 (1.69)	61	45.90 (20.20)	59	-3.90 (2.31)	-6.42 (-11.87, -0.97)	0.0212	-0.35 (-0.67, -0.04)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of absolute and relative changes from baseline of ALT at month 6 and 12 - Subgroup analysis
Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
			Baseline		Change from BL		Baseline		Change from BL					
Variable	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
Change from baseline	Month 6	Stratification variable: Baseline Pruritus NRS												0.6628
		< 4	79	45.05 (23.08)	79	-14.15 (1.63)	42	45.18 (22.77)	41	-6.52 (2.09)	-7.64 (-12.49, -2.78)	0.0023	-0.54 (-0.92, -0.15)	
		>= 4	49	51.31 (23.81)	47	-7.38 (3.77)	23	53.85 (22.33)	22	3.38 (5.61)	-10.77 (-24.25, 2.72)	0.1157	-0.41 (-0.92, 0.10)	
		Stratification variable: Baseline ALP Level												0.7817
		< 350 U/L	93	42.44 (21.08)	92	-11.56 (1.69)	47	44.54 (22.37)	45	-2.70 (2.37)	-8.86 (-14.47, -3.25)	0.0022	-0.55 (-0.91, -0.18)	
		>= 350 U/L	35	60.75 (24.59)	34	-9.62 (3.94)	18	57.92 (21.68)	18	-2.80 (5.52)	-6.82 (-20.52, 6.88)	0.3205	-0.29 (-0.86, 0.28)	
		Gamma-GT (GGT)												0.0077
		<= 3 x ULN	33	35.38 (18.99)	32	-1.84 (2.11)	14	34.26 (15.94)	13	-3.07 (2.84)	1.24 (-4.48, 6.95)	0.6642	0.11 (-0.54, 0.75)	
		> 3 x ULN	95	51.64 (23.51)	94	-12.52 (2.14)	51	52.09 (23.04)	50	-1.66 (2.90)	-10.86 (-17.88, -3.83)	0.0027	-0.52 (-0.87, -0.17)	
		Total Bilirubin I												0.8366
		<= 1 x ULN	108	45.66 (23.38)	106	-10.97 (1.89)	60	46.42 (21.24)	59	-2.98 (2.45)	-7.99 (-13.83, -2.15)	0.0077	-0.41 (-0.74, -0.09)	
		> 1 x ULN	20	57.10 (22.07)	20	-10.81 (3.65)	5	70.22 (32.04)	4	-0.60 (9.73)	-10.21 (-32.44, 12.03)	0.3407	-0.59 (-1.68, 0.50)	
		Total Bilirubin II												0.8673
		< 0.6 x ULN	59	42.73 (21.29)	58	-13.75 (2.15)	32	43.54 (20.90)	31	-5.08 (2.72)	-8.67 (-14.97, -2.37)	0.0076	-0.54 (-0.98, -0.09)	
		>= 0.6 x ULN	69	51.48 (24.63)	68	-9.06 (2.59)	33	52.82 (23.98)	32	-1.32 (3.79)	-7.74 (-16.80, 1.31)	0.0928	-0.36 (-0.78, 0.06)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of absolute and relative changes from baseline of ALT at month 6 and 12 - Subgroup analysis
Intention-to-treat

Variable	Timepoint	Subgroup Level	Seladelpar 10 mg (N=128) Baseline N	Seladelpar 10 mg (N=128) Baseline Mean (SD)	Seladelpar 10 mg (N=128) Change from BL N	Seladelpar 10 mg (N=128) Change from BL LSMean (SE)	Placebo (N=65) Baseline N	Placebo (N=65) Baseline Mean (SD)	Placebo (N=65) Change from BL N	Placebo (N=65) Change from BL LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
Change from baseline	Month 12	Age at screening												0.7573
		< 65 years	99	50.64 (23.44)	97	-12.32 (1.97)	53	50.72 (23.37)	51	-3.71 (2.68)	-8.61 (-15.02, -2.21)	0.0088	-0.44 (-0.79, -0.10)	
		>= 65 years	29	36.56 (20.42)	29	-10.21 (1.80)	12	37.31 (16.98)	12	-2.95 (2.67)	-7.26 (-13.22, -1.30)	0.0183	-0.74 (-1.44, -0.05)	
		Age at PBC diagnosis												0.4400
		< 50 years	61	54.36 (24.06)	59	-9.68 (2.92)	32	52.53 (20.32)	30	-3.61 (4.13)	-6.07 (-15.97, 3.82)	0.2251	-0.27 (-0.71, 0.17)	
		>= 50 years	67	41.16 (21.20)	67	-14.46 (1.54)	33	44.10 (24.62)	33	-4.15 (2.03)	-10.32 (-15.03, -5.60)	<.0001	-0.83 (-1.26, -0.40)	
		Sex												NE
		female	123	47.50 (23.27)	121	-12.04 (1.68)	60	47.08 (22.67)	58	-4.01 (2.35)	-8.03 (-13.55, -2.51)	0.0046	-0.44 (-0.75, -0.12)	
		male	5	46.13 (31.23)	5	NE	5	62.33 (22.11)	5	NE	NE		NE	
		Race												
		white	114	47.01 (23.15)	113		56	47.34 (22.28)	54					
		black	2	98.67 (8.49)	2		2	33.50 (12.02)	2					
		asian	7	42.67 (14.57)	7		4	54.33 (20.86)	4					
		other	5	43.55 (25.32)	4		3	66.92 (38.25)	3					
		Region												0.2955
		North America	50	46.39 (25.22)	49	-15.20 (2.66)	13	58.19 (28.65)	12	-0.73 (5.20)	-14.48 (-25.73, -3.22)	0.0128	-0.77 (-1.42, -0.12)	
		Europe	39	49.93 (22.05)	39	-12.17 (3.21)	24	43.27 (17.14)	23	-2.12 (4.08)	-10.06 (-20.31, 0.19)	0.0543	-0.50 (-1.02, 0.02)	
		Rest-of-World	39	46.33 (22.92)	38	-9.73 (2.59)	28	47.90 (23.46)	28	-5.39 (2.93)	-4.34 (-11.88, 3.20)	0.2534	-0.27 (-0.76, 0.22)	
		Cirrhosis												0.8681
		yes	18	45.55 (18.93)	18	-5.06 (3.85)	9	52.64 (12.98)	9	1.94 (6.05)	-7.00 (-23.01, 9.01)	0.3492	-0.40 (-1.21, 0.41)	
		no	110	47.76 (24.19)	108	-12.93 (1.76)	56	47.54 (24.04)	54	-4.66 (2.37)	-8.27 (-13.90, -2.64)	0.0042	-0.46 (-0.79, -0.13)	
		UDCA												0.0505
		UDCA Use	120	46.33 (23.15)	118	-11.13 (1.69)	62	46.23 (20.20)	60	-4.34 (2.26)	-6.79 (-12.16, -1.42)	0.0136	-0.37 (-0.69, -0.06)	
		UDCA Intolerance	8	64.25 (23.25)	8	-25.09 (7.53)	3	90.03 (38.48)	3	17.84 (16.62)	-42.92 (-93.23, 7.39)	0.0772	-1.69 (-3.29, -0.10)	
		Prior Use of OCA and/or Fibrates												0.7358
		yes	20	60.40 (31.12)	18	-9.89 (5.27)	13	54.85 (27.39)	12	-4.50 (6.52)	-5.39 (-22.60, 11.82)	0.5249	-0.23 (-0.97, 0.50)	
		no	108	45.05 (21.09)	108	-12.20 (1.67)	52	46.60 (21.53)	51	-3.84 (2.35)	-8.36 (-13.83, -2.89)	0.0030	-0.48 (-0.82, -0.15)	
		Therapy												0.2732
		Monotherapy (SEL)	8	64.25 (23.25)	8	-24.83 (8.23)	4	84.10 (33.58)	4	2.07 (15.70)	-26.90 (-75.50, 21.69)	0.2014	-0.96 (-2.24, 0.33)	
		Combinationtherapy (SEL + UDCA)	120	46.33 (23.15)	118	-11.07 (1.69)	61	45.90 (20.20)	59	-3.81 (2.28)	-7.26 (-12.65, -1.86)	0.0087	-0.40 (-0.71, -0.08)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of absolute and relative changes from baseline of ALT at month 6 and 12 - Subgroup analysis
Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
			Baseline		Change from BL		Baseline		Change from BL					
Variable	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
Change from baseline	Month 12	Stratification variable: Baseline Pruritus NRS												0.6937
		< 4	79	45.05 (23.08)	79	-15.05 (1.90)	42	45.18 (22.77)	41	-5.34 (2.48)	-9.71 (-15.57, -3.85)	0.0014	-0.58 (-0.97, -0.20)	
		>= 4	49	51.31 (23.81)	47	-10.00 (2.89)	23	53.85 (22.33)	22	-2.63 (4.28)	-7.37 (-17.70, 2.96)	0.1583	-0.37 (-0.88, 0.14)	
		Stratification variable: Baseline ALP Level												0.3333
		< 350 U/L	93	42.44 (21.08)	92	-12.31 (1.76)	47	44.54 (22.37)	45	-1.38 (2.51)	-10.94 (-16.86, -5.01)	0.0004	-0.64 (-1.01, -0.28)	
		>= 350 U/L	35	60.75 (24.59)	34	-12.54 (3.58)	18	57.92 (21.68)	18	-8.04 (4.76)	-4.49 (-16.61, 7.63)	0.4559	-0.21 (-0.79, 0.36)	
		Gamma-GT (GGT)												0.2641
		<= 3 x ULN	33	35.38 (18.99)	32	-3.50 (2.45)	14	34.26 (15.94)	13	0.58 (3.43)	-4.08 (-11.46, 3.31)	0.2712	-0.30 (-0.95, 0.35)	
		> 3 x ULN	95	51.64 (23.51)	94	-13.87 (2.00)	51	52.09 (23.04)	50	-4.30 (2.68)	-9.57 (-16.07, -3.07)	0.0042	-0.49 (-0.84, -0.15)	
		Total Bilirubin I												0.8042
		<= 1 x ULN	108	45.66 (23.38)	106	-12.07 (1.77)	60	46.42 (21.24)	59	-3.38 (2.26)	-8.69 (-14.09, -3.29)	0.0018	-0.48 (-0.81, -0.16)	
		> 1 x ULN	20	57.10 (22.07)	20	-14.84 (4.72)	5	70.22 (32.04)	4	-9.36 (11.78)	-5.48 (-33.16, 22.20)	0.6730	-0.25 (-1.32, 0.83)	
		Total Bilirubin II												0.5692
		< 0.6 x ULN	59	42.73 (21.29)	58	-14.77 (2.38)	32	43.54 (20.90)	31	-5.18 (3.15)	-9.59 (-16.94, -2.25)	0.0111	-0.53 (-0.97, -0.09)	
		>= 0.6 x ULN	69	51.48 (24.63)	68	-10.97 (2.13)	33	52.82 (23.98)	32	-4.33 (3.02)	-6.64 (-13.89, 0.60)	0.0719	-0.38 (-0.80, 0.05)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of absolute and relative changes from baseline of ALT at month 6 and 12 - Subgroup analysis
Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
			Baseline		Change from BL		Baseline		Change from BL					
Variable	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
Percent change from baseline	Month 6	Age at screening												0.3170
		< 65 years	99	50.64 (23.44)	97	-18.44 (4.19)	53	50.72 (23.37)	51	-3.26 (5.65)	-15.17 (-28.75, -1.59)	0.0288	-0.37 (-0.71, -0.03)	
		>= 65 years	29	36.56 (20.42)	29	-24.58 (4.71)	12	37.31 (16.98)	12	-19.96 (7.33)	-4.63 (-20.81, 11.56)	0.5661	-0.18 (-0.85, 0.50)	
		Age at PBC diagnosis												0.2143
		< 50 years	61	54.36 (24.06)	59	-14.23 (5.52)	32	52.53 (20.32)	30	-8.32 (7.68)	-5.91 (-24.44, 12.62)	0.5274	-0.14 (-0.58, 0.30)	
		>= 50 years	67	41.16 (21.20)	67	-26.53 (4.30)	33	44.10 (24.62)	33	-6.19 (5.91)	-20.34 (-34.14, -6.54)	0.0043	-0.58 (-1.00, -0.15)	
		Sex												NE
		female	123	47.50 (23.27)	121	-20.42 (3.61)	60	47.08 (22.67)	58	-6.85 (5.12)	-13.57 (-25.58, -1.56)	0.0270	-0.34 (-0.66, -0.03)	
		male	5	46.13 (31.23)	5	NE	5	62.33 (22.11)	5	NE	NE		NE	
		Race												
		white	114	47.01 (23.15)	113		56	47.34 (22.28)	54					
		black	2	98.67 (8.49)	2		2	33.50 (12.02)	2					
		asian	7	42.67 (14.57)	7		4	54.33 (20.86)	4					
		other	5	43.55 (25.32)	4		3	66.92 (38.25)	3					
		Region												0.8966
		North America	50	46.39 (25.22)	49	-25.20 (6.78)	13	58.19 (28.65)	12	-7.18 (12.97)	-18.02 (-46.60, 10.56)	0.2117	-0.38 (-1.01, 0.26)	
		Europe	39	49.93 (22.05)	39	-26.11 (4.97)	24	43.27 (17.14)	23	-11.90 (6.53)	-14.20 (-30.29, 1.88)	0.0824	-0.45 (-0.97, 0.07)	
		Rest-of-World	39	46.33 (22.92)	38	-13.45 (5.95)	28	47.90 (23.46)	28	-2.91 (6.98)	-10.54 (-28.32, 7.24)	0.2404	-0.28 (-0.77, 0.21)	
		Cirrhosis												0.5405
		yes	18	45.55 (18.93)	18	-19.80 (8.11)	9	52.64 (12.98)	9	2.06 (11.68)	-21.86 (-51.13, 7.41)	0.1355	-0.61 (-1.43, 0.21)	
		no	110	47.76 (24.19)	108	-20.46 (3.83)	56	47.54 (24.04)	54	-8.06 (5.28)	-12.41 (-24.88, 0.06)	0.0512	-0.31 (-0.64, 0.02)	
		UDCA												0.9991
		UDCA Use	120	46.33 (23.15)	118	-21.72 (3.33)	62	46.23 (20.20)	60	-8.33 (4.50)	-13.40 (-24.01, -2.78)	0.0137	-0.37 (-0.69, -0.06)	
		UDCA Intolerance	8	64.25 (23.25)	8	-2.80 (2004.92)	3	90.03 (38.48)	3	16.20 (2724.64)	-19.00 (-11731.07, 11693.08)	0.9972	-0.00 (-1.33, 1.32)	
		Prior Use of OCA and/or Fibrates												0.0894
		yes	20	60.40 (31.12)	18	-12.57 (9.41)	13	54.85 (27.39)	12	-22.14 (11.47)	9.56 (-20.81, 39.94)	0.5234	0.23 (-0.50, 0.97)	
		no	108	45.05 (21.09)	108	-21.51 (3.73)	52	46.60 (21.53)	51	-3.83 (5.30)	-17.68 (-29.94, -5.41)	0.0050	-0.46 (-0.79, -0.12)	
		Therapy												0.9893
		Monotherapy (SEL)	8	64.25 (23.25)	8	-4.09 (26.01)	4	84.10 (33.58)	4	8.01 (37.00)	-12.10 (-113.21, 89.00)	0.7947	-0.15 (-1.35, 1.05)	
		Combinationtherapy (SEL + UDCA)	120	46.33 (23.15)	118	-21.71 (3.33)	61	45.90 (20.20)	59	-8.99 (4.54)	-12.71 (-23.38, -2.05)	0.0197	-0.35 (-0.67, -0.04)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of absolute and relative changes from baseline of ALT at month 6 and 12 - Subgroup analysis
Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
			Baseline		Change from BL		Baseline		Change from BL					
Variable	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
Percent change from baseline	Month 6	Stratification variable: Baseline Pruritus NRS												0.9842
		< 4	79	45.05 (23.08)	79	-28.70 (3.80)	42	45.18 (22.77)	41	-14.80 (4.92)	-13.90 (-25.35, -2.45)	0.0178	-0.42 (-0.80, -0.04)	
		>= 4	49	51.31 (23.81)	47	-11.66 (6.83)	23	53.85 (22.33)	22	2.50 (10.20)	-14.17 (-38.62, 10.28)	0.2514	-0.30 (-0.81, 0.21)	
		Stratification variable: Baseline ALP Level												0.3343
		< 350 U/L	93	42.44 (21.08)	92	-24.76 (3.45)	47	44.54 (22.37)	45	-6.72 (4.82)	-18.04 (-29.44, -6.64)	0.0022	-0.55 (-0.91, -0.18)	
		>= 350 U/L	35	60.75 (24.59)	34	-12.06 (8.11)	18	57.92 (21.68)	18	-8.65 (11.42)	-3.41 (-31.63, 24.81)	0.8088	-0.07 (-0.64, 0.50)	
		Gamma-GT (GGT)												0.1171
		<= 3 x ULN	33	35.38 (18.99)	32	0.76 (7.04)	14	34.26 (15.94)	13	0.22 (9.59)	0.54 (-18.97, 20.05)	0.9556	0.01 (-0.63, 0.66)	
		> 3 x ULN	95	51.64 (23.51)	94	-23.92 (4.15)	51	52.09 (23.04)	50	-5.85 (5.63)	-18.06 (-31.69, -4.43)	0.0098	-0.45 (-0.80, -0.10)	
		Total Bilirubin I												0.8245
		<= 1 x ULN	108	45.66 (23.38)	106	-21.02 (3.99)	60	46.42 (21.24)	59	-7.51 (5.15)	-13.51 (-25.84, -1.17)	0.0321	-0.33 (-0.65, -0.01)	
		> 1 x ULN	20	57.10 (22.07)	20	-20.56 (5.30)	5	70.22 (32.04)	4	-10.64 (13.98)	-9.92 (-41.27, 21.43)	0.5142	-0.39 (-1.47, 0.69)	
		Total Bilirubin II												0.6088
		< 0.6 x ULN	59	42.73 (21.29)	58	-28.14 (4.74)	32	43.54 (20.90)	31	-11.32 (5.91)	-16.82 (-30.32, -3.31)	0.0153	-0.48 (-0.92, -0.03)	
		>= 0.6 x ULN	69	51.48 (24.63)	68	-16.06 (5.14)	33	52.82 (23.98)	32	-5.04 (7.54)	-11.02 (-29.01, 6.97)	0.2268	-0.26 (-0.68, 0.16)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
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N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

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RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of absolute and relative changes from baseline of ALT at month 6 and 12 - Subgroup analysis
Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
			Baseline		Change from BL		Baseline		Change from BL					
Variable	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
Percent change from baseline	Month 12	Age at screening												0.8595
		< 65 years	99	50.64 (23.44)	97	-22.82 (4.04)	53	50.72 (23.37)	51	-5.21 (5.53)	-17.61 (-30.83, -4.39)	0.0094	-0.44 (-0.78, -0.10)	
		>= 65 years	29	36.56 (20.42)	29	-24.13 (5.24)	12	37.31 (16.98)	12	-8.46 (7.70)	-15.68 (-33.16, 1.80)	0.0771	-0.55 (-1.24, 0.13)	
		Age at PBC diagnosis												0.0919
		< 50 years	61	54.36 (24.06)	59	-14.97 (5.89)	32	52.53 (20.32)	30	-7.86 (8.36)	-7.12 (-27.21, 12.97)	0.4826	-0.16 (-0.60, 0.28)	
		>= 50 years	67	41.16 (21.20)	67	-31.75 (3.61)	33	44.10 (24.62)	33	-5.24 (4.77)	-26.52 (-37.53, -15.50)	<.0001	-0.91 (-1.35, -0.48)	
		Sex												NE
		female	123	47.50 (23.27)	121	-23.41 (3.56)	60	47.08 (22.67)	58	-7.04 (4.99)	-16.38 (-28.12, -4.63)	0.0066	-0.42 (-0.74, -0.10)	
		male	5	46.13 (31.23)	5	NE	5	62.33 (22.11)	5	NE	NE		NE	
		Race												
		white	114	47.01 (23.15)	113		56	47.34 (22.28)	54					
		black	2	98.67 (8.49)	2		2	33.50 (12.02)	2					
		asian	7	42.67 (14.57)	7		4	54.33 (20.86)	4					
		other	5	43.55 (25.32)	4		3	66.92 (38.25)	3					
		Region												0.6986
		North America	50	46.39 (25.22)	49	-31.01 (4.14)	13	58.19 (28.65)	12	-9.25 (7.88)	-21.76 (-38.37, -5.14)	0.0113	-0.75 (-1.40, -0.10)	
		Europe	39	49.93 (22.05)	39	-19.72 (8.13)	24	43.27 (17.14)	23	-2.18 (10.33)	-17.54 (-43.66, 8.58)	0.1839	-0.34 (-0.86, 0.17)	
		Rest-of-World	39	46.33 (22.92)	38	-20.62 (5.21)	28	47.90 (23.46)	28	-8.33 (5.94)	-12.29 (-27.43, 2.85)	0.1094	-0.38 (-0.87, 0.11)	
		Cirrhosis												0.8651
		yes	18	45.55 (18.93)	18	-14.28 (8.32)	9	52.64 (12.98)	9	5.56 (12.96)	-19.84 (-52.49, 12.82)	0.2135	-0.53 (-1.34, 0.29)	
		no	110	47.76 (24.19)	108	-24.88 (3.72)	56	47.54 (24.04)	54	-7.83 (5.03)	-17.06 (-28.99, -5.12)	0.0054	-0.45 (-0.78, -0.11)	
		UDCA												NE
		UDCA Use	120	46.33 (23.15)	118	-22.61 (3.66)	62	46.23 (20.20)	60	-6.87 (4.91)	-15.75 (-27.45, -4.04)	0.0087	-0.40 (-0.71, -0.09)	
		UDCA Intolerance	8	64.25 (23.25)	8	-33.78 (582.44)	3	90.03 (38.48)	3	-1.54 (0.00)	-32.24 (,)	<.0001	-0.02 (-1.35, 1.31)	
		Prior Use of OCA and/or Fibrates												0.3600
		yes	20	60.40 (31.12)	18	-13.81 (7.83)	13	54.85 (27.39)	12	-8.27 (9.66)	-5.54 (-31.08, 20.01)	0.6591	-0.16 (-0.89, 0.57)	
		no	108	45.05 (21.09)	108	-24.79 (3.83)	52	46.60 (21.53)	51	-6.50 (5.40)	-18.28 (-30.83, -5.73)	0.0046	-0.46 (-0.80, -0.13)	
		Therapy												0.8494
		Monotherapy (SEL)	8	64.25 (23.25)	8	-35.08 (10.24)	4	84.10 (33.58)	4	-22.70 (18.09)	-12.38 (-62.25, 37.49)	0.5720	-0.37 (-1.58, 0.85)	
		Combinationtherapy (SEL + UDCA)	120	46.33 (23.15)	118	-22.59 (3.66)	61	45.90 (20.20)	59	-6.10 (4.96)	-16.49 (-28.27, -4.72)	0.0064	-0.42 (-0.73, -0.10)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of absolute and relative changes from baseline of ALT at month 6 and 12 - Subgroup analysis
Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
			Baseline		Change from BL		Baseline		Change from BL					
Variable	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
Percent change from baseline	Month 12	Stratification variable: Baseline Pruritus NRS												0.5732
		< 4	79	45.05 (23.08)	79	-30.43 (4.54)	42	45.18 (22.77)	41	-10.52 (5.97)	-19.91 (-34.08, -5.75)	0.0063	-0.50 (-0.88, -0.12)	
		>= 4	49	51.31 (23.81)	47	-17.18 (5.09)	23	53.85 (22.33)	22	-3.77 (7.55)	-13.40 (-31.59, 4.78)	0.1455	-0.38 (-0.89, 0.13)	
		Stratification variable: Baseline ALP Level												0.1617
		< 350 U/L	93	42.44 (21.08)	92	-26.12 (4.01)	47	44.54 (22.37)	45	-3.21 (5.75)	-22.90 (-36.48, -9.32)	0.0011	-0.59 (-0.96, -0.23)	
		>= 350 U/L	35	60.75 (24.59)	34	-18.44 (6.07)	18	57.92 (21.68)	18	-12.64 (8.09)	-5.80 (-26.31, 14.72)	0.5703	-0.16 (-0.74, 0.41)	
		Gamma-GT (GGT)												0.8023
		<= 3 x ULN	33	35.38 (18.99)	32	-4.69 (7.86)	14	34.26 (15.94)	13	10.24 (10.91)	-14.93 (-38.32, 8.46)	0.2045	-0.34 (-0.99, 0.31)	
		> 3 x ULN	95	51.64 (23.51)	94	-25.97 (3.93)	51	52.09 (23.04)	50	-7.71 (5.29)	-18.25 (-31.07, -5.44)	0.0056	-0.48 (-0.83, -0.13)	
		Total Bilirubin I												0.9159
		<= 1 x ULN	108	45.66 (23.38)	106	-23.67 (3.89)	60	46.42 (21.24)	59	-6.75 (5.00)	-16.92 (-28.89, -4.95)	0.0059	-0.43 (-0.75, -0.11)	
		> 1 x ULN	20	57.10 (22.07)	20	-24.93 (6.96)	5	70.22 (32.04)	4	-5.94 (17.32)	-18.99 (-58.53, 20.55)	0.3237	-0.58 (-1.67, 0.51)	
		Total Bilirubin II												0.5444
		< 0.6 x ULN	59	42.73 (21.29)	58	-29.26 (5.97)	32	43.54 (20.90)	31	-8.77 (7.95)	-20.49 (-39.12, -1.86)	0.0315	-0.45 (-0.89, -0.01)	
		>= 0.6 x ULN	69	51.48 (24.63)	68	-20.85 (3.58)	33	52.82 (23.98)	32	-7.13 (5.05)	-13.71 (-25.84, -1.58)	0.0272	-0.47 (-0.89, -0.04)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Summary of mean values, absolute and relative changes from baseline of AST by visit
Intention-to-treat

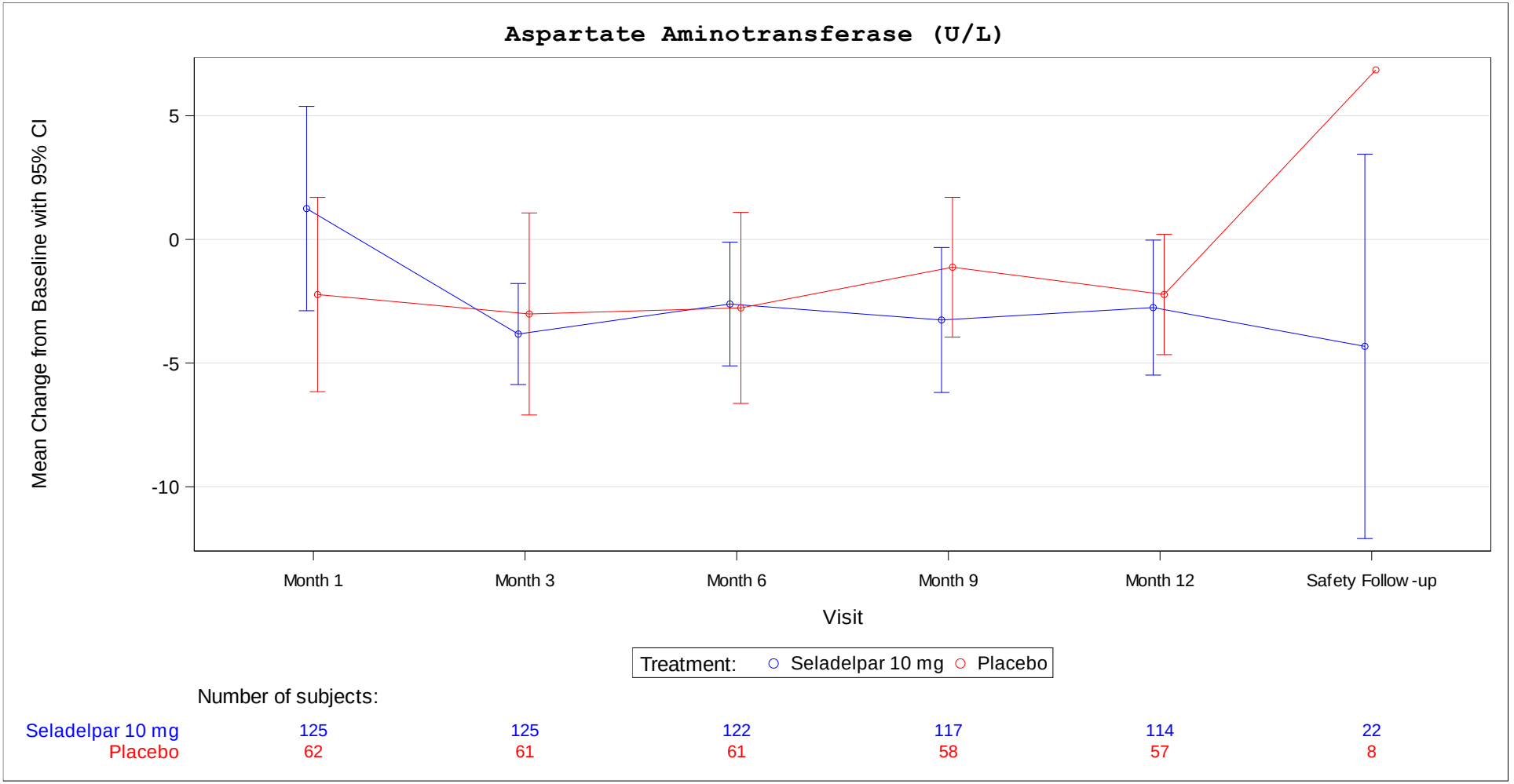
		Seladelpar 10 mg (N=128)				Placebo (N=65)			
		Value at Timepoint		Change from Baseline		Value at Timepoint		Change from Baseline	
Variable	Timepoint	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Change from baseline	Baseline	128	39.62 (16.14)	0	-	65	41.67 (16.03)	0	-
	Month 1	125	40.94 (28.54)	125	1.25 (23.33)	62	38.82 (20.79)	62	-2.23 (15.46)
	Month 3	125	35.91 (16.85)	125	-3.82 (11.53)	61	38.07 (18.68)	61	-3.01 (15.95)
	Month 6	122	37.10 (19.41)	122	-2.61 (13.95)	61	38.38 (20.31)	61	-2.77 (15.08)
	Month 9	117	36.13 (21.14)	117	-3.26 (16.00)	58	38.45 (17.26)	58	-1.12 (10.74)
	Month 12	114	36.53 (20.09)	114	-2.76 (14.71)	57	37.46 (14.13)	57	-2.23 (9.17)
	Safety Follow-up	22	41.45 (25.39)	22	-4.32 (17.53)	8	58.13 (24.91)	8	6.85 (14.91)

N describes number of patients with non-missing value at the respective timepoint.
N=Number of subjects included in the analysis, SD: Standard Deviation; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Summary of mean values, absolute and relative changes from baseline of AST by visit
Intention-to-treat

		Seladelpar 10 mg (N=128)				Placebo (N=65)			
		Value at Timepoint		Change from Baseline		Value at Timepoint		Change from Baseline	
Variable	Timepoint	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Percent change from baseline	Baseline	128	39.62 (16.14)	0	-	65	41.67 (16.03)	0	-
	Month 1	125	40.94 (28.54)	125	4.25 (49.68)	62	38.82 (20.79)	62	-4.94 (25.57)
	Month 3	125	35.91 (16.85)	125	-7.91 (22.83)	61	38.07 (18.68)	61	-4.99 (29.92)
	Month 6	122	37.10 (19.41)	122	-4.75 (32.88)	61	38.38 (20.31)	61	-6.40 (30.82)
	Month 9	117	36.13 (21.14)	117	-6.97 (36.88)	58	38.45 (17.26)	58	-2.56 (26.58)
	Month 12	114	36.53 (20.09)	114	-5.59 (37.59)	57	37.46 (14.13)	57	-4.01 (20.72)
	Safety Follow-up	22	41.45 (25.39)	22	-10.00 (35.38)	8	58.13 (24.91)	8	14.26 (33.01)

N describes number of patients with non-missing value at the respective timepoint.
N=Number of subjects included in the analysis, SD: Standard Deviation; CI=Confidence Interval



Number of subjects:

	Month 1	Month 3	Month 6	Month 9	Month 12	Safety Follow-up
Seladelpar 10 mg	125	125	122	117	114	22
Placebo	62	61	61	58	57	8

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of absolute and relative changes from baseline of AST by visit
Intention-to-treat

		Seladelpar 10 mg (N=128)		Placebo (N=65)				
Score	Visit	N	LSMean (SE)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)
Change from baseline	Month 1	126	1.42 (1.93)	63	-1.94 (2.71)	3.37 (-3.10, 9.83)	0.3056	0.15 (-0.15, 0.46)
	Month 3	126	-3.60 (1.22)	63	-2.36 (1.71)	-1.25 (-5.20, 2.71)	0.5351	-0.09 (-0.39, 0.21)
	Month 6	126	-2.43 (1.34)	63	-1.91 (1.86)	-0.52 (-4.88, 3.83)	0.8135	-0.03 (-0.34, 0.27)
	Month 9	126	-2.82 (1.42)	63	-0.43 (1.96)	-2.39 (-7.02, 2.24)	0.3101	-0.15 (-0.45, 0.15)
	Month 12	126	-2.49 (1.31)	63	-1.50 (1.80)	-0.98 (-5.22, 3.25)	0.6473	-0.07 (-0.37, 0.24)

(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
N=Number of subjects included in the analysis, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of absolute and relative changes from baseline of AST by visit
Intention-to-treat

Score	Visit	Seladelpar 10 mg (N=128) N	Seladelpar 10 mg (N=128) LSMean (SE)	Placebo (N=65) N	Placebo (N=65) LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)
Percent change from baseline	Month 1	126	4.72 (3.94)	63	-4.17 (5.54)	8.89 (-4.28, 22.06)	0.1848	0.20 (-0.10, 0.50)
	Month 3	126	-7.36 (2.44)	63	-3.82 (3.39)	-3.54 (-11.36, 4.28)	0.3730	-0.13 (-0.43, 0.17)
	Month 6	126	-4.33 (3.00)	63	-4.77 (4.17)	0.44 (-9.37, 10.25)	0.9298	0.01 (-0.29, 0.32)
	Month 9	126	-5.98 (3.25)	63	-1.02 (4.52)	-4.96 (-15.66, 5.73)	0.3610	-0.14 (-0.44, 0.17)
	Month 12	126	-4.76 (3.21)	63	-2.36 (4.45)	-2.40 (-12.93, 8.12)	0.6527	-0.07 (-0.37, 0.24)

(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
N=Number of subjects included in the analysis, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of absolute and relative changes from baseline of AST at month 6 and 12 - Subgroup analysis
Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
			Baseline		Change from BL		Baseline		Change from BL					
Variable	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
Change from baseline	Month 6	Age at screening												0.5628
		< 65 years	99	40.33 (16.11)	97	-1.81 (1.63)	53	42.32 (16.40)	51	-0.66 (2.20)	-1.15 (-6.42, 4.12)	0.6669	-0.07 (-0.41, 0.27)	
		>= 65 years	29	37.19 (16.29)	29	-2.74 (1.78)	12	38.81 (14.60)	12	-3.92 (2.79)	1.18 (-4.98, 7.34)	0.6983	0.12 (-0.55, 0.79)	
		Age at PBC diagnosis												0.1472
		< 50 years	61	43.22 (15.89)	59	-0.59 (2.21)	32	44.33 (16.17)	30	-3.55 (3.07)	2.96 (-4.39, 10.31)	0.4249	0.17 (-0.27, 0.61)	
		>= 50 years	67	36.33 (15.77)	67	-4.09 (1.57)	33	39.10 (15.71)	33	-0.54 (2.17)	-3.55 (-8.62, 1.52)	0.1681	-0.28 (-0.69, 0.14)	
		Sex												0.5827
		female	123	39.82 (16.10)	121	-2.44 (1.39)	60	41.61 (16.35)	58	-1.82 (1.98)	-0.63 (-5.24, 3.99)	0.7896	-0.04 (-0.35, 0.27)	
		male	5	34.72 (18.35)	5	0.14 (3.45)	5	42.40 (13.02)	5	-1.84 (2.91)	1.98 (-8.55, 12.51)	0.6510	0.25 (-1.00, 1.50)	
		Race												
		white	114	39.30 (15.95)	113		56	41.43 (16.49)	54					
		black	2	75.67 (7.07)	2		2	34.33 (16.97)	2					
		asian	7	39.10 (10.07)	7		4	42.33 (7.09)	4					
		other	5	33.15 (14.61)	4		3	50.19 (18.91)	3					
		Region												0.2545
		North America	50	39.19 (16.06)	49	-5.76 (2.40)	13	49.79 (18.71)	12	1.26 (4.53)	-7.02 (-16.84, 2.80)	0.1578	-0.42 (-1.05, 0.22)	
		Europe	39	39.83 (15.78)	39	-4.27 (1.74)	24	35.95 (12.63)	23	-2.43 (2.25)	-1.84 (-7.36, 3.67)	0.5056	-0.17 (-0.68, 0.35)	
		Rest-of-World	39	39.95 (16.99)	38	1.40 (2.53)	28	42.82 (15.99)	28	-1.70 (2.98)	3.10 (-4.51, 10.72)	0.4182	0.20 (-0.29, 0.69)	
		Cirrhosis												0.4222
		yes	18	46.47 (14.74)	18	-1.90 (4.40)	9	46.61 (14.16)	9	4.19 (6.23)	-6.10 (-21.84, 9.65)	0.4239	-0.32 (-1.12, 0.49)	
		no	110	38.50 (16.14)	108	-2.33 (1.43)	56	40.88 (16.29)	54	-2.48 (1.98)	0.16 (-4.49, 4.81)	0.9464	0.01 (-0.32, 0.34)	
		UDCA												0.9253
		UDCA Use	120	39.07 (16.04)	118	-2.37 (1.35)	62	40.11 (14.66)	60	-2.35 (1.83)	-0.02 (-4.33, 4.28)	0.9913	-0.00 (-0.31, 0.31)	
		UDCA Intolerance	8	47.88 (16.32)	8	-1.29 (8.82)	3	73.94 (5.58)	3	-2.94 (15.10)	1.65 (-38.34, 41.64)	0.9278	0.06 (-1.27, 1.39)	
		Prior Use of OCA and/or Fibrates												0.4342
		yes	20	48.63 (18.48)	18	-2.43 (4.00)	13	44.67 (16.49)	12	-6.23 (4.84)	3.80 (-9.15, 16.74)	0.5497	0.22 (-0.51, 0.95)	
		no	108	37.95 (15.18)	108	-2.16 (1.42)	52	40.92 (15.99)	51	-0.73 (2.03)	-1.44 (-6.17, 3.29)	0.5488	-0.10 (-0.43, 0.24)	
		Therapy												0.8266
		Monotherapy (SEL)	8	47.88 (16.32)	8	-1.39 (8.17)	4	69.88 (9.33)	4	1.63 (11.89)	-3.02 (-35.59, 29.54)	0.8404	-0.12 (-1.32, 1.08)	
		Combinationtherapy (SEL + UDCA)	120	39.07 (16.04)	118	-2.37 (1.35)	61	39.83 (14.60)	59	-2.58 (1.85)	0.22 (-4.11, 4.54)	0.9210	0.01 (-0.30, 0.33)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of absolute and relative changes from baseline of AST at month 6 and 12 - Subgroup analysis
Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
			Baseline		Change from BL		Baseline		Change from BL					
Variable	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
Change from baseline	Month 6	Stratification variable: Baseline Pruritus NRS												0.7245
		< 4	79	37.82 (16.16)	79	-4.61 (1.48)	42	40.99 (16.59)	41	-4.59 (1.94)	-0.02 (-4.52, 4.47)	0.9923	-0.00 (-0.38, 0.38)	
		>= 4	49	42.52 (15.83)	47	0.22 (2.65)	23	42.93 (15.23)	22	2.10 (3.95)	-1.88 (-11.36, 7.61)	0.6939	-0.10 (-0.61, 0.41)	
		Stratification variable: Baseline ALP Level												0.8421
		< 350 U/L	93	35.15 (14.13)	92	-3.26 (1.33)	47	39.44 (16.94)	45	-2.29 (1.86)	-0.96 (-5.37, 3.45)	0.6669	-0.08 (-0.43, 0.28)	
		>= 350 U/L	35	51.49 (15.27)	34	-0.69 (3.21)	18	47.50 (11.88)	18	-0.92 (4.51)	0.23 (-10.97, 11.43)	0.9672	0.01 (-0.56, 0.58)	
		Gamma-GT (GGT)												0.1782
		<= 3 x ULN	33	31.67 (13.09)	32	5.54 (2.17)	14	32.96 (16.30)	13	1.95 (3.01)	3.59 (-2.39, 9.56)	0.2327	0.30 (-0.35, 0.94)	
		> 3 x ULN	95	42.38 (16.24)	94	-3.35 (1.65)	51	44.07 (15.26)	50	-1.51 (2.24)	-1.84 (-7.24, 3.56)	0.5019	-0.11 (-0.46, 0.23)	
		Total Bilirubin I												0.8224
		<= 1 x ULN	108	38.12 (16.34)	106	-2.67 (1.51)	60	40.39 (15.24)	59	-2.32 (1.95)	-0.35 (-4.97, 4.28)	0.8825	-0.02 (-0.34, 0.30)	
		> 1 x ULN	20	47.71 (12.49)	20	-1.99 (2.75)	5	57.05 (19.13)	4	0.18 (7.34)	-2.18 (-18.58, 14.22)	0.7836	-0.17 (-1.24, 0.91)	
		Total Bilirubin II												0.6452
		< 0.6 x ULN	59	34.89 (15.77)	58	-3.57 (1.82)	32	37.51 (15.77)	31	-3.92 (2.32)	0.35 (-4.96, 5.65)	0.8971	0.03 (-0.41, 0.46)	
		>= 0.6 x ULN	69	43.66 (15.44)	68	-2.07 (2.01)	33	45.71 (15.46)	32	-0.38 (2.95)	-1.69 (-8.72, 5.33)	0.6332	-0.10 (-0.52, 0.32)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of absolute and relative changes from baseline of AST at month 6 and 12 - Subgroup analysis
Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
			Baseline		Change from BL		Baseline		Change from BL					
Variable	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
Change from baseline	Month 12	Age at screening												0.7349
		< 65 years	99	40.33 (16.11)	97	-2.25 (1.57)	53	42.32 (16.40)	51	-1.40 (2.13)	-0.86 (-5.94, 4.23)	0.7396	-0.06 (-0.39, 0.28)	
		>= 65 years	29	37.19 (16.29)	29	-1.67 (1.76)	12	38.81 (14.60)	12	0.49 (2.64)	-2.16 (-7.98, 3.66)	0.4566	-0.23 (-0.90, 0.45)	
		Age at PBC diagnosis												0.5399
		< 50 years	61	43.22 (15.89)	59	-0.57 (2.34)	32	44.33 (16.17)	30	-1.18 (3.31)	0.60 (-7.33, 8.53)	0.8798	0.03 (-0.41, 0.47)	
		>= 50 years	67	36.33 (15.77)	67	-4.00 (1.41)	33	39.10 (15.71)	33	-1.82 (1.90)	-2.19 (-6.60, 2.23)	0.3279	-0.19 (-0.61, 0.23)	
		Sex												0.3750
		female	123	39.82 (16.10)	121	-2.61 (1.36)	60	41.61 (16.35)	58	-1.46 (1.91)	-1.15 (-5.61, 3.31)	0.6114	-0.08 (-0.39, 0.24)	
		male	5	34.72 (18.35)	5	2.34 (4.27)	5	42.40 (13.02)	5	-1.82 (3.97)	4.15 (-9.33, 17.64)	0.4808	0.41 (-0.85, 1.67)	
		Race												
		white	114	39.30 (15.95)	113		56	41.43 (16.49)	54					
		black	2	75.67 (7.07)	2		2	34.33 (16.97)	2					
		asian	7	39.10 (10.07)	7		4	42.33 (7.09)	4					
		other	5	33.15 (14.61)	4		3	50.19 (18.91)	3					
		Region												0.5103
		North America	50	39.19 (16.06)	49	-4.83 (2.18)	13	49.79 (18.71)	12	1.34 (4.38)	-6.17 (-15.55, 3.20)	0.1918	-0.40 (-1.04, 0.24)	
		Europe	39	39.83 (15.78)	39	-2.70 (2.51)	24	35.95 (12.63)	23	-1.70 (3.17)	-0.99 (-8.97, 6.98)	0.8039	-0.06 (-0.58, 0.45)	
		Rest-of-World	39	39.95 (16.99)	38	-1.19 (2.16)	28	42.82 (15.99)	28	-1.49 (2.48)	0.30 (-6.04, 6.64)	0.9243	0.02 (-0.47, 0.51)	
		Cirrhosis												0.5436
		yes	18	46.47 (14.74)	18	1.49 (4.86)	9	46.61 (14.16)	9	7.86 (7.17)	-6.37 (-24.44, 11.70)	0.4642	-0.30 (-1.10, 0.51)	
		no	110	38.50 (16.14)	108	-2.99 (1.38)	56	40.88 (16.29)	54	-1.95 (1.88)	-1.04 (-5.46, 3.38)	0.6420	-0.07 (-0.40, 0.25)	
		UDCA												0.3240
		UDCA Use	120	39.07 (16.04)	118	-2.01 (1.37)	62	40.11 (14.66)	60	-1.82 (1.83)	-0.19 (-4.54, 4.16)	0.9311	-0.01 (-0.32, 0.30)	
		UDCA Intolerance	8	47.88 (16.32)	8	-7.04 (7.63)	3	73.94 (5.58)	3	10.28 (15.17)	-17.32 (-63.50, 28.87)	0.3669	-0.70 (-2.07, 0.68)	
		Prior Use of OCA and/or Fibrates												0.4507
		yes	20	48.63 (18.48)	18	2.60 (4.46)	13	44.67 (16.49)	12	-1.54 (5.48)	4.14 (-10.48, 18.75)	0.5635	0.21 (-0.52, 0.95)	
		no	108	37.95 (15.18)	108	-3.09 (1.31)	52	40.92 (15.99)	51	-1.66 (1.86)	-1.43 (-5.75, 2.88)	0.5119	-0.11 (-0.44, 0.23)	
		Therapy												0.4415
		Monotherapy (SEL)	8	47.88 (16.32)	8	-7.14 (8.15)	4	69.88 (9.33)	4	5.34 (12.89)	-12.48 (-52.76, 27.79)	0.4566	-0.48 (-1.70, 0.74)	
		Combinationtherapy (SEL + UDCA)	120	39.07 (16.04)	118	-1.99 (1.38)	61	39.83 (14.60)	59	-1.48 (1.86)	-0.50 (-4.88, 3.87)	0.8205	-0.03 (-0.35, 0.28)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of absolute and relative changes from baseline of AST at month 6 and 12 - Subgroup analysis
Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
			Baseline		Change from BL		Baseline		Change from BL					
Variable	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
Change from baseline	Month 12	Stratification variable: Baseline Pruritus NRS												0.7556
		< 4	79	37.82 (16.16)	79	-4.62 (1.64)	42	40.99 (16.59)	41	-2.89 (2.16)	-1.73 (-6.81, 3.36)	0.5015	-0.12 (-0.50, 0.26)	
		>= 4	49	42.52 (15.83)	47	-0.17 (2.18)	23	42.93 (15.23)	22	0.11 (3.23)	-0.28 (-8.08, 7.52)	0.9428	-0.02 (-0.52, 0.49)	
		Stratification variable: Baseline ALP Level												0.3939
		< 350 U/L	93	35.15 (14.13)	92	-3.01 (1.40)	47	39.44 (16.94)	45	-0.49 (2.01)	-2.53 (-7.26, 2.20)	0.2914	-0.19 (-0.54, 0.17)	
		>= 350 U/L	35	51.49 (15.27)	34	-1.20 (2.91)	18	47.50 (11.88)	18	-3.31 (3.89)	2.10 (-7.84, 12.05)	0.6695	0.12 (-0.45, 0.69)	
		Gamma-GT (GGT)												0.9161
		<= 3 x ULN	33	31.67 (13.09)	32	3.47 (2.02)	14	32.96 (16.30)	13	4.79 (2.59)	-1.32 (-6.35, 3.71)	0.5993	-0.12 (-0.76, 0.53)	
		> 3 x ULN	95	42.38 (16.24)	94	-2.61 (1.62)	51	44.07 (15.26)	50	-1.68 (2.19)	-0.93 (-6.24, 4.38)	0.7287	-0.06 (-0.40, 0.28)	
		Total Bilirubin I												0.6638
		<= 1 x ULN	108	38.12 (16.34)	106	-2.30 (1.47)	60	40.39 (15.24)	59	-1.19 (1.89)	-1.11 (-5.59, 3.38)	0.6270	-0.07 (-0.39, 0.24)	
		> 1 x ULN	20	47.71 (12.49)	20	-3.82 (3.22)	5	57.05 (19.13)	4	-6.64 (8.17)	2.83 (-15.75, 21.41)	0.7510	0.19 (-0.89, 1.26)	
		Total Bilirubin II												0.4726
		< 0.6 x ULN	59	34.89 (15.77)	58	-4.44 (1.83)	32	37.51 (15.77)	31	-1.85 (2.39)	-2.59 (-8.06, 2.89)	0.3501	-0.19 (-0.62, 0.25)	
		>= 0.6 x ULN	69	43.66 (15.44)	68	-1.23 (1.85)	33	45.71 (15.46)	32	-1.66 (2.63)	0.43 (-5.89, 6.75)	0.8922	0.03 (-0.39, 0.45)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of absolute and relative changes from baseline of AST at month 6 and 12 - Subgroup analysis
Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
			Baseline		Change from BL		Baseline		Change from BL					
Variable	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
Percent change from baseline	Month 6	Age at screening												0.4840
		< 65 years	99	40.33 (16.11)	97	-3.72 (3.67)	53	42.32 (16.40)	51	-2.34 (4.96)	-1.38 (-13.27, 10.52)	0.8192	-0.04 (-0.38, 0.30)	
		>= 65 years	29	37.19 (16.29)	29	-2.81 (4.13)	12	38.81 (14.60)	12	-7.84 (6.47)	5.03 (-8.97, 19.03)	0.4709	0.22 (-0.45, 0.90)	
		Age at PBC diagnosis												0.1074
		< 50 years	61	43.22 (15.89)	59	0.05 (4.84)	32	44.33 (16.17)	30	-8.79 (6.74)	8.84 (-7.35, 25.04)	0.2805	0.24 (-0.20, 0.68)	
		>= 50 years	67	36.33 (15.77)	67	-8.17 (3.69)	33	39.10 (15.71)	33	-0.79 (5.07)	-7.37 (-19.16, 4.41)	0.2172	-0.25 (-0.66, 0.17)	
		Sex												0.4230
		female	123	39.82 (16.10)	121	-4.34 (3.12)	60	41.61 (16.35)	58	-4.38 (4.45)	0.04 (-10.38, 10.45)	0.9947	0.00 (-0.31, 0.31)	
		male	5	34.72 (18.35)	5	0.69 (7.91)	5	42.40 (13.02)	5	-7.34 (5.95)	8.03 (-14.04, 30.09)	0.3884	0.46 (-0.80, 1.73)	
		Race												
		white	114	39.30 (15.95)	113		56	41.43 (16.49)	54					
		black	2	75.67 (7.07)	2		2	34.33 (16.97)	2					
		asian	7	39.10 (10.07)	7		4	42.33 (7.09)	4					
		other	5	33.15 (14.61)	4		3	50.19 (18.91)	3					
		Region												0.3831
		North America	50	39.19 (16.06)	49	-9.34 (5.41)	13	49.79 (18.71)	12	-2.80 (10.22)	-6.54 (-28.78, 15.71)	0.5583	-0.17 (-0.80, 0.46)	
		Europe	39	39.83 (15.78)	39	-10.92 (4.02)	24	35.95 (12.63)	23	-5.85 (5.27)	-5.07 (-18.00, 7.85)	0.4353	-0.20 (-0.72, 0.32)	
		Rest-of-World	39	39.95 (16.99)	38	4.93 (5.71)	28	42.82 (15.99)	28	-3.79 (6.74)	8.72 (-8.50, 25.95)	0.3151	0.24 (-0.25, 0.73)	
		Cirrhosis												0.5974
		yes	18	46.47 (14.74)	18	-3.27 (8.46)	9	46.61 (14.16)	9	3.82 (12.01)	-7.09 (-36.94, 22.76)	0.6264	-0.19 (-0.99, 0.61)	
		no	110	38.50 (16.14)	108	-4.45 (3.26)	56	40.88 (16.29)	54	-5.46 (4.52)	1.01 (-9.64, 11.65)	0.8523	0.03 (-0.30, 0.36)	
		UDCA												0.5324
		UDCA Use	120	39.07 (16.04)	118	-4.96 (2.99)	62	40.11 (14.66)	60	-5.55 (4.06)	0.59 (-8.98, 10.16)	0.9027	0.02 (-0.29, 0.33)	
		UDCA Intolerance	8	47.88 (16.32)	8	8.93 (23.44)	3	73.94 (5.58)	3	-21.26 (40.17)	30.19 (-77.52, 137.90)	0.5390	0.41 (-0.93, 1.76)	
		Prior Use of OCA and/or Fibrates												0.1540
		yes	20	48.63 (18.48)	18	-1.93 (7.14)	13	44.67 (16.49)	12	-17.02 (8.62)	15.09 (-7.84, 38.02)	0.1875	0.49 (-0.26, 1.23)	
		no	108	37.95 (15.18)	108	-4.58 (3.31)	52	40.92 (15.99)	51	-1.91 (4.74)	-2.67 (-13.69, 8.35)	0.6330	-0.08 (-0.41, 0.26)	
		Therapy												0.7465
		Monotherapy (SEL)	8	47.88 (16.32)	8	7.94 (21.02)	4	69.88 (9.33)	4	-5.29 (30.41)	13.23 (-70.49, 96.95)	0.7310	0.20 (-1.00, 1.41)	
		Combinationtherapy (SEL + UDCA)	120	39.07 (16.04)	118	-4.96 (3.00)	61	39.83 (14.60)	59	-6.01 (4.10)	1.04 (-8.59, 10.68)	0.8308	0.03 (-0.28, 0.34)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
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N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of absolute and relative changes from baseline of AST at month 6 and 12 - Subgroup analysis
Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
			Baseline		Change from BL		Baseline		Change from BL					
Variable	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
Percent change from baseline	Month 6	Stratification variable: Baseline Pruritus NRS												0.9716
		< 4	79	37.82 (16.16)	79	-10.69 (3.25)	42	40.99 (16.59)	41	-10.85 (4.26)	0.16 (-9.72, 10.04)	0.9745	0.01 (-0.37, 0.38)	
		>= 4	49	42.52 (15.83)	47	3.89 (5.93)	23	42.93 (15.23)	22	4.15 (8.85)	-0.26 (-21.49, 20.98)	0.9807	-0.01 (-0.51, 0.50)	
		Stratification variable: Baseline ALP Level												0.5872
		< 350 U/L	93	35.15 (14.13)	92	-7.60 (2.91)	47	39.44 (16.94)	45	-5.29 (4.08)	-2.31 (-11.96, 7.34)	0.6365	-0.08 (-0.44, 0.27)	
		>= 350 U/L	35	51.49 (15.27)	34	3.21 (7.39)	18	47.50 (11.88)	18	-1.91 (10.41)	5.12 (-20.66, 30.90)	0.6909	0.12 (-0.46, 0.69)	
		Gamma-GT (GGT)												0.3505
		<= 3 x ULN	33	31.67 (13.09)	32	11.05 (5.78)	14	32.96 (16.30)	13	3.80 (8.05)	7.25 (-8.89, 23.39)	0.3701	0.22 (-0.42, 0.87)	
		> 3 x ULN	95	42.38 (16.24)	94	-6.38 (3.65)	51	44.07 (15.26)	50	-4.26 (4.96)	-2.12 (-14.12, 9.87)	0.7267	-0.06 (-0.40, 0.28)	
		Total Bilirubin I												0.8378
		<= 1 x ULN	108	38.12 (16.34)	106	-4.73 (3.41)	60	40.39 (15.24)	59	-5.30 (4.42)	0.58 (-9.96, 11.12)	0.9141	0.02 (-0.30, 0.33)	
		> 1 x ULN	20	47.71 (12.49)	20	-3.97 (5.91)	5	57.05 (19.13)	4	-0.96 (15.66)	-3.01 (-37.94, 31.92)	0.8588	-0.11 (-1.18, 0.97)	
		Total Bilirubin II												0.8281
		< 0.6 x ULN	59	34.89 (15.77)	58	-8.75 (3.93)	32	37.51 (15.77)	31	-9.77 (4.96)	1.01 (-10.28, 12.31)	0.8588	0.03 (-0.40, 0.47)	
		>= 0.6 x ULN	69	43.66 (15.44)	68	-2.27 (4.61)	33	45.71 (15.46)	32	-1.13 (6.78)	-1.14 (-17.30, 15.02)	0.8889	-0.03 (-0.45, 0.39)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
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N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
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Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
			Baseline		Change from BL		Baseline		Change from BL					
Variable	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
Percent change from baseline	Month 12	Age at screening												0.9716
		< 65 years	99	40.33 (16.11)	97	-4.86 (3.77)	53	42.32 (16.40)	51	-1.92 (5.19)	-2.94 (-15.35, 9.46)	0.6397	-0.08 (-0.42, 0.26)	
		>= 65 years	29	37.19 (16.29)	29	-1.57 (4.99)	12	38.81 (14.60)	12	1.74 (7.47)	-3.31 (-20.22, 13.59)	0.6931	-0.12 (-0.80, 0.55)	
		Age at PBC diagnosis												0.3718
		< 50 years	61	43.22 (15.89)	59	0.88 (5.50)	32	44.33 (16.17)	30	-1.59 (7.83)	2.47 (-16.33, 21.28)	0.7941	0.06 (-0.38, 0.50)	
		>= 50 years	67	36.33 (15.77)	67	-9.82 (3.58)	33	39.10 (15.71)	33	-2.46 (4.82)	-7.35 (-18.61, 3.90)	0.1974	-0.25 (-0.67, 0.17)	
		Sex												0.3056
		female	123	39.82 (16.10)	121	-4.95 (3.33)	60	41.61 (16.35)	58	-1.95 (4.71)	-3.00 (-14.10, 8.10)	0.5939	-0.08 (-0.40, 0.23)	
		male	5	34.72 (18.35)	5	4.07 (10.40)	5	42.40 (13.02)	5	-7.63 (9.58)	11.70 (-19.75, 43.16)	0.4060	0.47 (-0.80, 1.74)	
		Race												
		white	114	39.30 (15.95)	113		56	41.43 (16.49)	54					
		black	2	75.67 (7.07)	2		2	34.33 (16.97)	2					
		asian	7	39.10 (10.07)	7		4	42.33 (7.09)	4					
		other	5	33.15 (14.61)	4		3	50.19 (18.91)	3					
		Region												0.6932
		North America	50	39.19 (16.06)	49	-10.87 (4.16)	13	49.79 (18.71)	12	-1.87 (8.27)	-9.00 (-26.41, 8.41)	0.3045	-0.31 (-0.94, 0.33)	
		Europe	39	39.83 (15.78)	39	-1.76 (7.41)	24	35.95 (12.63)	23	-2.34 (9.48)	0.59 (-23.33, 24.51)	0.9609	0.01 (-0.50, 0.53)	
		Rest-of-World	39	39.95 (16.99)	38	-2.32 (4.93)	28	42.82 (15.99)	28	-2.26 (5.66)	-0.06 (-14.57, 14.44)	0.9929	-0.00 (-0.49, 0.49)	
		Cirrhosis												0.6022
		yes	18	46.47 (14.74)	18	2.81 (11.13)	9	46.61 (14.16)	9	16.58 (16.55)	-13.77 (-55.20, 27.65)	0.4933	-0.28 (-1.08, 0.53)	
		no	110	38.50 (16.14)	108	-6.06 (3.42)	56	40.88 (16.29)	54	-2.95 (4.66)	-3.10 (-14.17, 7.96)	0.5800	-0.09 (-0.41, 0.24)	
		UDCA												0.8622
		UDCA Use	120	39.07 (16.04)	118	-3.83 (3.41)	62	40.11 (14.66)	60	-2.78 (4.61)	-1.05 (-12.05, 9.96)	0.8513	-0.03 (-0.34, 0.28)	
		UDCA Intolerance	8	47.88 (16.32)	8	-11.73 (11.92)	3	73.94 (5.58)	3	-15.95 (26.25)	4.22 (-65.15, 73.59)	0.8911	0.11 (-1.22, 1.43)	
		Prior Use of OCA and/or Fibrates												0.3507
		yes	20	48.63 (18.48)	18	5.01 (7.54)	13	44.67 (16.49)	12	-3.92 (9.25)	8.93 (-15.64, 33.50)	0.4611	0.27 (-0.46, 1.01)	
		no	108	37.95 (15.18)	108	-6.24 (3.55)	52	40.92 (15.99)	51	-2.72 (5.06)	-3.53 (-15.38, 8.32)	0.5567	-0.10 (-0.43, 0.24)	
		Therapy												0.8833
		Monotherapy (SEL)	8	47.88 (16.32)	8	-12.72 (10.49)	4	69.88 (9.33)	4	-14.41 (18.28)	1.69 (-47.18, 50.56)	0.9395	0.05 (-1.15, 1.25)	
		Combinationtherapy (SEL + UDCA)	120	39.07 (16.04)	118	-3.83 (3.42)	61	39.83 (14.60)	59	-2.23 (4.67)	-1.60 (-12.69, 9.49)	0.7765	-0.04 (-0.36, 0.27)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of absolute and relative changes from baseline of AST at month 6 and 12 - Subgroup analysis
Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
			Baseline		Change from BL		Baseline		Change from BL					
Variable	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
Percent change from baseline	Month 12	Stratification variable: Baseline Pruritus NRS												0.7223
		< 4	79	37.82 (16.16)	79	-10.56 (4.19)	42	40.99 (16.59)	41	-6.44 (5.58)	-4.13 (-17.41, 9.15)	0.5391	-0.11 (-0.49, 0.27)	
		>= 4	49	42.52 (15.83)	47	1.91 (4.78)	23	42.93 (15.23)	22	2.18 (7.09)	-0.27 (-17.37, 16.83)	0.9746	-0.01 (-0.51, 0.50)	
		Stratification variable: Baseline ALP Level												0.2606
		< 350 U/L	93	35.15 (14.13)	92	-7.16 (3.68)	47	39.44 (16.94)	45	-0.11 (5.30)	-7.05 (-19.60, 5.50)	0.2685	-0.20 (-0.56, 0.16)	
		>= 350 U/L	35	51.49 (15.27)	34	1.04 (6.17)	18	47.50 (11.88)	18	-5.57 (8.27)	6.61 (-14.46, 27.68)	0.5276	0.18 (-0.39, 0.75)	
		Gamma-GT (GGT)												0.7430
		<= 3 x ULN	33	31.67 (13.09)	32	4.36 (6.38)	14	32.96 (16.30)	13	9.60 (8.85)	-5.24 (-24.05, 13.56)	0.5765	-0.15 (-0.79, 0.50)	
		> 3 x ULN	95	42.38 (16.24)	94	-4.40 (3.84)	51	44.07 (15.26)	50	-2.86 (5.20)	-1.54 (-14.15, 11.06)	0.8088	-0.04 (-0.38, 0.30)	
		Total Bilirubin I												0.8216
		<= 1 x ULN	108	38.12 (16.34)	106	-4.34 (3.66)	60	40.39 (15.24)	59	-1.94 (4.76)	-2.40 (-13.83, 9.04)	0.6793	-0.06 (-0.38, 0.25)	
		> 1 x ULN	20	47.71 (12.49)	20	-8.39 (6.21)	5	57.05 (19.13)	4	-10.02 (15.76)	1.63 (-34.05, 37.31)	0.9242	0.06 (-1.02, 1.13)	
		Total Bilirubin II												0.5639
		< 0.6 x ULN	59	34.89 (15.77)	58	-8.56 (5.21)	32	37.51 (15.77)	31	-2.77 (7.01)	-5.80 (-22.29, 10.69)	0.4864	-0.15 (-0.58, 0.29)	
		>= 0.6 x ULN	69	43.66 (15.44)	68	-3.19 (3.88)	33	45.71 (15.46)	32	-3.53 (5.52)	0.34 (-12.92, 13.60)	0.9594	0.01 (-0.41, 0.43)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Summary of mean values, absolute and relative changes from baseline of GGT by visit
Intention-to-treat

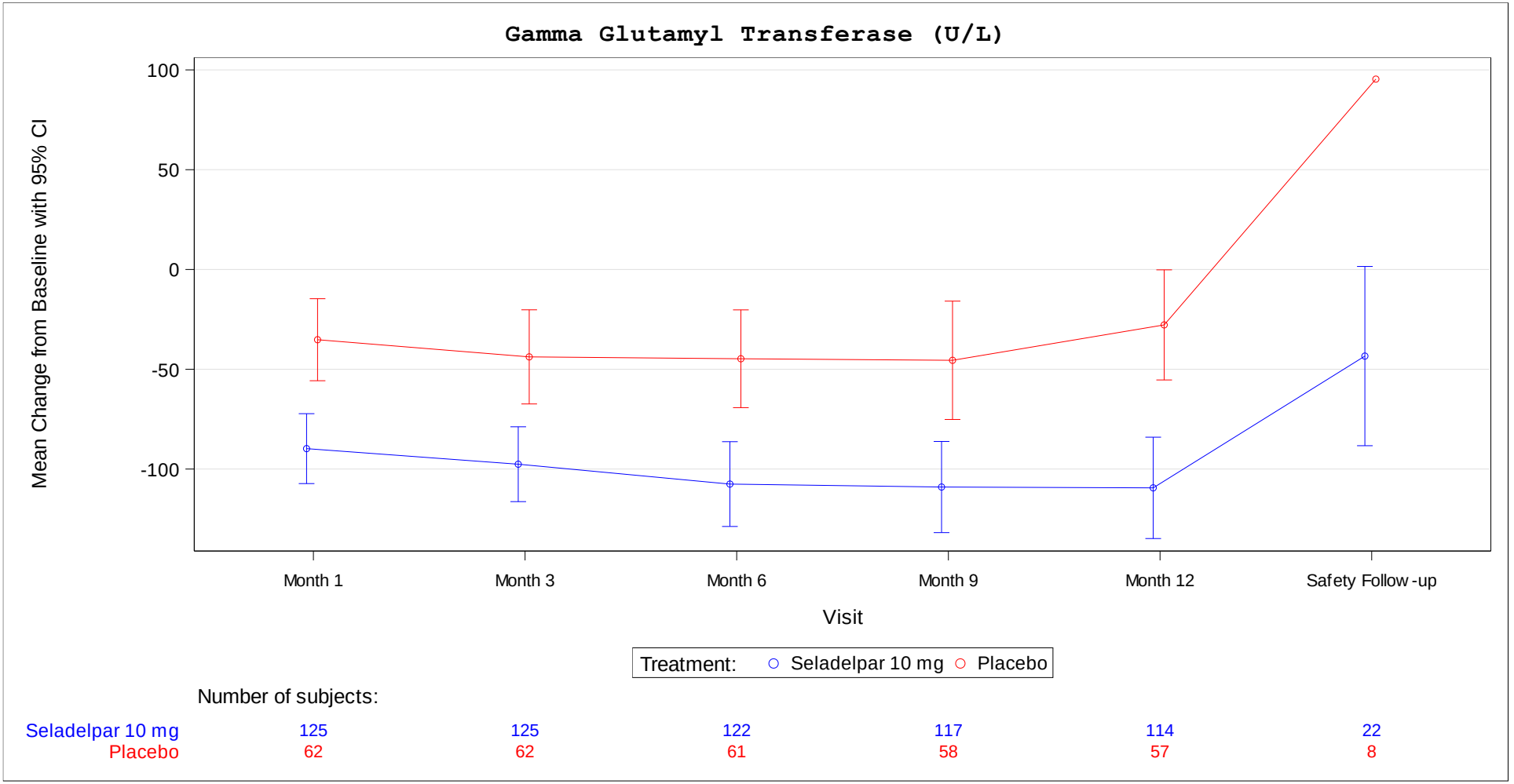
		Seladelpar 10 mg (N=128)				Placebo (N=65)			
		Value at Timepoint		Change from Baseline		Value at Timepoint		Change from Baseline	
Variable	Timepoint	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Change from baseline	Baseline	128	269.04 (240.04)	0	-	65	287.51 (249.56)	0	-
	Month 1	125	178.87 (167.01)	125	-89.76 (98.91)	62	248.11 (239.78)	62	-35.19 (80.91)
	Month 3	125	173.74 (165.59)	125	-97.57 (105.91)	62	238.95 (210.77)	62	-43.79 (92.88)
	Month 6	122	165.47 (162.62)	122	-107.52 (118.51)	61	239.38 (212.75)	61	-44.73 (95.62)
	Month 9	117	164.03 (155.56)	117	-109.01 (124.73)	58	231.36 (208.50)	58	-45.51 (112.75)
	Month 12	114	161.60 (154.59)	114	-109.42 (136.85)	57	250.04 (233.28)	57	-27.77 (103.95)
	Safety Follow-up	22	194.95 (208.31)	22	-43.40 (101.28)	8	544.88 (595.68)	8	95.40 (265.62)

N describes number of patients with non-missing value at the respective timepoint.
N=Number of subjects included in the analysis, SD: Standard Deviation; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Summary of mean values, absolute and relative changes from baseline of GGT by visit
Intention-to-treat

		Seladelpar 10 mg (N=128)				Placebo (N=65)			
		Value at Timepoint		Change from Baseline		Value at Timepoint		Change from Baseline	
Variable	Timepoint	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Percent change from baseline	Baseline	128	269.04 (240.04)	0	-	65	287.51 (249.56)	0	-
	Month 1	125	178.87 (167.01)	125	-31.12 (32.29)	62	248.11 (239.78)	62	-13.76 (21.26)
	Month 3	125	173.74 (165.59)	125	-35.61 (19.41)	62	238.95 (210.77)	62	-15.25 (25.30)
	Month 6	122	165.47 (162.62)	122	-38.67 (22.43)	61	239.38 (212.75)	61	-14.19 (35.97)
	Month 9	117	164.03 (155.56)	117	-38.13 (32.47)	58	231.36 (208.50)	58	-16.26 (30.67)
	Month 12	114	161.60 (154.59)	114	-39.73 (26.28)	57	250.04 (233.28)	57	-12.62 (29.11)
	Safety Follow-up	22	194.95 (208.31)	22	-27.20 (33.32)	8	544.88 (595.68)	8	0.30 (45.23)

N describes number of patients with non-missing value at the respective timepoint.
N=Number of subjects included in the analysis, SD: Standard Deviation; CI=Confidence Interval



Number of subjects:

	Month 1	Month 3	Month 6	Month 9	Month 12	Safety Follow-up
Seladelpar 10 mg	125	125	122	117	114	22
Placebo	62	62	61	58	57	8

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of absolute and relative changes from baseline of GGT by visit
Intention-to-treat

		Seladelpar 10 mg (N=128)		Placebo (N=65)				
Score	Visit	N	LSMean (SE)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)
Change from baseline	Month 1	126	-89.20 (6.22)	63	-33.17 (8.51)	-56.03 (-75.66, -36.40)	<.0001	-0.81 (-1.12, -0.49)
	Month 3	126	-95.93 (6.97)	63	-34.67 (9.60)	-61.26 (-83.66, -38.86)	<.0001	-0.79 (-1.10, -0.47)
	Month 6	126	-105.62 (7.40)	63	-35.86 (10.22)	-69.76 (-93.70, -45.81)	<.0001	-0.84 (-1.16, -0.53)
	Month 9	126	-104.62 (8.18)	63	-34.33 (11.37)	-70.29 (-97.08, -43.50)	<.0001	-0.77 (-1.08, -0.45)
	Month 12	126	-107.97 (8.49)	63	-18.33 (11.79)	-89.65 (-117.47, -61.82)	<.0001	-0.94 (-1.26, -0.63)

(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
N=Number of subjects included in the analysis, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of absolute and relative changes from baseline of GGT by visit
Intention-to-treat

		Seladelpar 10 mg (N=128)		Placebo (N=65)		Difference of		
Score	Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)
Percent change from baseline	Month 1	126	-30.32 (2.73)	63	-12.92 (3.79)	-17.40 (-26.32, -8.47)	0.0002	-0.57 (-0.88, -0.26)
	Month 3	126	-34.77 (2.10)	63	-14.10 (2.88)	-20.67 (-27.31, -14.04)	<.0001	-0.88 (-1.20, -0.57)
	Month 6	126	-37.98 (2.62)	63	-12.97 (3.63)	-25.01 (-33.53, -16.49)	<.0001	-0.85 (-1.17, -0.54)
	Month 9	126	-36.55 (3.09)	63	-14.50 (4.33)	-22.04 (-32.29, -11.80)	<.0001	-0.63 (-0.94, -0.33)
	Month 12	126	-39.15 (2.63)	63	-11.36 (3.64)	-27.78 (-36.33, -19.23)	<.0001	-0.94 (-1.26, -0.63)

(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
N=Number of subjects included in the analysis, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of absolute and relative changes from baseline of GGT at month 6 and 12 - Subgroup analysis
Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
			Baseline		Change from BL		Baseline		Change from BL					
Variable	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
Change from baseline	Month 6	Age at screening												0.0340
		< 65 years	99	277.59 (258.08)	97	-106.86 (8.84)	53	280.94 (235.58)	51	-25.80 (11.84)	-81.06 (-109.41, -52.71)	<.0001	-0.94 (-1.29, -0.58)	
		>= 65 years	29	239.86 (164.57)	29	-103.44 (8.28)	12	316.53 (314.45)	12	-65.14 (13.40)	-38.31 (-67.19, -9.42)	0.0109	-0.83 (-1.53, -0.13)	
		Age at PBC diagnosis												0.4415
		< 50 years	61	303.59 (283.40)	59	-105.57 (11.46)	32	265.60 (196.18)	30	-19.20 (15.91)	-86.38 (-124.64, -48.11)	<.0001	-0.98 (-1.44, -0.51)	
		>= 50 years	67	237.59 (189.08)	67	-106.68 (9.26)	33	308.77 (293.83)	33	-38.99 (12.82)	-67.68 (-97.14, -38.23)	<.0001	-0.89 (-1.33, -0.46)	
		Sex												NE
		female	123	268.29 (242.17)	121	-102.90 (7.07)	60	250.99 (202.80)	58	-23.42 (9.98)	-79.48 (-102.85, -56.12)	<.0001	-1.02 (-1.36, -0.69)	
		male	5	287.58 (200.45)	5	NE	5	725.80 (360.22)	5	NE	NE		NE	
		Race												
		white	114	267.48 (227.05)	113		56	298.15 (260.31)	54					
		black	2	898.17 (712.53)	2		2	186.83 (153.91)	2					
		asian	7	175.81 (101.31)	7		4	304.42 (203.71)	4					
		other	5	183.58 (91.36)	4		3	133.44 (77.58)	3					
		Region												0.4228
		North America	50	276.20 (267.63)	49	-111.08 (12.14)	13	344.13 (238.99)	12	-16.34 (22.74)	-94.73 (-144.29, -45.18)	0.0003	-1.12 (-1.78, -0.45)	
		Europe	39	288.56 (261.30)	39	-114.90 (14.14)	24	315.36 (320.27)	23	-45.86 (18.66)	-69.04 (-115.57, -22.50)	0.0050	-0.77 (-1.30, -0.23)	
		Rest-of-World	39	240.35 (175.00)	38	-87.07 (12.22)	28	237.35 (173.28)	28	-32.56 (14.26)	-54.51 (-90.83, -18.18)	0.0039	-0.71 (-1.22, -0.21)	
		Cirrhosis												0.9884
		yes	18	241.16 (145.52)	18	-93.37 (30.28)	9	461.85 (339.06)	9	-28.81 (45.12)	-64.56 (-177.34, 48.23)	0.2471	-0.48 (-1.29, 0.33)	
		no	110	273.61 (252.35)	108	-106.52 (7.59)	56	259.49 (223.56)	54	-42.77 (10.42)	-63.75 (-88.31, -39.18)	<.0001	-0.81 (-1.15, -0.47)	
		UDCA												0.0914
		UDCA Use	120	255.78 (218.30)	118	-98.86 (7.57)	62	269.16 (236.44)	60	-38.14 (10.22)	-60.73 (-84.78, -36.67)	<.0001	-0.74 (-1.07, -0.42)	
		UDCA Intolerance	8	468.00 (432.43)	8	-203.42 (36.92)	3	666.89 (248.21)	3	26.19 (91.20)	-229.61 (-474.58, 15.36)	0.0615	-1.77 (-3.39, -0.16)	
		Prior Use of OCA and/or Fibrates												0.8901
		yes	20	403.05 (365.26)	18	-138.28 (24.07)	13	356.11 (295.14)	12	-72.72 (29.28)	-65.56 (-143.38, 12.27)	0.0949	-0.63 (-1.38, 0.12)	
		no	108	244.23 (201.79)	108	-98.32 (7.70)	52	270.36 (236.99)	51	-27.27 (10.86)	-71.05 (-95.94, -46.16)	<.0001	-0.89 (-1.24, -0.54)	
		Therapy												0.0077
		Monotherapy (SEL)	8	468.00 (432.43)	8	-194.90 (35.60)	4	568.00 (283.17)	4	48.95 (57.93)	-243.85 (-417.05, -70.64)	0.0149	-2.13 (-3.72, -0.54)	
		Combinationtherapy (SEL + UDCA)	120	255.78 (218.30)	118	-98.79 (7.57)	61	269.12 (238.40)	59	-39.37 (10.33)	-59.41 (-83.58, -35.24)	<.0001	-0.73 (-1.05, -0.41)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
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N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of absolute and relative changes from baseline of GGT at month 6 and 12 - Subgroup analysis
Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
			Baseline		Change from BL		Baseline		Change from BL					
Variable	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
Change from baseline	Month 6	Stratification variable: Baseline Pruritus NRS												0.4107
		< 4	79	257.76 (233.17)	79	-106.91 (8.54)	42	271.24 (250.77)	41	-46.28 (11.15)	-60.63 (-86.59, -34.68)	<.0001	-0.81 (-1.20, -0.42)	
		>= 4	49	287.23 (252.10)	47	-109.86 (13.51)	23	317.22 (250.12)	22	-26.64 (20.12)	-83.22 (-131.52, -34.91)	0.0011	-0.88 (-1.41, -0.35)	
		Stratification variable: Baseline ALP Level												0.8513
		< 350 U/L	93	213.58 (183.54)	92	-94.06 (7.56)	47	235.41 (209.67)	45	-25.20 (10.63)	-68.86 (-94.15, -43.57)	<.0001	-0.95 (-1.32, -0.57)	
		>= 350 U/L	35	416.42 (305.44)	34	-151.08 (15.12)	18	423.55 (297.35)	18	-76.78 (21.20)	-74.30 (-127.22, -21.37)	0.0073	-0.82 (-1.42, -0.23)	
		Gamma-GT (GGT)												0.0006
		<= 3 x ULN	33	77.10 (27.55)	32	-23.59 (5.57)	14	85.75 (18.97)	13	0.71 (8.27)	-24.30 (-42.15, -6.44)	0.0088	-0.77 (-1.43, -0.10)	
		> 3 x ULN	95	335.72 (245.28)	94	-131.83 (9.57)	51	342.90 (255.15)	50	-45.61 (12.94)	-86.23 (-117.47, -54.98)	<.0001	-0.93 (-1.29, -0.57)	
		Total Bilirubin I												0.0935
		<= 1 x ULN	108	261.96 (228.65)	106	-106.62 (7.62)	60	269.01 (221.05)	59	-38.62 (9.80)	-68.00 (-91.34, -44.66)	<.0001	-0.87 (-1.21, -0.54)	
		> 1 x ULN	20	307.29 (298.13)	20	-117.94 (24.06)	5	509.53 (457.16)	4	65.37 (63.33)	-183.31 (-341.75, -24.87)	0.0288	-1.60 (-2.79, -0.42)	
		Total Bilirubin II												0.7911
		< 0.6 x ULN	59	243.04 (223.93)	58	-103.17 (10.28)	32	223.65 (210.14)	31	-37.80 (13.15)	-65.38 (-96.45, -34.30)	<.0001	-0.85 (-1.30, -0.39)	
		>= 0.6 x ULN	69	291.28 (252.49)	68	-111.05 (10.94)	33	349.44 (271.57)	32	-39.11 (16.12)	-71.94 (-110.25, -33.63)	0.0004	-0.79 (-1.22, -0.35)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of absolute and relative changes from baseline of GGT at month 6 and 12 - Subgroup analysis
Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
			Baseline		Change from BL		Baseline		Change from BL					
Variable	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
Change from baseline	Month 12	Age at screening												0.3466
		< 65 years	99	277.59 (258.08)	97	-112.67 (10.37)	53	280.94 (235.58)	51	-11.61 (14.19)	-101.06 (-135.10, -67.03)	<.0001	-0.99 (-1.34, -0.63)	
		>= 65 years	29	239.86 (164.57)	29	-97.62 (16.27)	12	316.53 (314.45)	12	-27.89 (24.36)	-69.74 (-128.97, -10.50)	0.0232	-0.79 (-1.48, -0.09)	
		Age at PBC diagnosis												0.6458
		< 50 years	61	303.59 (283.40)	59	-109.43 (11.90)	32	265.60 (196.18)	30	-5.97 (16.79)	-103.46 (-143.66, -63.26)	<.0001	-1.12 (-1.59, -0.65)	
		>= 50 years	67	237.59 (189.08)	67	-109.16 (11.60)	33	308.77 (293.83)	33	-18.46 (16.05)	-90.70 (-128.57, -52.84)	<.0001	-0.96 (-1.39, -0.52)	
		Sex												NE
		female	123	268.29 (242.17)	121	-104.07 (7.84)	60	250.99 (202.80)	58	-12.33 (11.06)	-91.74 (-117.79, -65.68)	<.0001	-1.07 (-1.40, -0.73)	
		male	5	287.58 (200.45)	5	NE	5	725.80 (360.22)	5	NE	NE		NE	
		Race												
		white	114	267.48 (227.05)	113		56	298.15 (260.31)	54					
		black	2	898.17 (712.53)	2		2	186.83 (153.91)	2					
		asian	7	175.81 (101.31)	7		4	304.42 (203.71)	4					
		other	5	183.58 (91.36)	4		3	133.44 (77.58)	3					
		Region												0.5209
		North America	50	276.20 (267.63)	49	-105.15 (15.67)	13	344.13 (238.99)	12	17.37 (31.72)	-122.52 (-192.05, -52.98)	0.0009	-1.10 (-1.76, -0.44)	
		Europe	39	288.56 (261.30)	39	-130.41 (13.37)	24	315.36 (320.27)	23	-44.59 (17.09)	-85.82 (-127.81, -43.83)	0.0001	-1.02 (-1.57, -0.47)	
		Rest-of-World	39	240.35 (175.00)	38	-88.07 (15.21)	28	237.35 (173.28)	28	-12.46 (17.48)	-75.62 (-121.06, -30.17)	0.0015	-0.80 (-1.31, -0.29)	
		Cirrhosis												0.9751
		yes	18	241.16 (145.52)	18	-76.11 (45.42)	9	461.85 (339.06)	9	10.33 (68.03)	-86.44 (-256.57, 83.68)	0.3021	-0.43 (-1.24, 0.38)	
		no	110	273.61 (252.35)	108	-112.44 (8.37)	56	259.49 (223.56)	54	-23.41 (11.40)	-89.03 (-116.17, -61.89)	<.0001	-1.03 (-1.38, -0.69)	
		UDCA												0.1317
		UDCA Use	120	255.78 (218.30)	118	-99.29 (8.84)	62	269.16 (236.44)	60	-18.69 (11.99)	-80.60 (-109.09, -52.11)	<.0001	-0.84 (-1.17, -0.52)	
		UDCA Intolerance	8	468.00 (432.43)	8	-231.80 (33.09)	3	666.89 (248.21)	3	2.68 (94.50)	-234.48 (-495.90, 26.94)	0.0691	-1.90 (-3.55, -0.24)	
		Prior Use of OCA and/or Fibrates												0.3448
		yes	20	403.05 (365.26)	18	-143.69 (29.31)	13	356.11 (295.14)	12	-14.26 (36.11)	-129.43 (-226.48, -32.39)	0.0116	-1.01 (-1.79, -0.23)	
		no	108	244.23 (201.79)	108	-100.33 (8.72)	52	270.36 (236.99)	51	-16.81 (12.37)	-83.52 (-112.16, -54.88)	<.0001	-0.92 (-1.27, -0.58)	
		Therapy												0.7302
		Monotherapy (SEL)	8	468.00 (432.43)	8	-223.27 (75.09)	4	568.00 (283.17)	4	-190.28 (126.18)	-32.99 (-709.70, 643.71)	0.8444	-0.14 (-1.34, 1.07)	
		Combinationtherapy (SEL + UDCA)	120	255.78 (218.30)	118	-99.26 (8.80)	61	269.12 (238.40)	59	-15.37 (12.04)	-83.89 (-112.35, -55.43)	<.0001	-0.88 (-1.21, -0.56)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of absolute and relative changes from baseline of GGT at month 6 and 12 - Subgroup analysis
Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
			Baseline		Change from BL		Baseline		Change from BL					
Variable	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
Change from baseline	Month 12	Stratification variable: Baseline Pruritus NRS												0.4234
		< 4	79	257.76 (233.17)	79	-110.27 (10.90)	42	271.24 (250.77)	41	-29.99 (14.61)	-80.29 (-114.98, -45.60)	<.0001	-0.83 (-1.23, -0.44)	
		>= 4	49	287.23 (252.10)	47	-111.21 (13.03)	23	317.22 (250.12)	22	-7.67 (19.28)	-103.54 (-149.98, -57.11)	<.0001	-1.14 (-1.68, -0.60)	
		Stratification variable: Baseline ALP Level												0.6632
		< 350 U/L	93	213.58 (183.54)	92	-91.41 (8.93)	47	235.41 (209.67)	45	-5.78 (12.81)	-85.62 (-116.10, -55.15)	<.0001	-0.99 (-1.37, -0.62)	
		>= 350 U/L	35	416.42 (305.44)	34	-167.30 (18.92)	18	423.55 (297.35)	18	-66.38 (25.25)	-100.91 (-164.59, -37.23)	0.0026	-0.91 (-1.51, -0.31)	
		Gamma-GT (GGT)												<.0001
		<= 3 x ULN	33	77.10 (27.55)	32	-25.34 (4.56)	14	85.75 (18.97)	13	-0.49 (6.54)	-24.85 (-38.05, -11.65)	0.0005	-0.97 (-1.65, -0.29)	
		> 3 x ULN	95	335.72 (245.28)	94	-134.22 (11.13)	51	342.90 (255.15)	50	-22.89 (15.08)	-111.33 (-147.91, -74.75)	<.0001	-1.03 (-1.39, -0.67)	
		Total Bilirubin I												0.8216
		<= 1 x ULN	108	261.96 (228.65)	106	-108.01 (9.17)	60	269.01 (221.05)	59	-16.98 (11.94)	-91.03 (-119.84, -62.22)	<.0001	-0.97 (-1.30, -0.63)	
		> 1 x ULN	20	307.29 (298.13)	20	-122.49 (17.35)	5	509.53 (457.16)	4	-19.25 (49.30)	-103.23 (-227.87, 21.40)	0.0904	-1.23 (-2.37, -0.09)	
		Total Bilirubin II												0.4441
		< 0.6 x ULN	59	243.04 (223.93)	58	-104.51 (9.69)	32	223.65 (210.14)	31	-28.12 (12.67)	-76.39 (-106.03, -46.75)	<.0001	-1.04 (-1.50, -0.58)	
		>= 0.6 x ULN	69	291.28 (252.49)	68	-113.87 (14.00)	33	349.44 (271.57)	32	-15.60 (20.28)	-98.28 (-146.88, -49.68)	0.0001	-0.85 (-1.28, -0.41)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of absolute and relative changes from baseline of GGT at month 6 and 12 - Subgroup analysis
Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
			Baseline		Change from BL		Baseline		Change from BL					
Variable	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
Percent change from baseline	Month 6	Age at screening												0.0548
		< 65 years	99	277.59 (258.08)	97	-38.18 (3.21)	53	280.94 (235.58)	51	-9.89 (4.32)	-28.29 (-38.64, -17.94)	<.0001	-0.90 (-1.25, -0.54)	
		>= 65 years	29	239.86 (164.57)	29	-36.88 (3.30)	12	316.53 (314.45)	12	-23.47 (5.32)	-13.41 (-24.96, -1.86)	0.0240	-0.73 (-1.43, -0.04)	
		Age at PBC diagnosis												0.6195
		< 50 years	61	303.59 (283.40)	59	-36.37 (3.49)	32	265.60 (196.18)	30	-12.78 (4.82)	-23.60 (-35.20, -11.99)	0.0001	-0.88 (-1.34, -0.42)	
		>= 50 years	67	237.59 (189.08)	67	-38.48 (3.90)	33	308.77 (293.83)	33	-10.58 (5.44)	-27.90 (-40.61, -15.18)	<.0001	-0.87 (-1.31, -0.44)	
		Sex												0.0540
		female	123	268.29 (242.17)	121	-38.45 (2.70)	60	250.99 (202.80)	58	-11.54 (3.81)	-26.90 (-35.83, -17.98)	<.0001	-0.91 (-1.24, -0.58)	
		male	5	287.58 (200.45)	5	-31.55 (23.78)	5	725.80 (360.22)	5	-56.70 (16.05)	25.14 (-71.96, 122.24)	0.4292	0.50 (-0.77, 1.77)	
		Race												
		white	114	267.48 (227.05)	113		56	298.15 (260.31)	54					
		black	2	898.17 (712.53)	2		2	186.83 (153.91)	2					
		asian	7	175.81 (101.31)	7		4	304.42 (203.71)	4					
		other	5	183.58 (91.36)	4		3	133.44 (77.58)	3					
		Region												0.9789
		North America	50	276.20 (267.63)	49	-35.59 (4.06)	13	344.13 (238.99)	12	-11.34 (7.57)	-24.26 (-40.54, -7.98)	0.0042	-0.85 (-1.51, -0.20)	
		Europe	39	288.56 (261.30)	39	-41.05 (3.60)	24	315.36 (320.27)	23	-16.46 (4.78)	-24.58 (-36.14, -13.02)	<.0001	-1.07 (-1.62, -0.52)	
		Rest-of-World	39	240.35 (175.00)	38	-36.17 (5.79)	28	237.35 (173.28)	28	-9.68 (6.75)	-26.50 (-43.91, -9.09)	0.0034	-0.73 (-1.24, -0.23)	
		Cirrhosis												0.7359
		yes	18	241.16 (145.52)	18	-32.19 (6.75)	9	461.85 (339.06)	9	-11.19 (10.19)	-21.01 (-46.40, 4.38)	0.1007	-0.70 (-1.52, 0.13)	
		no	110	273.61 (252.35)	108	-38.76 (2.88)	56	259.49 (223.56)	54	-13.30 (3.94)	-25.45 (-34.74, -16.16)	<.0001	-0.86 (-1.20, -0.52)	
		UDCA												0.2030
		UDCA Use	120	255.78 (218.30)	118	-37.89 (2.75)	62	269.16 (236.44)	60	-13.77 (3.74)	-24.12 (-32.96, -15.28)	<.0001	-0.81 (-1.13, -0.49)	
		UDCA Intolerance	8	468.00 (432.43)	8	-41.09 (8.21)	3	666.89 (248.21)	3	12.96 (20.91)	-54.05 (-108.08, -0.01)	0.0500	-1.85 (-3.49, -0.21)	
		Prior Use of OCA and/or Fibrates												0.0693
		yes	20	403.05 (365.26)	18	-29.87 (5.91)	13	356.11 (295.14)	12	-20.68 (7.19)	-9.19 (-28.19, 9.80)	0.3299	-0.36 (-1.09, 0.38)	
		no	108	244.23 (201.79)	108	-38.96 (2.87)	52	270.36 (236.99)	51	-10.79 (4.10)	-28.17 (-37.67, -18.66)	<.0001	-0.94 (-1.29, -0.60)	
		Therapy												0.0399
		Monotherapy (SEL)	8	468.00 (432.43)	8	-40.72 (7.40)	4	568.00 (283.17)	4	13.71 (12.11)	-54.43 (-86.42, -22.44)	0.0037	-2.29 (-3.93, -0.65)	
		Combinationtherapy (SEL + UDCA)	120	255.78 (218.30)	118	-37.95 (2.75)	61	269.12 (238.40)	59	-14.28 (3.78)	-23.67 (-32.56, -14.78)	<.0001	-0.80 (-1.12, -0.47)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
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N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of absolute and relative changes from baseline of GGT at month 6 and 12 - Subgroup analysis
Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
			Baseline		Change from BL		Baseline		Change from BL					
Variable	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
Percent change from baseline	Month 6	Stratification variable: Baseline Pruritus NRS												0.4877
		< 4	79	257.76 (233.17)	79	-41.42 (3.49)	42	271.24 (250.77)	41	-14.17 (4.62)	-27.25 (-38.19, -16.31)	<.0001	-0.89 (-1.28, -0.49)	
		>= 4	49	287.23 (252.10)	47	-34.54 (3.83)	23	317.22 (250.12)	22	-13.38 (5.70)	-21.16 (-34.79, -7.53)	0.0029	-0.79 (-1.32, -0.27)	
		Stratification variable: Baseline ALP Level												0.1447
		< 350 U/L	93	213.58 (183.54)	92	-41.29 (3.13)	47	235.41 (209.67)	45	-12.10 (4.38)	-29.19 (-39.62, -18.76)	<.0001	-0.97 (-1.35, -0.60)	
		>= 350 U/L	35	416.42 (305.44)	34	-32.81 (4.24)	18	423.55 (297.35)	18	-16.73 (5.92)	-16.07 (-30.75, -1.39)	0.0326	-0.64 (-1.22, -0.05)	
		Gamma-GT (GGT)												0.4817
		<= 3 x ULN	33	77.10 (27.55)	32	-28.03 (7.17)	14	85.75 (18.97)	13	5.52 (10.68)	-33.56 (-57.16, -9.95)	0.0064	-0.82 (-1.49, -0.16)	
		> 3 x ULN	95	335.72 (245.28)	94	-39.67 (2.63)	51	342.90 (255.15)	50	-14.91 (3.56)	-24.77 (-33.36, -16.17)	<.0001	-0.97 (-1.33, -0.61)	
		Total Bilirubin I												0.4036
		<= 1 x ULN	108	261.96 (228.65)	106	-38.65 (3.02)	60	269.01 (221.05)	59	-13.67 (3.88)	-24.98 (-34.22, -15.74)	<.0001	-0.81 (-1.14, -0.48)	
		> 1 x ULN	20	307.29 (298.13)	20	-36.48 (4.82)	5	509.53 (457.16)	4	0.16 (12.17)	-36.64 (-64.14, -9.14)	0.0117	-1.61 (-2.80, -0.43)	
		Total Bilirubin II												0.3280
		< 0.6 x ULN	59	243.04 (223.93)	58	-42.75 (4.68)	32	223.65 (210.14)	31	-13.17 (5.94)	-29.58 (-43.52, -15.65)	<.0001	-0.84 (-1.30, -0.39)	
		>= 0.6 x ULN	69	291.28 (252.49)	68	-34.52 (3.00)	33	349.44 (271.57)	32	-13.52 (4.40)	-21.00 (-31.47, -10.53)	0.0001	-0.84 (-1.28, -0.40)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of absolute and relative changes from baseline of GGT at month 6 and 12 - Subgroup analysis
Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
			Baseline		Change from BL		Baseline		Change from BL					
Variable	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
Percent change from baseline	Month 12	Age at screening												0.1472
		< 65 years	99	277.59 (258.08)	97	-40.39 (3.12)	53	280.94 (235.58)	51	-9.41 (4.24)	-30.98 (-41.10, -20.87)	<.0001	-1.01 (-1.37, -0.65)	
		>= 65 years	29	239.86 (164.57)	29	-34.88 (4.49)	12	316.53 (314.45)	12	-17.43 (6.88)	-17.45 (-33.28, -1.61)	0.0317	-0.71 (-1.40, -0.02)	
		Age at PBC diagnosis												0.5762
		< 50 years	61	303.59 (283.40)	59	-35.87 (4.05)	32	265.60 (196.18)	30	-9.83 (5.71)	-26.05 (-39.77, -12.32)	0.0003	-0.83 (-1.29, -0.37)	
		>= 50 years	67	237.59 (189.08)	67	-41.09 (3.48)	33	308.77 (293.83)	33	-10.08 (4.78)	-31.01 (-42.10, -19.91)	<.0001	-1.09 (-1.54, -0.65)	
		Sex												0.3405
		female	123	268.29 (242.17)	121	-39.37 (2.69)	60	250.99 (202.80)	58	-11.37 (3.79)	-28.00 (-36.88, -19.12)	<.0001	-0.95 (-1.28, -0.62)	
		male	5	287.58 (200.45)	5	-37.99 (25.62)	5	725.80 (360.22)	5	-38.86 (18.88)	0.88 (-81.60, 83.35)	0.9781	0.02 (-1.22, 1.26)	
		Race												
		white	114	267.48 (227.05)	113		56	298.15 (260.31)	54					
		black	2	898.17 (712.53)	2		2	186.83 (153.91)	2					
		asian	7	175.81 (101.31)	7		4	304.42 (203.71)	4					
		other	5	183.58 (91.36)	4		3	133.44 (77.58)	3					
		Region												0.9486
		North America	50	276.20 (267.63)	49	-33.00 (4.94)	13	344.13 (238.99)	12	0.21 (9.76)	-33.21 (-54.46, -11.95)	0.0028	-0.95 (-1.61, -0.30)	
		Europe	39	288.56 (261.30)	39	-44.44 (4.11)	24	315.36 (320.27)	23	-12.88 (5.32)	-31.56 (-44.63, -18.49)	<.0001	-1.22 (-1.78, -0.66)	
		Rest-of-World	39	240.35 (175.00)	38	-40.04 (4.88)	28	237.35 (173.28)	28	-10.73 (5.61)	-29.31 (-43.76, -14.87)	0.0001	-0.97 (-1.49, -0.45)	
		Cirrhosis												0.7585
		yes	18	241.16 (145.52)	18	-26.66 (8.61)	9	461.85 (339.06)	9	-2.84 (13.24)	-23.83 (-56.88, 9.23)	0.1484	-0.61 (-1.43, 0.20)	
		no	110	273.61 (252.35)	108	-40.93 (2.81)	56	259.49 (223.56)	54	-12.03 (3.81)	-28.90 (-37.89, -19.91)	<.0001	-1.00 (-1.34, -0.65)	
		UDCA												0.6587
		UDCA Use	120	255.78 (218.30)	118	-38.73 (2.80)	62	269.16 (236.44)	60	-12.06 (3.79)	-26.67 (-35.64, -17.70)	<.0001	-0.88 (-1.21, -0.56)	
		UDCA Intolerance	8	468.00 (432.43)	8	-46.78 (9.41)	3	666.89 (248.21)	3	-7.64 (25.71)	-39.14 (-182.03, 103.76)	0.3152	-1.14 (-2.59, 0.32)	
		Prior Use of OCA and/or Fibrates												0.6496
		yes	20	403.05 (365.26)	18	-27.32 (8.54)	13	356.11 (295.14)	12	-5.12 (10.52)	-22.21 (-49.97, 5.56)	0.1124	-0.59 (-1.34, 0.15)	
		no	108	244.23 (201.79)	108	-40.80 (2.63)	52	270.36 (236.99)	51	-12.14 (3.73)	-28.66 (-37.27, -20.06)	<.0001	-1.05 (-1.40, -0.70)	
		Therapy												0.4997
		Monotherapy (SEL)	8	468.00 (432.43)	8	-46.42 (15.73)	4	568.00 (283.17)	4	-38.62 (24.55)	-7.80 (-80.68, 65.09)	0.7992	-0.16 (-1.36, 1.05)	
		Combinationtherapy (SEL + UDCA)	120	255.78 (218.30)	118	-38.80 (2.77)	61	269.12 (238.40)	59	-11.05 (3.79)	-27.75 (-36.68, -18.82)	<.0001	-0.93 (-1.25, -0.60)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of absolute and relative changes from baseline of GGT at month 6 and 12 - Subgroup analysis
Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
			Baseline		Change from BL		Baseline		Change from BL					
Variable	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
Percent change from baseline	Month 12	Stratification variable: Baseline Pruritus NRS												0.7477
		< 4	79	257.76 (233.17)	79	-42.45 (3.31)	42	271.24 (250.77)	41	-15.25 (4.40)	-27.19 (-37.54, -16.84)	<.0001	-0.93 (-1.33, -0.54)	
		>= 4	49	287.23 (252.10)	47	-35.93 (4.37)	23	317.22 (250.12)	22	-5.72 (6.49)	-30.21 (-45.77, -14.64)	0.0003	-0.99 (-1.53, -0.46)	
		Stratification variable: Baseline ALP Level												0.4453
		< 350 U/L	93	213.58 (183.54)	92	-41.52 (2.96)	47	235.41 (209.67)	45	-11.43 (4.22)	-30.09 (-40.04, -20.14)	<.0001	-1.05 (-1.43, -0.68)	
		>= 350 U/L	35	416.42 (305.44)	34	-35.77 (5.22)	18	423.55 (297.35)	18	-13.34 (6.94)	-22.43 (-39.94, -4.92)	0.0132	-0.73 (-1.32, -0.14)	
		Gamma-GT (GGT)												0.8894
		<= 3 x ULN	33	77.10 (27.55)	32	-31.58 (5.34)	14	85.75 (18.97)	13	-1.16 (7.56)	-30.42 (-45.70, -15.14)	0.0003	-1.02 (-1.70, -0.33)	
		> 3 x ULN	95	335.72 (245.28)	94	-39.85 (3.14)	51	342.90 (255.15)	50	-10.71 (4.26)	-29.14 (-39.48, -18.81)	<.0001	-0.96 (-1.32, -0.59)	
		Total Bilirubin I												0.2625
		<= 1 x ULN	108	261.96 (228.65)	106	-39.60 (2.96)	60	269.01 (221.05)	59	-12.83 (3.80)	-26.77 (-35.81, -17.73)	<.0001	-0.89 (-1.22, -0.56)	
		> 1 x ULN	20	307.29 (298.13)	20	-39.73 (6.51)	5	509.53 (457.16)	4	8.01 (16.94)	-47.74 (-85.94, -9.55)	0.0172	-1.55 (-2.72, -0.37)	
		Total Bilirubin II												0.7683
		< 0.6 x ULN	59	243.04 (223.93)	58	-42.89 (3.92)	32	223.65 (210.14)	31	-13.31 (4.95)	-29.57 (-40.84, -18.30)	<.0001	-1.01 (-1.47, -0.55)	
		>= 0.6 x ULN	69	291.28 (252.49)	68	-36.46 (3.80)	33	349.44 (271.57)	32	-9.46 (5.53)	-27.00 (-40.23, -13.76)	0.0001	-0.85 (-1.29, -0.42)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
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p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Summary of mean values, absolute and relative changes from baseline of direct bilirubin by visit
Intention-to-treat

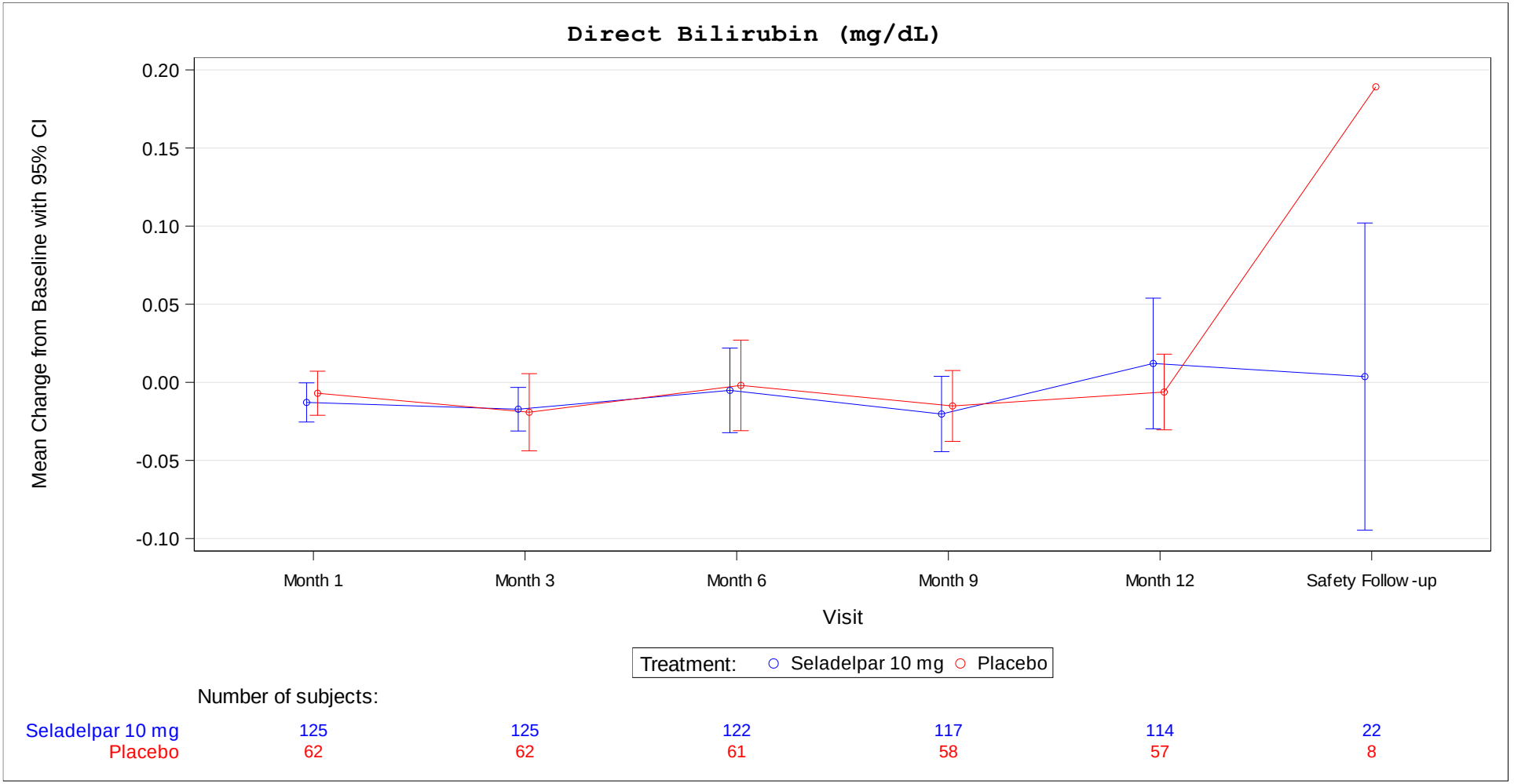
		Seladelpar 10 mg (N=128)				Placebo (N=65)			
		Value at Timepoint		Change from Baseline		Value at Timepoint		Change from Baseline	
Variable	Timepoint	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Change from baseline	Baseline	128	0.24 (0.16)	0	-	65	0.21 (0.14)	0	-
	Month 1	125	0.22 (0.16)	125	-0.01 (0.07)	62	0.20 (0.14)	62	-0.01 (0.06)
	Month 3	125	0.22 (0.16)	125	-0.02 (0.08)	62	0.18 (0.11)	62	-0.02 (0.10)
	Month 6	122	0.23 (0.22)	122	-0.01 (0.15)	61	0.20 (0.15)	61	-0.00 (0.11)
	Month 9	117	0.22 (0.19)	117	-0.02 (0.13)	58	0.19 (0.09)	58	-0.02 (0.09)
	Month 12	114	0.24 (0.28)	114	0.01 (0.23)	57	0.20 (0.12)	57	-0.01 (0.09)
	Safety Follow-up	22	0.30 (0.25)	22	0.00 (0.22)	8	0.48 (0.51)	8	0.19 (0.41)

N describes number of patients with non-missing value at the respective timepoint.
N=Number of subjects included in the analysis, SD: Standard Deviation; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Summary of mean values, absolute and relative changes from baseline of direct bilirubin by visit
Intention-to-treat

		Seladelpar 10 mg (N=128)				Placebo (N=65)			
		Value at Timepoint		Change from Baseline		Value at Timepoint		Change from Baseline	
Variable	Timepoint	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Percent change from baseline	Baseline	128	0.24 (0.16)	0	-	65	0.21 (0.14)	0	-
	Month 1	125	0.22 (0.16)	125	-2.17 (37.36)	62	0.20 (0.14)	62	-1.57 (19.80)
	Month 3	125	0.22 (0.16)	125	-5.37 (24.43)	62	0.18 (0.11)	62	-5.42 (21.89)
	Month 6	122	0.23 (0.22)	122	-2.68 (39.41)	61	0.20 (0.15)	61	-1.00 (33.55)
	Month 9	117	0.22 (0.19)	117	-7.38 (36.34)	58	0.19 (0.09)	58	-1.40 (23.18)
	Month 12	114	0.24 (0.28)	114	3.87 (68.06)	57	0.20 (0.12)	57	0.78 (28.71)
	Safety Follow-up	22	0.30 (0.25)	22	1.63 (52.43)	8	0.48 (0.51)	8	46.56 (106.42)

N describes number of patients with non-missing value at the respective timepoint.
N=Number of subjects included in the analysis, SD: Standard Deviation; CI=Confidence Interval


Direct Bilirubin (mg/dL)
Mean Change from Baseline with 95% CI
0.20
0.15
0.10
0.05
0.00
-0.05
-0.10
Month 1
Month 3
Month 6
Month 9
Month 12
Safety Follow-up
Visit
Treatment: Seladelpar 10 mg Placebo
Number of subjects:
Seladelpar 10 mg 125 125 122 117 114 22
Placebo 62 62 61 58 57 8

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of absolute and relative changes from baseline of direct bilirubin by visit
Intention-to-treat

		Seladelpar 10 mg (N=128)		Placebo (N=65)				
Score	Visit	N	LSMean (SE)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)
Change from baseline	Month 1	126	-0.01 (0.01)	63	-0.01 (0.01)	-0.00 (-0.02, 0.02)	0.7951	-0.04 (-0.34, 0.26)
	Month 3	126	-0.01 (0.01)	63	-0.02 (0.01)	0.01 (-0.02, 0.03)	0.6288	0.07 (-0.23, 0.37)
	Month 6	126	-0.00 (0.01)	63	-0.00 (0.02)	-0.00 (-0.04, 0.04)	0.9811	-0.00 (-0.31, 0.30)
	Month 9	126	0.00 (0.02)	63	-0.00 (0.02)	0.00 (-0.05, 0.06)	0.8829	0.02 (-0.28, 0.32)
	Month 12	126	0.03 (0.02)	63	0.01 (0.03)	0.03 (-0.05, 0.10)	0.5139	0.10 (-0.20, 0.40)

(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
N=Number of subjects included in the analysis, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of absolute and relative changes from baseline of direct bilirubin by visit
Intention-to-treat

		Seladelpar 10 mg (N=128)		Placebo (N=65)		Difference of		
Score	Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)
Percent change from baseline	Month 1	126	-1.49 (3.02)	63	-1.40 (4.17)	-0.10 (-9.99, 9.79)	0.9845	-0.00 (-0.31, 0.30)
	Month 3	126	-4.73 (2.28)	63	-5.36 (3.09)	0.63 (-6.58, 7.84)	0.8642	0.02 (-0.28, 0.33)
	Month 6	126	-1.91 (3.52)	63	-0.50 (4.89)	-1.40 (-13.06, 10.25)	0.8123	-0.04 (-0.34, 0.27)
	Month 9	126	-3.29 (3.69)	63	0.90 (5.16)	-4.19 (-16.56, 8.18)	0.5031	-0.10 (-0.40, 0.20)
	Month 12	126	8.11 (5.86)	63	3.12 (8.28)	4.98 (-14.98, 24.95)	0.6221	0.08 (-0.23, 0.38)

(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
N=Number of subjects included in the analysis, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of absolute and relative changes from baseline of direct bilirubin at month 6 and 12 - Subgroup analysis
Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
			Baseline		Change from BL		Baseline		Change from BL					
Variable	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
Change from baseline	Month 6	Age at screening												0.9854
		< 65 years	99	0.24 (0.17)	97	-0.00 (0.02)	53	0.21 (0.15)	51	0.00 (0.02)	-0.00 (-0.05, 0.05)	0.9924	-0.00 (-0.34, 0.34)	
		>= 65 years	29	0.22 (0.11)	29	-0.01 (0.01)	12	0.22 (0.10)	12	-0.01 (0.02)	-0.00 (-0.05, 0.05)	0.9709	-0.01 (-0.68, 0.66)	
		Age at PBC diagnosis												0.9407
		< 50 years	61	0.28 (0.20)	59	0.01 (0.03)	32	0.20 (0.13)	30	0.01 (0.04)	-0.00 (-0.09, 0.09)	0.9874	-0.00 (-0.44, 0.44)	
		>= 50 years	67	0.20 (0.10)	67	-0.01 (0.01)	33	0.22 (0.16)	33	-0.01 (0.01)	-0.00 (-0.03, 0.02)	0.7762	-0.06 (-0.47, 0.36)	
		Sex												0.0646
		female	123	0.23 (0.16)	121	-0.00 (0.01)	60	0.19 (0.11)	58	0.01 (0.02)	-0.01 (-0.05, 0.04)	0.6771	-0.07 (-0.38, 0.25)	
		male	5	0.32 (0.26)	5	0.07 (0.05)	5	0.41 (0.27)	5	-0.06 (0.05)	0.13 (-0.04, 0.30)	0.1090	1.00 (-0.36, 2.36)	
		Race												
		white	114	0.24 (0.17)	113		56	0.21 (0.15)	54					
		black	2	0.25 (0.08)	2		2	0.18 (0.15)	2					
		asian	7	0.23 (0.10)	7		4	0.22 (0.04)	4					
		other	5	0.16 (0.05)	4		3	0.23 (0.14)	3					
		Region												0.3652
		North America	50	0.21 (0.10)	49	-0.01 (0.02)	13	0.22 (0.12)	12	0.04 (0.03)	-0.05 (-0.11, 0.02)	0.1849	-0.40 (-1.04, 0.24)	
		Europe	39	0.24 (0.17)	39	-0.00 (0.03)	24	0.24 (0.19)	23	-0.01 (0.03)	0.01 (-0.08, 0.09)	0.8938	0.03 (-0.48, 0.55)	
		Rest-of-World	39	0.26 (0.20)	38	0.00 (0.03)	28	0.18 (0.10)	28	-0.02 (0.03)	0.02 (-0.05, 0.10)	0.5342	0.15 (-0.34, 0.64)	
		Cirrhosis												0.2798
		yes	18	0.36 (0.20)	18	-0.02 (0.05)	9	0.37 (0.25)	9	0.05 (0.07)	-0.07 (-0.24, 0.09)	0.3710	-0.36 (-1.17, 0.44)	
		no	110	0.21 (0.14)	108	0.00 (0.01)	56	0.19 (0.10)	54	-0.02 (0.02)	0.02 (-0.03, 0.06)	0.4512	0.12 (-0.20, 0.45)	
		UDCA												0.5474
		UDCA Use	120	0.24 (0.16)	118	-0.00 (0.01)	62	0.21 (0.14)	60	-0.00 (0.02)	-0.00 (-0.05, 0.04)	0.9748	-0.00 (-0.32, 0.31)	
		UDCA Intolerance	8	0.24 (0.15)	8	-0.01 (0.04)	3	0.23 (0.12)	3	0.04 (0.07)	-0.05 (-0.28, 0.17)	0.5602	-0.41 (-1.75, 0.93)	
		Prior Use of OCA and/or Fibrates												0.2131
		yes	20	0.26 (0.13)	18	0.06 (0.04)	13	0.18 (0.11)	12	-0.02 (0.06)	0.08 (-0.07, 0.22)	0.2845	0.40 (-0.34, 1.13)	
		no	108	0.23 (0.17)	108	-0.01 (0.01)	52	0.22 (0.15)	51	0.00 (0.02)	-0.02 (-0.06, 0.03)	0.4917	-0.11 (-0.45, 0.22)	
		Therapy												0.9126
		Monotherapy (SEL)	8	0.24 (0.15)	8	-0.01 (0.05)	4	0.22 (0.10)	4	-0.01 (0.07)	0.01 (-0.19, 0.21)	0.9305	0.05 (-1.15, 1.25)	
		Combinationtherapy (SEL + UDCA)	120	0.24 (0.16)	118	-0.00 (0.01)	61	0.21 (0.14)	59	-0.00 (0.02)	-0.00 (-0.05, 0.04)	0.9340	-0.01 (-0.33, 0.30)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of absolute and relative changes from baseline of direct bilirubin at month 6 and 12 - Subgroup analysis
Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
			Baseline		Change from BL		Baseline		Change from BL					
Variable	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
Change from baseline	Month 6	Stratification variable: Baseline Pruritus NRS												0.5436
		< 4	79	0.21 (0.14)	79	-0.03 (0.01)	42	0.21 (0.14)	41	-0.01 (0.01)	-0.02 (-0.05, 0.02)	0.3331	-0.18 (-0.56, 0.20)	
		>= 4	49	0.28 (0.18)	47	0.03 (0.03)	23	0.21 (0.14)	22	0.01 (0.05)	0.02 (-0.09, 0.13)	0.7327	0.09 (-0.42, 0.59)	
		Stratification variable: Baseline ALP Level												0.1438
		< 350 U/L	93	0.20 (0.14)	92	-0.02 (0.01)	47	0.18 (0.09)	45	0.01 (0.01)	-0.03 (-0.06, -0.00)	0.0468	-0.36 (-0.72, 0.00)	
		>= 350 U/L	35	0.33 (0.19)	34	0.04 (0.04)	18	0.30 (0.21)	18	-0.03 (0.05)	0.07 (-0.06, 0.21)	0.2964	0.31 (-0.27, 0.88)	
		Gamma-GT (GGT)												0.9181
		<= 3 x ULN	33	0.19 (0.15)	32	-0.01 (0.01)	14	0.13 (0.05)	13	-0.01 (0.01)	0.00 (-0.03, 0.03)	0.9941	0.00 (-0.64, 0.65)	
		> 3 x ULN	95	0.25 (0.16)	94	0.00 (0.02)	51	0.23 (0.15)	50	0.00 (0.02)	0.00 (-0.05, 0.06)	0.9059	0.02 (-0.32, 0.36)	
		Total Bilirubin I												0.6749
		<= 1 x ULN	108	0.19 (0.09)	106	0.01 (0.01)	60	0.19 (0.10)	59	0.01 (0.02)	0.00 (-0.04, 0.05)	0.8711	0.03 (-0.29, 0.34)	
		> 1 x ULN	20	0.50 (0.20)	20	-0.08 (0.03)	5	0.52 (0.24)	4	-0.12 (0.07)	0.04 (-0.12, 0.20)	0.6331	0.28 (-0.79, 1.36)	
		Total Bilirubin II												0.8299
		< 0.6 x ULN	59	0.13 (0.04)	58	-0.01 (0.00)	32	0.12 (0.03)	31	-0.01 (0.01)	0.00 (-0.01, 0.02)	0.8542	0.04 (-0.40, 0.47)	
		>= 0.6 x ULN	69	0.32 (0.17)	68	-0.00 (0.02)	33	0.30 (0.15)	32	0.01 (0.03)	-0.01 (-0.09, 0.08)	0.8524	-0.04 (-0.46, 0.38)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of absolute and relative changes from baseline of direct bilirubin at month 6 and 12 - Subgroup analysis
Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
			Baseline		Change from BL		Baseline		Change from BL					
Variable	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
Change from baseline	Month 12	Age at screening												0.7828
		< 65 years	99	0.24 (0.17)	97	0.01 (0.02)	53	0.21 (0.15)	51	-0.00 (0.02)	0.01 (-0.04, 0.07)	0.6154	0.09 (-0.25, 0.43)	
		>= 65 years	29	0.22 (0.11)	29	0.05 (0.06)	12	0.22 (0.10)	12	0.01 (0.09)	0.04 (-0.17, 0.26)	0.6777	0.14 (-0.53, 0.81)	
		Age at PBC diagnosis												0.6592
		< 50 years	61	0.28 (0.20)	59	0.02 (0.02)	32	0.20 (0.13)	30	0.01 (0.03)	0.01 (-0.07, 0.08)	0.8714	0.04 (-0.40, 0.48)	
		>= 50 years	67	0.20 (0.10)	67	0.03 (0.03)	33	0.22 (0.16)	33	-0.01 (0.04)	0.03 (-0.07, 0.13)	0.5155	0.14 (-0.28, 0.55)	
		Sex												0.3216
		female	123	0.23 (0.16)	121	0.03 (0.02)	60	0.19 (0.11)	58	0.02 (0.03)	0.02 (-0.06, 0.10)	0.6907	0.06 (-0.25, 0.38)	
		male	5	0.32 (0.26)	5	0.17 (0.11)	5	0.41 (0.27)	5	-0.01 (0.12)	0.18 (-0.19, 0.55)	0.2939	0.64 (-0.65, 1.93)	
		Race												
		white	114	0.24 (0.17)	113		56	0.21 (0.15)	54					
		black	2	0.25 (0.08)	2		2	0.18 (0.15)	2					
		asian	7	0.23 (0.10)	7		4	0.22 (0.04)	4					
		other	5	0.16 (0.05)	4		3	0.23 (0.14)	3					
		Region												0.3434
		North America	50	0.21 (0.10)	49	0.02 (0.02)	13	0.22 (0.12)	12	0.05 (0.04)	-0.03 (-0.13, 0.06)	0.4751	-0.23 (-0.86, 0.40)	
		Europe	39	0.24 (0.17)	39	-0.01 (0.03)	24	0.24 (0.19)	23	-0.01 (0.04)	0.01 (-0.09, 0.10)	0.9083	0.03 (-0.49, 0.55)	
		Rest-of-World	39	0.26 (0.20)	38	0.12 (0.07)	28	0.18 (0.10)	28	-0.03 (0.08)	0.14 (-0.09, 0.37)	0.2144	0.31 (-0.18, 0.80)	
		Cirrhosis												0.7579
		yes	18	0.36 (0.20)	18	0.13 (0.13)	9	0.37 (0.25)	9	0.20 (0.20)	-0.07 (-0.58, 0.45)	0.7894	-0.11 (-0.91, 0.69)	
		no	110	0.21 (0.14)	108	0.00 (0.01)	56	0.19 (0.10)	54	-0.01 (0.02)	0.01 (-0.03, 0.05)	0.6712	0.07 (-0.26, 0.40)	
		UDCA												0.0827
		UDCA Use	120	0.24 (0.16)	118	0.04 (0.02)	62	0.21 (0.14)	60	0.01 (0.03)	0.03 (-0.05, 0.11)	0.4800	0.11 (-0.20, 0.42)	
		UDCA Intolerance	8	0.24 (0.15)	8	-0.03 (0.03)	3	0.23 (0.12)	3	0.08 (0.06)	-0.11 (-0.30, 0.08)	0.1867	-1.04 (-2.47, 0.39)	
		Prior Use of OCA and/or Fibrates												0.2447
		yes	20	0.26 (0.13)	18	0.13 (0.07)	13	0.18 (0.11)	12	-0.01 (0.08)	0.14 (-0.11, 0.39)	0.2313	0.47 (-0.27, 1.21)	
		no	108	0.23 (0.17)	108	0.02 (0.02)	52	0.22 (0.15)	51	0.01 (0.03)	0.01 (-0.08, 0.09)	0.8988	0.02 (-0.31, 0.35)	
		Therapy												0.4225
		Monotherapy (SEL)	8	0.24 (0.15)	8	-0.02 (0.04)	4	0.22 (0.10)	4	0.02 (0.06)	-0.04 (-0.22, 0.14)	0.6076	-0.31 (-1.52, 0.90)	
		Combinationtherapy (SEL + UDCA)	120	0.24 (0.16)	118	0.04 (0.02)	61	0.21 (0.14)	59	0.01 (0.03)	0.03 (-0.06, 0.11)	0.4989	0.11 (-0.21, 0.42)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
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N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of absolute and relative changes from baseline of direct bilirubin at month 6 and 12 - Subgroup analysis
Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
			Baseline		Change from BL		Baseline		Change from BL					
Variable	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
Change from baseline	Month 12	Stratification variable: Baseline Pruritus NRS												0.4201
		< 4	79	0.21 (0.14)	79	-0.00 (0.02)	42	0.21 (0.14)	41	-0.00 (0.02)	-0.00 (-0.06, 0.06)	0.9778	-0.01 (-0.38, 0.37)	
		>= 4	49	0.28 (0.18)	47	0.11 (0.06)	23	0.21 (0.14)	22	0.02 (0.09)	0.09 (-0.14, 0.32)	0.4189	0.21 (-0.29, 0.72)	
		Stratification variable: Baseline ALP Level												0.2819
		< 350 U/L	93	0.20 (0.14)	92	0.01 (0.01)	47	0.18 (0.09)	45	0.02 (0.02)	-0.00 (-0.05, 0.05)	0.9733	-0.01 (-0.36, 0.35)	
		>= 350 U/L	35	0.33 (0.19)	34	0.12 (0.08)	18	0.30 (0.21)	18	-0.03 (0.12)	0.16 (-0.15, 0.46)	0.2940	0.31 (-0.26, 0.89)	
		Gamma-GT (GGT)												0.3640
		<= 3 x ULN	33	0.19 (0.15)	32	-0.00 (0.01)	14	0.13 (0.05)	13	0.00 (0.01)	-0.01 (-0.04, 0.03)	0.6992	-0.11 (-0.75, 0.54)	
		> 3 x ULN	95	0.25 (0.16)	94	0.05 (0.03)	51	0.23 (0.15)	50	0.01 (0.04)	0.04 (-0.06, 0.14)	0.4111	0.14 (-0.20, 0.49)	
		Total Bilirubin I												0.5085
		<= 1 x ULN	108	0.19 (0.09)	106	0.07 (0.03)	60	0.19 (0.10)	59	0.03 (0.04)	0.04 (-0.06, 0.15)	0.4396	0.13 (-0.19, 0.44)	
		> 1 x ULN	20	0.50 (0.20)	20	-0.08 (0.03)	5	0.52 (0.24)	4	-0.19 (0.09)	0.11 (-0.08, 0.31)	0.2479	0.69 (-0.41, 1.78)	
		Total Bilirubin II												0.5175
		< 0.6 x ULN	59	0.13 (0.04)	58	-0.00 (0.00)	32	0.12 (0.03)	31	-0.00 (0.01)	-0.00 (-0.02, 0.01)	0.6065	-0.11 (-0.54, 0.33)	
		>= 0.6 x ULN	69	0.32 (0.17)	68	0.07 (0.04)	33	0.30 (0.15)	32	0.02 (0.06)	0.05 (-0.11, 0.20)	0.5539	0.13 (-0.29, 0.55)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
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p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of absolute and relative changes from baseline of direct bilirubin at month 6 and 12 - Subgroup analysis
Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
			Baseline		Change from BL		Baseline		Change from BL					
Variable	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
Percent change from baseline	Month 6	Age at screening												0.8995
		< 65 years	99	0.24 (0.17)	97	-1.66 (4.38)	53	0.21 (0.15)	51	0.03 (5.92)	-1.69 (-16.04, 12.66)	0.8164	-0.04 (-0.38, 0.30)	
		>= 65 years	29	0.22 (0.11)	29	-3.87 (4.63)	12	0.22 (0.10)	12	-3.56 (7.15)	-0.31 (-16.71, 16.08)	0.9693	-0.01 (-0.69, 0.66)	
		Age at PBC diagnosis												0.8902
		< 50 years	61	0.28 (0.20)	59	0.34 (6.62)	32	0.20 (0.13)	30	1.42 (9.26)	-1.08 (-23.63, 21.47)	0.9245	-0.02 (-0.46, 0.42)	
		>= 50 years	67	0.20 (0.10)	67	-4.72 (3.12)	33	0.22 (0.16)	33	-1.94 (4.26)	-2.79 (-12.60, 7.03)	0.5746	-0.11 (-0.53, 0.31)	
		Sex												0.0046
		female	123	0.23 (0.16)	121	-2.45 (3.64)	60	0.19 (0.11)	58	0.84 (5.17)	-3.29 (-15.58, 9.00)	0.5979	-0.08 (-0.40, 0.23)	
		male	5	0.32 (0.26)	5	36.41 (12.40)	5	0.41 (0.27)	5	-2.18 (9.61)	38.58 (6.75, 70.42)	0.0243	1.40 (-0.07, 2.88)	
		Race												
		white	114	0.24 (0.17)	113		56	0.21 (0.15)	54					
		black	2	0.25 (0.08)	2		2	0.18 (0.15)	2					
		asian	7	0.23 (0.10)	7		4	0.22 (0.04)	4					
		other	5	0.16 (0.05)	4		3	0.23 (0.14)	3					
		Region												0.5210
		North America	50	0.21 (0.10)	49	-3.84 (5.19)	13	0.22 (0.12)	12	7.52 (9.52)	-11.36 (-32.03, 9.31)	0.2752	-0.31 (-0.95, 0.32)	
		Europe	39	0.24 (0.17)	39	-2.58 (6.44)	24	0.24 (0.19)	23	0.91 (8.64)	-3.50 (-24.87, 17.87)	0.7444	-0.08 (-0.60, 0.43)	
		Rest-of-World	39	0.26 (0.20)	38	-1.46 (6.96)	28	0.18 (0.10)	28	-6.92 (8.04)	5.46 (-15.57, 26.49)	0.6059	0.13 (-0.36, 0.61)	
		Cirrhosis												0.1804
		yes	18	0.36 (0.20)	18	-2.72 (11.03)	9	0.37 (0.25)	9	21.60 (16.03)	-24.32 (-64.44, 15.80)	0.2221	-0.50 (-1.31, 0.31)	
		no	110	0.21 (0.14)	108	-2.08 (3.70)	56	0.19 (0.10)	54	-4.99 (5.09)	2.90 (-9.28, 15.09)	0.6385	0.08 (-0.25, 0.40)	
		UDCA												0.2785
		UDCA Use	120	0.24 (0.16)	118	-1.45 (3.73)	62	0.21 (0.14)	60	-0.31 (5.12)	-1.14 (-13.41, 11.13)	0.8549	-0.03 (-0.34, 0.28)	
		UDCA Intolerance	8	0.24 (0.15)	8	-9.16 (7.04)	3	0.23 (0.12)	3	12.37 (16.21)	-21.53 (-65.28, 22.22)	0.2722	-0.89 (-2.30, 0.51)	
		Prior Use of OCA and/or Fibrates												0.1040
		yes	20	0.26 (0.13)	18	18.19 (10.72)	13	0.18 (0.11)	12	-5.12 (13.11)	23.31 (-11.49, 58.10)	0.1810	0.50 (-0.24, 1.24)	
		no	108	0.23 (0.17)	108	-5.72 (3.64)	52	0.22 (0.15)	51	0.35 (5.18)	-6.07 (-18.22, 6.08)	0.3250	-0.16 (-0.49, 0.17)	
		Therapy												0.9071
		Monotherapy (SEL)	8	0.24 (0.15)	8	-8.62 (12.12)	4	0.22 (0.10)	4	-4.12 (18.10)	-4.51 (-61.18, 52.16)	0.8445	-0.12 (-1.32, 1.08)	
		Combinationtherapy (SEL + UDCA)	120	0.24 (0.16)	118	-1.54 (3.74)	61	0.21 (0.14)	59	0.33 (5.17)	-1.86 (-14.21, 10.48)	0.7659	-0.05 (-0.36, 0.27)	

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BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of absolute and relative changes from baseline of direct bilirubin at month 6 and 12 - Subgroup analysis
Intention-to-treat

Variable	Timepoint	Subgroup Level	Seladelpar 10 mg (N=128) Baseline N	Seladelpar 10 mg (N=128) Baseline Mean (SD)	Seladelpar 10 mg (N=128) Change from BL N	Seladelpar 10 mg (N=128) Change from BL LSMean (SE)	Placebo (N=65) Baseline N	Placebo (N=65) Baseline Mean (SD)	Placebo (N=65) Change from BL N	Placebo (N=65) Change from BL LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
Percent change from baseline	Month 6	Stratification variable: Baseline Pruritus NRS												0.6353
		< 4	79	0.21 (0.14)	79	-8.61 (3.34)	42	0.21 (0.14)	41	-4.11 (4.41)	-4.51 (-14.97, 5.95)	0.3952	-0.15 (-0.53, 0.22)	
		>= 4	49	0.28 (0.18)	47	6.43 (7.73)	23	0.21 (0.14)	22	3.88 (11.55)	2.56 (-25.26, 30.37)	0.8549	0.05 (-0.46, 0.55)	
		Stratification variable: Baseline ALP Level												0.2053
		< 350 U/L	93	0.20 (0.14)	92	-5.74 (2.99)	47	0.18 (0.09)	45	2.03 (4.19)	-7.77 (-17.75, 2.22)	0.1262	-0.27 (-0.63, 0.09)	
		>= 350 U/L	35	0.33 (0.19)	34	7.28 (9.54)	18	0.30 (0.21)	18	-6.82 (13.47)	14.11 (-19.09, 47.30)	0.3972	0.25 (-0.33, 0.82)	
		Gamma-GT (GGT)												0.4920
		<= 3 x ULN	33	0.19 (0.15)	32	3.18 (4.91)	14	0.13 (0.05)	13	-1.40 (6.55)	4.59 (-8.99, 18.16)	0.4991	0.17 (-0.48, 0.81)	
		> 3 x ULN	95	0.25 (0.16)	94	-2.08 (4.46)	51	0.23 (0.15)	50	0.25 (6.08)	-2.33 (-17.14, 12.48)	0.7561	-0.05 (-0.40, 0.29)	
		Total Bilirubin I												0.9227
		<= 1 x ULN	108	0.19 (0.09)	106	0.83 (4.03)	60	0.19 (0.10)	59	1.06 (5.25)	-0.22 (-12.92, 12.47)	0.9722	-0.01 (-0.32, 0.31)	
		> 1 x ULN	20	0.50 (0.20)	20	-16.93 (4.71)	5	0.52 (0.24)	4	-15.30 (12.09)	-1.63 (-28.66, 25.40)	0.9012	-0.07 (-1.15, 1.00)	
		Total Bilirubin II												0.5460
		< 0.6 x ULN	59	0.13 (0.04)	58	-2.54 (3.43)	32	0.12 (0.03)	31	-4.42 (4.31)	1.88 (-8.28, 12.04)	0.7139	0.07 (-0.36, 0.51)	
		>= 0.6 x ULN	69	0.32 (0.17)	68	-1.44 (5.87)	33	0.30 (0.15)	32	3.69 (8.65)	-5.13 (-25.83, 15.57)	0.6239	-0.10 (-0.53, 0.32)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of absolute and relative changes from baseline of direct bilirubin at month 6 and 12 - Subgroup analysis
Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
			Baseline		Change from BL		Baseline		Change from BL					
Variable	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
Percent change from baseline	Month 12	Age at screening												0.7653
		< 65 years	99	0.24 (0.17)	97	4.95 (5.64)	53	0.21 (0.15)	51	2.84 (7.84)	2.11 (-16.90, 21.12)	0.8262	0.04 (-0.30, 0.38)	
		>= 65 years	29	0.22 (0.11)	29	10.18 (14.83)	12	0.22 (0.10)	12	-0.47 (22.66)	10.65 (-43.87, 65.17)	0.6950	0.13 (-0.54, 0.80)	
		Age at PBC diagnosis												0.6173
		< 50 years	61	0.28 (0.20)	59	6.35 (6.08)	32	0.20 (0.13)	30	7.43 (8.60)	-1.08 (-22.35, 20.19)	0.9184	-0.02 (-0.46, 0.42)	
		>= 50 years	67	0.20 (0.10)	67	7.02 (9.21)	33	0.22 (0.16)	33	-1.36 (12.93)	8.38 (-22.93, 39.69)	0.5964	0.11 (-0.31, 0.53)	
		Sex												0.2179
		female	123	0.23 (0.16)	121	6.84 (6.00)	60	0.19 (0.11)	58	3.95 (8.63)	2.89 (-17.83, 23.60)	0.7829	0.04 (-0.27, 0.36)	
		male	5	0.32 (0.26)	5	59.81 (27.61)	5	0.41 (0.27)	5	7.84 (27.98)	51.97 (-36.70, 140.63)	0.2134	0.76 (-0.56, 2.07)	
		Race												
		white	114	0.24 (0.17)	113		56	0.21 (0.15)	54					
		black	2	0.25 (0.08)	2		2	0.18 (0.15)	2					
		asian	7	0.23 (0.10)	7		4	0.22 (0.04)	4					
		other	5	0.16 (0.05)	4		3	0.23 (0.14)	3					
		Region												0.1819
		North America	50	0.21 (0.10)	49	2.09 (6.41)	13	0.22 (0.12)	12	22.02 (13.03)	-19.93 (-48.41, 8.56)	0.1654	-0.44 (-1.07, 0.20)	
		Europe	39	0.24 (0.17)	39	5.18 (11.51)	24	0.24 (0.19)	23	1.25 (14.55)	3.93 (-33.25, 41.11)	0.8326	0.05 (-0.46, 0.57)	
		Rest-of-World	39	0.26 (0.20)	38	17.13 (12.82)	28	0.18 (0.10)	28	-6.41 (14.90)	23.54 (-16.35, 63.43)	0.2383	0.29 (-0.20, 0.79)	
		Cirrhosis												0.5426
		yes	18	0.36 (0.20)	18	30.91 (34.01)	9	0.37 (0.25)	9	65.38 (50.70)	-34.47 (-164.69, 95.75)	0.5806	-0.23 (-1.03, 0.58)	
		no	110	0.21 (0.14)	108	1.52 (4.94)	56	0.19 (0.10)	54	-1.50 (6.78)	3.01 (-13.40, 19.43)	0.7168	0.06 (-0.27, 0.39)	
		UDCA												0.0384
		UDCA Use	120	0.24 (0.16)	118	9.57 (6.25)	62	0.21 (0.14)	60	2.86 (8.67)	6.71 (-14.36, 27.78)	0.5291	0.10 (-0.21, 0.41)	
		UDCA Intolerance	8	0.24 (0.15)	8	-12.80 (12.15)	3	0.23 (0.12)	3	39.26 (23.31)	-52.06 (-124.41, 20.29)	0.1173	-1.33 (-2.83, 0.17)	
		Prior Use of OCA and/or Fibrates												0.3980
		yes	20	0.26 (0.13)	18	28.93 (13.82)	13	0.18 (0.11)	12	5.72 (17.10)	23.21 (-27.78, 74.20)	0.3236	0.38 (-0.35, 1.12)	
		no	108	0.23 (0.17)	108	4.47 (6.53)	52	0.22 (0.15)	51	2.24 (9.47)	2.24 (-20.38, 24.85)	0.8450	0.03 (-0.30, 0.37)	
		Therapy												0.2254
		Monotherapy (SEL)	8	0.24 (0.15)	8	-12.27 (12.68)	4	0.22 (0.10)	4	12.67 (19.53)	-24.94 (-80.94, 31.06)	0.3225	-0.62 (-1.86, 0.61)	
		Combinationtherapy (SEL + UDCA)	120	0.24 (0.16)	118	9.48 (6.27)	61	0.21 (0.14)	59	3.35 (8.78)	6.13 (-15.11, 27.37)	0.5683	0.09 (-0.22, 0.40)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of absolute and relative changes from baseline of direct bilirubin at month 6 and 12 - Subgroup analysis
Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
			Baseline		Change from BL		Baseline		Change from BL					
Variable	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
Percent change from baseline	Month 12	Stratification variable: Baseline Pruritus NRS												0.6411
		< 4	79	0.21 (0.14)	79	2.23 (6.19)	42	0.21 (0.14)	41	-1.14 (8.45)	3.38 (-17.13, 23.88)	0.7448	0.06 (-0.32, 0.44)	
		>= 4	49	0.28 (0.18)	47	20.40 (13.39)	23	0.21 (0.14)	22	4.81 (19.99)	15.59 (-33.85, 65.03)	0.5228	0.17 (-0.34, 0.67)	
		Stratification variable: Baseline ALP Level												0.3437
		< 350 U/L	93	0.20 (0.14)	92	5.36 (5.64)	47	0.18 (0.09)	45	5.72 (8.18)	-0.36 (-19.92, 19.20)	0.9709	-0.01 (-0.36, 0.35)	
		>= 350 U/L	35	0.33 (0.19)	34	24.55 (17.97)	18	0.30 (0.21)	18	-5.65 (24.92)	30.20 (-34.67, 95.06)	0.3396	0.28 (-0.29, 0.86)	
		Gamma-GT (GGT)												0.3899
		<= 3 x ULN	33	0.19 (0.15)	32	6.04 (5.90)	14	0.13 (0.05)	13	10.98 (8.36)	-4.94 (-23.31, 13.43)	0.5899	-0.15 (-0.79, 0.50)	
		> 3 x ULN	95	0.25 (0.16)	94	11.32 (7.81)	51	0.23 (0.15)	50	2.45 (10.71)	8.86 (-17.51, 35.24)	0.5051	0.12 (-0.23, 0.46)	
		Total Bilirubin I												0.7515
		<= 1 x ULN	108	0.19 (0.09)	106	12.94 (6.76)	60	0.19 (0.10)	59	5.58 (8.97)	7.36 (-14.72, 29.44)	0.5097	0.11 (-0.21, 0.42)	
		> 1 x ULN	20	0.50 (0.20)	20	-17.07 (5.43)	5	0.52 (0.24)	4	-30.25 (13.65)	13.19 (-17.41, 43.78)	0.3793	0.51 (-0.57, 1.60)	
		Total Bilirubin II												0.4745
		< 0.6 x ULN	59	0.13 (0.04)	58	-1.12 (3.70)	32	0.12 (0.03)	31	2.24 (4.89)	-3.36 (-14.88, 8.16)	0.5636	-0.12 (-0.56, 0.32)	
		>= 0.6 x ULN	69	0.32 (0.17)	68	20.49 (11.82)	33	0.30 (0.15)	32	8.40 (17.16)	12.10 (-30.23, 54.43)	0.5651	0.12 (-0.30, 0.54)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Summary of mean values, absolute and relative changes from baseline of indirect bilirubin by visit
Intention-to-treat

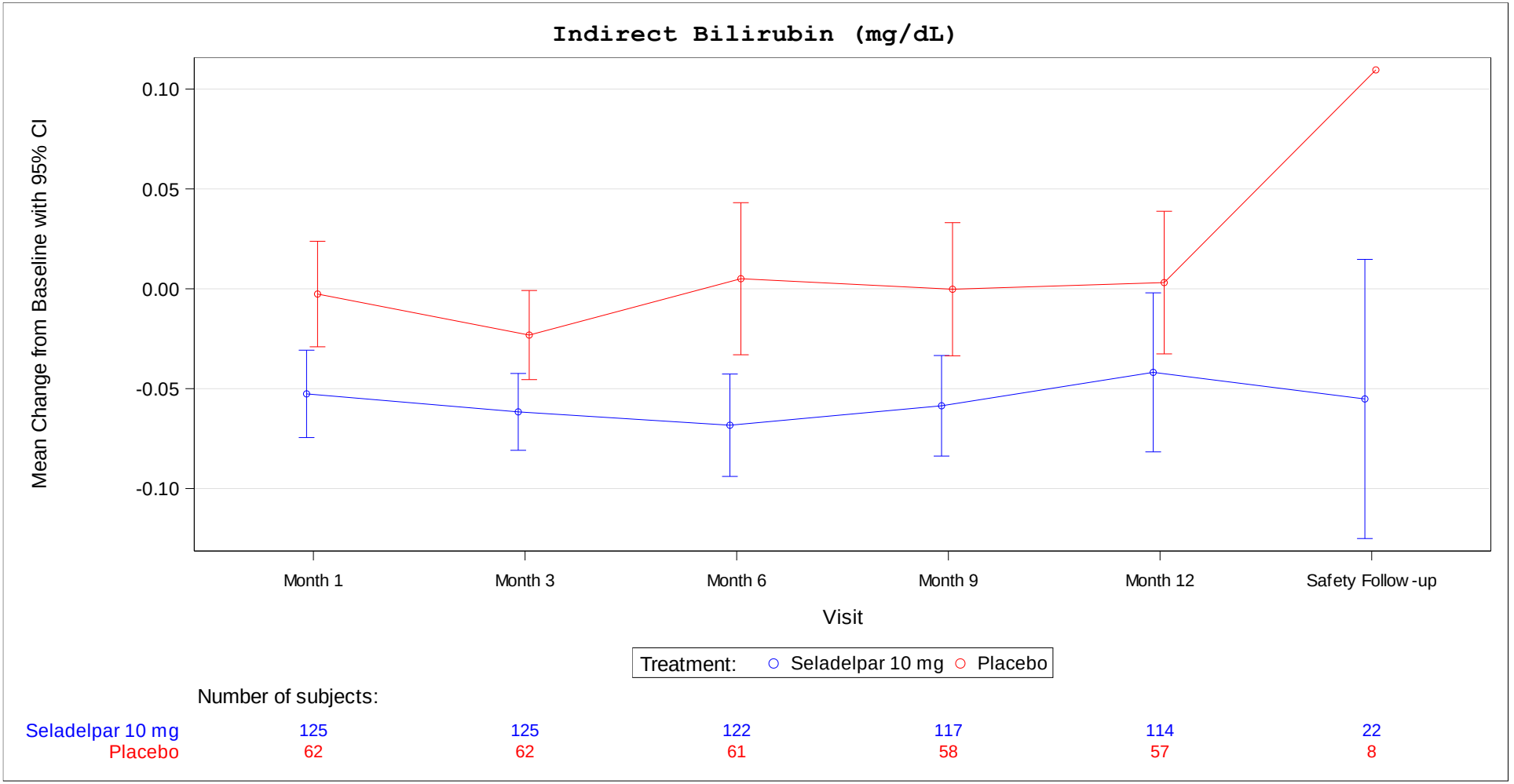
		Seladelpar 10 mg (N=128)				Placebo (N=65)			
		Value at Timepoint		Change from Baseline		Value at Timepoint		Change from Baseline	
Variable	Timepoint	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Change from baseline	Baseline	128	0.53 (0.19)	0	-	65	0.53 (0.20)	0	-
	Month 1	125	0.48 (0.16)	125	-0.05 (0.12)	62	0.51 (0.19)	62	-0.00 (0.10)
	Month 3	125	0.47 (0.17)	125	-0.06 (0.11)	62	0.48 (0.18)	62	-0.02 (0.09)
	Month 6	122	0.47 (0.17)	122	-0.07 (0.14)	61	0.51 (0.21)	61	0.01 (0.15)
	Month 9	117	0.48 (0.18)	117	-0.06 (0.14)	58	0.51 (0.17)	58	-0.00 (0.13)
	Month 12	114	0.49 (0.23)	114	-0.04 (0.21)	57	0.51 (0.20)	57	0.00 (0.13)
	Safety Follow-up	22	0.54 (0.20)	22	-0.06 (0.16)	8	0.76 (0.46)	8	0.11 (0.42)

N describes number of patients with non-missing value at the respective timepoint.
N=Number of subjects included in the analysis, SD: Standard Deviation; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Summary of mean values, absolute and relative changes from baseline of indirect bilirubin by visit
Intention-to-treat

		Seladelpar 10 mg (N=128)				Placebo (N=65)			
		Value at Timepoint		Change from Baseline		Value at Timepoint		Change from Baseline	
Variable	Timepoint	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Percent change from baseline	Baseline	128	0.53 (0.19)	0	-	65	0.53 (0.20)	0	-
	Month 1	125	0.48 (0.16)	125	-7.57 (21.00)	62	0.51 (0.19)	62	0.49 (21.94)
	Month 3	125	0.47 (0.17)	125	-10.06 (17.50)	62	0.48 (0.18)	62	-4.98 (19.25)
	Month 6	122	0.47 (0.17)	122	-10.88 (21.72)	61	0.51 (0.21)	61	2.46 (31.09)
	Month 9	117	0.48 (0.18)	117	-8.81 (27.05)	58	0.51 (0.17)	58	2.85 (28.33)
	Month 12	114	0.49 (0.23)	114	-4.66 (43.48)	57	0.51 (0.20)	57	3.15 (34.02)
	Safety Follow-up	22	0.54 (0.20)	22	-7.56 (24.51)	8	0.76 (0.46)	8	21.74 (66.19)

N describes number of patients with non-missing value at the respective timepoint.
N=Number of subjects included in the analysis, SD: Standard Deviation; CI=Confidence Interval


Indirect Bilirubin (mg/dL)
Mean Change from Baseline with 95% CI
0.10
0.05
0.00
-0.05
-0.10
Month 1
Month 3
Month 6
Month 9
Month 12
Safety Follow-up
Visit
Treatment: Seladelpar 10 mg Placebo
Number of subjects:
Seladelpar 10 mg 125 125 122 117 114 22
Placebo 62 62 61 58 57 8

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of absolute and relative changes from baseline of indirect bilirubin by visit
Intention-to-treat

		Seladelpar 10 mg (N=128)		Placebo (N=65)		Difference of		
Score	Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)
Change from baseline	Month 1	126	-0.05 (0.01)	63	-0.00 (0.01)	-0.05 (-0.08, -0.01)	0.0044	-0.43 (-0.73, -0.12)
	Month 3	126	-0.06 (0.01)	63	-0.02 (0.01)	-0.04 (-0.06, -0.01)	0.0134	-0.37 (-0.67, -0.06)
	Month 6	126	-0.06 (0.01)	63	0.01 (0.02)	-0.07 (-0.11, -0.03)	0.0007	-0.52 (-0.82, -0.21)
	Month 9	126	-0.05 (0.01)	63	0.01 (0.02)	-0.06 (-0.10, -0.02)	0.0055	-0.42 (-0.73, -0.12)
	Month 12	126	-0.03 (0.02)	63	0.01 (0.02)	-0.04 (-0.10, 0.02)	0.1470	-0.22 (-0.53, 0.08)

(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
N=Number of subjects included in the analysis, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of absolute and relative changes from baseline of indirect bilirubin by visit
Intention-to-treat

		Seladelpar 10 mg (N=128)		Placebo (N=65)		Difference of		
Score	Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)
Percent change from baseline	Month 1	126	-7.42 (1.94)	63	0.17 (2.70)	-7.59 (-13.96, -1.22)	0.0198	-0.35 (-0.65, -0.04)
	Month 3	126	-9.91 (1.71)	63	-5.30 (2.36)	-4.62 (-10.13, 0.90)	0.1006	-0.24 (-0.55, 0.06)
	Month 6	126	-10.70 (2.31)	63	2.20 (3.22)	-12.89 (-20.56, -5.23)	0.0011	-0.50 (-0.80, -0.19)
	Month 9	126	-7.89 (2.57)	63	3.65 (3.61)	-11.54 (-20.14, -2.94)	0.0088	-0.40 (-0.71, -0.09)
	Month 12	126	-3.48 (3.74)	63	3.79 (5.29)	-7.27 (-19.98, 5.43)	0.2600	-0.17 (-0.48, 0.13)

(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
N=Number of subjects included in the analysis, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
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RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of absolute and relative changes from baseline of indirect bilirubin at month 6 and 12 - Subgroup analysis
Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
			Baseline		Change from BL		Baseline		Change from BL					
Variable	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
Change from baseline	Month 6	Age at screening												0.3159
		< 65 years	99	0.54 (0.20)	97	-0.06 (0.01)	53	0.51 (0.21)	51	-0.00 (0.02)	-0.06 (-0.11, -0.01)	0.0127	-0.43 (-0.77, -0.08)	
		>= 65 years	29	0.52 (0.16)	29	-0.07 (0.02)	12	0.57 (0.18)	12	0.03 (0.03)	-0.11 (-0.17, -0.04)	0.0036	-1.00 (-1.71, -0.29)	
		Age at PBC diagnosis												0.7453
		< 50 years	61	0.54 (0.16)	59	-0.06 (0.02)	32	0.51 (0.24)	30	0.00 (0.03)	-0.06 (-0.14, 0.01)	0.0740	-0.40 (-0.84, 0.04)	
		>= 50 years	67	0.53 (0.22)	67	-0.08 (0.01)	33	0.54 (0.16)	33	0.00 (0.02)	-0.08 (-0.12, -0.03)	0.0008	-0.68 (-1.11, -0.26)	
		Sex												NE
		female	123	0.53 (0.19)	121	-0.07 (0.01)	60	0.52 (0.21)	58	0.01 (0.02)	-0.08 (-0.12, -0.03)	0.0005	-0.55 (-0.87, -0.23)	
		male	5	0.62 (0.22)	5	NE	5	0.58 (0.16)	5	NE	NE		NE	
		Race												
		white	114	0.53 (0.20)	113		56	0.53 (0.21)	54					
		black	2	0.64 (0.01)	2		2	0.32 (0.19)	2					
		asian	7	0.61 (0.18)	7		4	0.55 (0.06)	4					
		other	5	0.47 (0.10)	4		3	0.54 (0.20)	3					
		Region												0.3427
		North America	50	0.52 (0.19)	49	-0.08 (0.02)	13	0.61 (0.34)	12	0.05 (0.04)	-0.12 (-0.21, -0.03)	0.0072	-0.81 (-1.45, -0.16)	
		Europe	39	0.52 (0.22)	39	-0.05 (0.02)	24	0.52 (0.16)	23	-0.00 (0.03)	-0.04 (-0.11, 0.03)	0.2355	-0.31 (-0.83, 0.21)	
		Rest-of-World	39	0.56 (0.17)	38	-0.07 (0.02)	28	0.49 (0.14)	28	0.01 (0.03)	-0.08 (-0.15, -0.01)	0.0327	-0.53 (-1.03, -0.04)	
		Cirrhosis												0.1039
		yes	18	0.61 (0.18)	18	-0.09 (0.05)	9	0.61 (0.16)	9	0.09 (0.07)	-0.19 (-0.35, -0.02)	0.0297	-0.91 (-1.76, -0.07)	
		no	110	0.52 (0.19)	108	-0.06 (0.01)	56	0.51 (0.20)	54	-0.01 (0.02)	-0.05 (-0.09, -0.01)	0.0117	-0.41 (-0.74, -0.08)	
		UDCA												0.3798
		UDCA Use	120	0.53 (0.20)	118	-0.06 (0.01)	62	0.52 (0.20)	60	0.01 (0.02)	-0.07 (-0.11, -0.03)	0.0017	-0.49 (-0.81, -0.18)	
		UDCA Intolerance	8	0.54 (0.12)	8	-0.08 (0.05)	3	0.61 (0.19)	3	0.08 (0.09)	-0.16 (-0.52, 0.21)	0.2304	-1.06 (-2.50, 0.38)	
		Prior Use of OCA and/or Fibrates												0.0407
		yes	20	0.51 (0.13)	18	-0.01 (0.03)	13	0.44 (0.11)	12	-0.03 (0.04)	0.02 (-0.08, 0.12)	0.7018	0.14 (-0.59, 0.87)	
		no	108	0.54 (0.20)	108	-0.07 (0.01)	52	0.55 (0.21)	51	0.02 (0.02)	-0.09 (-0.14, -0.04)	0.0002	-0.64 (-0.98, -0.30)	
		Therapy												0.0382
		Monotherapy (SEL)	8	0.54 (0.12)	8	-0.08 (0.02)	4	0.58 (0.17)	4	0.09 (0.04)	-0.16 (-0.26, -0.06)	0.0069	-2.34 (-3.99, -0.68)	
		Combinationtherapy (SEL + UDCA)	120	0.53 (0.20)	118	-0.06 (0.01)	61	0.52 (0.20)	59	0.00 (0.02)	-0.07 (-0.11, -0.02)	0.0026	-0.47 (-0.79, -0.16)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of absolute and relative changes from baseline of indirect bilirubin at month 6 and 12 - Subgroup analysis
Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
			Baseline		Change from BL		Baseline		Change from BL					
Variable	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
Change from baseline	Month 6	Stratification variable: Baseline Pruritus NRS												0.2996
		< 4	79	0.53 (0.20)	79	-0.07 (0.02)	42	0.54 (0.23)	41	0.01 (0.02)	-0.09 (-0.14, -0.04)	0.0003	-0.67 (-1.05, -0.28)	
		>= 4	49	0.55 (0.18)	47	-0.05 (0.02)	23	0.51 (0.15)	22	-0.01 (0.03)	-0.04 (-0.12, 0.04)	0.2907	-0.27 (-0.78, 0.23)	
		Stratification variable: Baseline ALP Level												0.0292
		< 350 U/L	93	0.53 (0.20)	92	-0.08 (0.01)	47	0.52 (0.22)	45	0.02 (0.02)	-0.10 (-0.15, -0.06)	<.0001	-0.80 (-1.17, -0.44)	
		>= 350 U/L	35	0.55 (0.16)	34	-0.02 (0.03)	18	0.54 (0.14)	18	-0.02 (0.04)	0.01 (-0.08, 0.10)	0.8737	0.05 (-0.53, 0.62)	
		Gamma-GT (GGT)												0.4435
		<= 3 x ULN	33	0.57 (0.23)	32	-0.08 (0.02)	14	0.41 (0.13)	13	0.01 (0.04)	-0.09 (-0.17, -0.02)	0.0144	-0.71 (-1.37, -0.05)	
		> 3 x ULN	95	0.52 (0.18)	94	-0.06 (0.02)	51	0.56 (0.21)	50	0.00 (0.02)	-0.06 (-0.11, -0.01)	0.0189	-0.41 (-0.76, -0.06)	
		Total Bilirubin I												0.1013
		<= 1 x ULN	108	0.47 (0.11)	106	-0.05 (0.01)	60	0.49 (0.14)	59	0.01 (0.02)	-0.05 (-0.09, -0.01)	0.0154	-0.38 (-0.70, -0.06)	
		> 1 x ULN	20	0.85 (0.24)	20	-0.19 (0.03)	5	0.96 (0.31)	4	0.00 (0.08)	-0.19 (-0.38, -0.01)	0.0394	-1.37 (-2.52, -0.21)	
		Total Bilirubin II												0.1481
		< 0.6 x ULN	59	0.39 (0.07)	58	-0.04 (0.01)	32	0.38 (0.08)	31	-0.00 (0.02)	-0.04 (-0.08, -0.00)	0.0412	-0.42 (-0.86, 0.02)	
		>= 0.6 x ULN	69	0.65 (0.19)	68	-0.09 (0.02)	33	0.66 (0.19)	32	0.01 (0.03)	-0.10 (-0.17, -0.03)	0.0068	-0.59 (-1.02, -0.16)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of absolute and relative changes from baseline of indirect bilirubin at month 6 and 12 - Subgroup analysis
Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
			Baseline		Change from BL		Baseline		Change from BL					
Variable	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
Change from baseline	Month 12	Age at screening												0.7930
		< 65 years	99	0.54 (0.20)	97	-0.04 (0.02)	53	0.51 (0.21)	51	0.01 (0.02)	-0.05 (-0.10, 0.00)	0.0615	-0.32 (-0.66, 0.02)	
		>= 65 years	29	0.52 (0.16)	29	-0.02 (0.05)	12	0.57 (0.18)	12	0.00 (0.08)	-0.03 (-0.21, 0.16)	0.7857	-0.09 (-0.76, 0.58)	
		Age at PBC diagnosis												0.6720
		< 50 years	61	0.54 (0.16)	59	-0.03 (0.02)	32	0.51 (0.24)	30	0.02 (0.03)	-0.06 (-0.13, 0.02)	0.1188	-0.35 (-0.79, 0.09)	
		>= 50 years	67	0.53 (0.22)	67	-0.04 (0.03)	33	0.54 (0.16)	33	-0.01 (0.04)	-0.03 (-0.12, 0.05)	0.4413	-0.16 (-0.58, 0.26)	
		Sex												NE
		female	123	0.53 (0.19)	121	-0.04 (0.02)	60	0.52 (0.21)	58	0.02 (0.03)	-0.06 (-0.12, 0.00)	0.0628	-0.30 (-0.61, 0.02)	
		male	5	0.62 (0.22)	5	NE	5	0.58 (0.16)	5	NE	NE		NE	
		Race												
		white	114	0.53 (0.20)	113		56	0.53 (0.21)	54					
		black	2	0.64 (0.01)	2		2	0.32 (0.19)	2					
		asian	7	0.61 (0.18)	7		4	0.55 (0.06)	4					
		other	5	0.47 (0.10)	4		3	0.54 (0.20)	3					
		Region												0.0476
		North America	50	0.52 (0.19)	49	-0.04 (0.03)	13	0.61 (0.34)	12	0.14 (0.05)	-0.18 (-0.30, -0.06)	0.0033	-0.98 (-1.63, -0.32)	
		Europe	39	0.52 (0.22)	39	-0.05 (0.02)	24	0.52 (0.16)	23	-0.01 (0.03)	-0.05 (-0.12, 0.02)	0.1625	-0.36 (-0.88, 0.16)	
		Rest-of-World	39	0.56 (0.17)	38	0.00 (0.04)	28	0.49 (0.14)	28	-0.02 (0.05)	0.02 (-0.10, 0.14)	0.7435	0.08 (-0.41, 0.57)	
		Cirrhosis												0.6357
		yes	18	0.61 (0.18)	18	0.04 (0.10)	9	0.61 (0.16)	9	0.18 (0.15)	-0.14 (-0.53, 0.25)	0.4704	-0.30 (-1.10, 0.51)	
		no	110	0.52 (0.19)	108	-0.05 (0.01)	56	0.51 (0.20)	54	-0.00 (0.02)	-0.05 (-0.09, -0.00)	0.0379	-0.34 (-0.67, -0.01)	
		UDCA												0.0008
		UDCA Use	120	0.53 (0.20)	118	-0.03 (0.02)	62	0.52 (0.20)	60	0.00 (0.03)	-0.03 (-0.09, 0.03)	0.2993	-0.16 (-0.47, 0.15)	
		UDCA Intolerance	8	0.54 (0.12)	8	-0.07 (0.03)	3	0.61 (0.19)	3	0.28 (0.08)	-0.35 (-0.61, -0.09)	0.0226	-2.93 (-4.95, -0.91)	
		Prior Use of OCA and/or Fibrates												0.0836
		yes	20	0.51 (0.13)	18	0.05 (0.04)	13	0.44 (0.11)	12	-0.02 (0.05)	0.06 (-0.08, 0.20)	0.3378	0.36 (-0.37, 1.10)	
		no	108	0.54 (0.20)	108	-0.05 (0.02)	52	0.55 (0.21)	51	0.02 (0.03)	-0.06 (-0.13, 0.00)	0.0670	-0.31 (-0.64, 0.03)	
		Therapy												0.0255
		Monotherapy (SEL)	8	0.54 (0.12)	8	-0.06 (0.05)	4	0.58 (0.17)	4	0.21 (0.09)	-0.27 (-0.53, -0.02)	0.0400	-1.58 (-3.00, -0.15)	
		Combinationtherapy (SEL + UDCA)	120	0.53 (0.20)	118	-0.03 (0.02)	61	0.52 (0.20)	59	0.00 (0.03)	-0.03 (-0.09, 0.03)	0.2814	-0.17 (-0.48, 0.14)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
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p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of absolute and relative changes from baseline of indirect bilirubin at month 6 and 12 - Subgroup analysis
Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
			Baseline		Change from BL		Baseline		Change from BL					
Variable	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
Change from baseline	Month 12	Stratification variable: Baseline Pruritus NRS												0.2977
		< 4	79	0.53 (0.20)	79	-0.05 (0.02)	42	0.54 (0.23)	41	0.02 (0.02)	-0.07 (-0.12, -0.01)	0.0198	-0.43 (-0.82, -0.05)	
		>= 4	49	0.55 (0.18)	47	0.01 (0.04)	23	0.51 (0.15)	22	-0.00 (0.06)	0.01 (-0.13, 0.15)	0.8922	0.04 (-0.47, 0.54)	
		Stratification variable: Baseline ALP Level												0.0923
		< 350 U/L	93	0.53 (0.20)	92	-0.05 (0.02)	47	0.52 (0.22)	45	0.03 (0.02)	-0.08 (-0.14, -0.02)	0.0052	-0.51 (-0.87, -0.15)	
		>= 350 U/L	35	0.55 (0.16)	34	0.02 (0.05)	18	0.54 (0.14)	18	-0.04 (0.06)	0.06 (-0.10, 0.22)	0.4391	0.22 (-0.35, 0.80)	
		Gamma-GT (GGT)												0.4858
		<= 3 x ULN	33	0.57 (0.23)	32	-0.06 (0.03)	14	0.41 (0.13)	13	0.01 (0.04)	-0.07 (-0.16, 0.02)	0.1044	-0.48 (-1.13, 0.17)	
		> 3 x ULN	95	0.52 (0.18)	94	-0.02 (0.02)	51	0.56 (0.21)	50	0.01 (0.03)	-0.03 (-0.11, 0.04)	0.3760	-0.15 (-0.50, 0.19)	
		Total Bilirubin I												0.4691
		<= 1 x ULN	108	0.47 (0.11)	106	-0.01 (0.02)	60	0.49 (0.14)	59	0.01 (0.02)	-0.02 (-0.08, 0.04)	0.4363	-0.12 (-0.44, 0.19)	
		> 1 x ULN	20	0.85 (0.24)	20	-0.18 (0.04)	5	0.96 (0.31)	4	-0.08 (0.09)	-0.10 (-0.30, 0.11)	0.3287	-0.58 (-1.66, 0.51)	
		Total Bilirubin II												0.9531
		< 0.6 x ULN	59	0.39 (0.07)	58	-0.04 (0.01)	32	0.38 (0.08)	31	0.01 (0.02)	-0.05 (-0.09, -0.00)	0.0394	-0.44 (-0.88, 0.01)	
		>= 0.6 x ULN	69	0.65 (0.19)	68	-0.03 (0.03)	33	0.66 (0.19)	32	0.02 (0.04)	-0.04 (-0.15, 0.06)	0.4228	-0.17 (-0.59, 0.25)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
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p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
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Gilead Sciences, Inc.
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RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of absolute and relative changes from baseline of indirect bilirubin at month 6 and 12 - Subgroup analysis
Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
			Baseline		Change from BL		Baseline		Change from BL					
Variable	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
Percent change from baseline	Month 6	Age at screening												0.4447
		< 65 years	99	0.54 (0.20)	97	-10.29 (2.80)	53	0.51 (0.21)	51	1.22 (3.80)	-11.51 (-20.69, -2.32)	0.0145	-0.42 (-0.76, -0.07)	
		>= 65 years	29	0.52 (0.16)	29	-11.86 (3.68)	12	0.57 (0.18)	12	5.80 (5.77)	-17.66 (-30.98, -4.35)	0.0107	-0.87 (-1.57, -0.17)	
		Age at PBC diagnosis												0.8440
		< 50 years	61	0.54 (0.16)	59	-11.22 (3.87)	32	0.51 (0.24)	30	2.55 (5.42)	-13.76 (-26.92, -0.61)	0.0405	-0.46 (-0.90, -0.01)	
		>= 50 years	67	0.53 (0.22)	67	-10.92 (2.79)	33	0.54 (0.16)	33	1.26 (3.82)	-12.19 (-21.15, -3.22)	0.0082	-0.54 (-0.96, -0.11)	
		Sex												NE
		female	123	0.53 (0.19)	121	-11.13 (2.40)	60	0.52 (0.21)	58	3.05 (3.43)	-14.17 (-22.30, -6.05)	0.0007	-0.54 (-0.85, -0.22)	
		male	5	0.62 (0.22)	5	NE	5	0.58 (0.16)	5	NE	NE		NE	
		Race												
		white	114	0.53 (0.20)	113		56	0.53 (0.21)	54					
		black	2	0.64 (0.01)	2		2	0.32 (0.19)	2					
		asian	7	0.61 (0.18)	7		4	0.55 (0.06)	4					
		other	5	0.47 (0.10)	4		3	0.54 (0.20)	3					
		Region												0.1700
		North America	50	0.52 (0.19)	49	-14.44 (4.13)	13	0.61 (0.34)	12	9.13 (7.54)	-23.57 (-39.90, -7.24)	0.0054	-0.82 (-1.47, -0.17)	
		Europe	39	0.52 (0.22)	39	-5.11 (3.65)	24	0.52 (0.16)	23	-0.18 (4.88)	-4.93 (-16.96, 7.10)	0.4149	-0.21 (-0.73, 0.31)	
		Rest-of-World	39	0.56 (0.17)	38	-12.96 (4.44)	28	0.49 (0.14)	28	1.79 (5.18)	-14.75 (-28.26, -1.24)	0.0329	-0.53 (-1.03, -0.04)	
		Cirrhosis												0.2076
		yes	18	0.61 (0.18)	18	-13.42 (7.93)	9	0.61 (0.16)	9	15.03 (11.46)	-28.45 (-57.10, 0.20)	0.0515	-0.81 (-1.65, 0.02)	
		no	110	0.52 (0.19)	108	-10.40 (2.36)	56	0.51 (0.20)	54	-0.10 (3.28)	-10.30 (-18.09, -2.51)	0.0099	-0.42 (-0.75, -0.09)	
		UDCA												0.4673
		UDCA Use	120	0.53 (0.20)	118	-10.61 (2.45)	62	0.52 (0.20)	60	2.05 (3.37)	-12.66 (-20.72, -4.60)	0.0023	-0.48 (-0.79, -0.16)	
		UDCA Intolerance	8	0.54 (0.12)	8	-14.71 (8.62)	3	0.61 (0.19)	3	10.98 (14.94)	-25.69 (-71.06, 19.68)	0.2031	-0.95 (-2.37, 0.47)	
		Prior Use of OCA and/or Fibrates												0.0257
		yes	20	0.51 (0.13)	18	-3.67 (5.03)	13	0.44 (0.11)	12	-7.62 (6.14)	3.94 (-12.42, 20.31)	0.6249	0.18 (-0.55, 0.91)	
		no	108	0.54 (0.20)	108	-12.25 (2.58)	52	0.55 (0.21)	51	4.12 (3.70)	-16.37 (-25.07, -7.66)	0.0003	-0.61 (-0.95, -0.27)	
		Therapy												0.0301
		Monotherapy (SEL)	8	0.54 (0.12)	8	-14.10 (4.01)	4	0.58 (0.17)	4	16.59 (6.45)	-30.69 (-48.90, -12.48)	0.0059	-2.40 (-4.07, -0.72)	
		Combinationtherapy (SEL + UDCA)	120	0.53 (0.20)	118	-10.66 (2.44)	61	0.52 (0.20)	59	1.46 (3.39)	-12.12 (-20.22, -4.03)	0.0035	-0.46 (-0.77, -0.14)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of absolute and relative changes from baseline of indirect bilirubin at month 6 and 12 - Subgroup analysis
Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
			Baseline		Change from BL		Baseline		Change from BL					
Variable	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
Percent change from baseline	Month 6	Stratification variable: Baseline Pruritus NRS												0.1355
		< 4	79	0.53 (0.20)	79	-12.13 (3.08)	42	0.54 (0.23)	41	4.91 (4.09)	-17.05 (-26.77, -7.32)	0.0007	-0.63 (-1.01, -0.24)	
		>= 4	49	0.55 (0.18)	47	-7.58 (3.52)	23	0.51 (0.15)	22	-2.49 (5.27)	-5.09 (-17.74, 7.56)	0.4242	-0.21 (-0.71, 0.30)	
		Stratification variable: Baseline ALP Level												0.0275
		< 350 U/L	93	0.53 (0.20)	92	-13.54 (2.59)	47	0.52 (0.22)	45	4.88 (3.64)	-18.42 (-27.10, -9.73)	<.0001	-0.74 (-1.11, -0.37)	
		>= 350 U/L	35	0.55 (0.16)	34	-4.04 (4.52)	18	0.54 (0.14)	18	-5.35 (6.36)	1.32 (-14.38, 17.01)	0.8667	0.05 (-0.52, 0.62)	
		Gamma-GT (GGT)												0.2515
		<= 3 x ULN	33	0.57 (0.23)	32	-10.40 (5.70)	14	0.41 (0.13)	13	10.61 (8.25)	-21.02 (-38.02, -4.01)	0.0166	-0.65 (-1.31, 0.01)	
		> 3 x ULN	95	0.52 (0.18)	94	-9.81 (2.68)	51	0.56 (0.21)	50	0.24 (3.65)	-10.05 (-18.93, -1.18)	0.0267	-0.39 (-0.73, -0.04)	
		Total Bilirubin I												0.5018
		<= 1 x ULN	108	0.47 (0.11)	106	-9.48 (2.66)	60	0.49 (0.14)	59	2.79 (3.47)	-12.27 (-20.65, -3.88)	0.0044	-0.45 (-0.77, -0.13)	
		> 1 x ULN	20	0.85 (0.24)	20	-19.15 (3.69)	5	0.96 (0.31)	4	0.53 (9.52)	-19.68 (-40.99, 1.62)	0.0682	-1.13 (-2.25, 0.00)	
		Total Bilirubin II												0.8681
		< 0.6 x ULN	59	0.39 (0.07)	58	-10.29 (3.42)	32	0.38 (0.08)	31	1.75 (4.36)	-12.05 (-22.28, -1.81)	0.0216	-0.47 (-0.91, -0.03)	
		>= 0.6 x ULN	69	0.65 (0.19)	68	-11.81 (3.20)	33	0.66 (0.19)	32	1.51 (4.73)	-13.32 (-24.62, -2.02)	0.0214	-0.50 (-0.92, -0.07)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of absolute and relative changes from baseline of indirect bilirubin at month 6 and 12 - Subgroup analysis
Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
			Baseline		Change from BL		Baseline		Change from BL					
Variable	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
Percent change from baseline	Month 12	Age at screening												0.7232
		< 65 years	99	0.54 (0.20)	97	-5.34 (3.17)	53	0.51 (0.21)	51	4.03 (4.40)	-9.37 (-19.98, 1.23)	0.0826	-0.30 (-0.64, 0.04)	
		>= 65 years	29	0.52 (0.16)	29	0.07 (12.21)	12	0.57 (0.18)	12	1.38 (18.54)	-1.31 (-46.06, 43.44)	0.9531	-0.02 (-0.69, 0.65)	
		Age at PBC diagnosis												0.3519
		< 50 years	61	0.54 (0.16)	59	-4.96 (4.65)	32	0.51 (0.24)	30	8.75 (6.65)	-13.71 (-29.82, 2.40)	0.0940	-0.38 (-0.82, 0.07)	
		>= 50 years	67	0.53 (0.22)	67	-2.65 (5.80)	33	0.54 (0.16)	33	-0.83 (8.14)	-1.82 (-21.47, 17.84)	0.8547	-0.04 (-0.46, 0.38)	
		Sex												NE
		female	123	0.53 (0.19)	121	-4.42 (3.88)	60	0.52 (0.21)	58	5.46 (5.61)	-9.88 (-23.26, 3.50)	0.1468	-0.23 (-0.54, 0.08)	
		male	5	0.62 (0.22)	5	NE	5	0.58 (0.16)	5	NE	NE		NE	
		Race												
		white	114	0.53 (0.20)	113		56	0.53 (0.21)	54					
		black	2	0.64 (0.01)	2		2	0.32 (0.19)	2					
		asian	7	0.61 (0.18)	7		4	0.55 (0.06)	4					
		other	5	0.47 (0.10)	4		3	0.54 (0.20)	3					
		Region												0.0271
		North America	50	0.52 (0.19)	49	-6.82 (5.51)	13	0.61 (0.34)	12	31.83 (11.26)	-38.65 (-63.17, -14.14)	0.0026	-0.99 (-1.64, -0.33)	
		Europe	39	0.52 (0.22)	39	-4.96 (3.76)	24	0.52 (0.16)	23	0.49 (4.75)	-5.45 (-17.41, 6.52)	0.3651	-0.23 (-0.75, 0.29)	
		Rest-of-World	39	0.56 (0.17)	38	1.43 (9.01)	28	0.49 (0.14)	28	-3.31 (10.48)	4.74 (-22.84, 32.32)	0.7322	0.08 (-0.40, 0.57)	
		Cirrhosis												0.7272
		yes	18	0.61 (0.18)	18	14.45 (24.49)	9	0.61 (0.16)	9	40.16 (36.71)	-25.70 (-119.62, 68.22)	0.5686	-0.24 (-1.04, 0.57)	
		no	110	0.52 (0.19)	108	-7.77 (2.84)	56	0.51 (0.20)	54	2.46 (3.91)	-10.23 (-19.61, -0.84)	0.0329	-0.35 (-0.68, -0.02)	
		UDCA												0.0174
		UDCA Use	120	0.53 (0.20)	118	-3.15 (3.97)	62	0.52 (0.20)	60	2.18 (5.52)	-5.33 (-18.67, 8.00)	0.4310	-0.12 (-0.43, 0.19)	
		UDCA Intolerance	8	0.54 (0.12)	8	-11.12 (6.83)	3	0.61 (0.19)	3	34.95 (13.74)	-46.07 (-85.71, -6.43)	0.0301	-2.07 (-3.77, -0.36)	
		Prior Use of OCA and/or Fibrates												0.2442
		yes	20	0.51 (0.13)	18	7.58 (7.59)	13	0.44 (0.11)	12	0.05 (9.45)	7.53 (-17.91, 32.97)	0.5423	0.23 (-0.51, 0.96)	
		no	108	0.54 (0.20)	108	-5.66 (4.20)	52	0.55 (0.21)	51	3.32 (6.11)	-8.99 (-23.52, 5.54)	0.2235	-0.20 (-0.54, 0.13)	
		Therapy												0.0478
		Monotherapy (SEL)	8	0.54 (0.12)	8	-10.50 (9.88)	4	0.58 (0.17)	4	34.44 (15.84)	-44.94 (-91.08, 1.20)	0.0544	-1.42 (-2.81, -0.04)	
		Combinationtherapy (SEL + UDCA)	120	0.53 (0.20)	118	-3.17 (3.98)	61	0.52 (0.20)	59	2.51 (5.59)	-5.68 (-19.14, 7.77)	0.4054	-0.13 (-0.44, 0.18)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
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N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of absolute and relative changes from baseline of indirect bilirubin at month 6 and 12 - Subgroup analysis
Intention-to-treat

Variable	Timepoint	Subgroup Level	Seladelpar 10 mg (N=128) Baseline N	Seladelpar 10 mg (N=128) Baseline Mean (SD)	Seladelpar 10 mg (N=128) Change from BL N	Seladelpar 10 mg (N=128) Change from BL LSMean (SE)	Placebo (N=65) Baseline N	Placebo (N=65) Baseline Mean (SD)	Placebo (N=65) Change from BL N	Placebo (N=65) Change from BL LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
Percent change from baseline	Month 12	Stratification variable: Baseline Pruritus NRS												0.2729
		< 4	79	0.53 (0.20)	79	-7.28 (3.65)	42	0.54 (0.23)	41	4.88 (4.92)	-12.16 (-23.95, -0.37)	0.0433	-0.38 (-0.76, 0.00)	
		>= 4	49	0.55 (0.18)	47	5.96 (8.56)	23	0.51 (0.15)	22	0.07 (12.75)	5.89 (-24.90, 36.68)	0.7028	0.10 (-0.41, 0.61)	
		Stratification variable: Baseline ALP Level												0.0926
		< 350 U/L	93	0.53 (0.20)	92	-7.55 (3.28)	47	0.52 (0.22)	45	8.11 (4.73)	-15.65 (-26.93, -4.38)	0.0069	-0.49 (-0.85, -0.13)	
		>= 350 U/L	35	0.55 (0.16)	34	9.45 (10.65)	18	0.54 (0.14)	18	-6.59 (14.46)	16.05 (-20.21, 52.30)	0.3768	0.26 (-0.32, 0.83)	
		Gamma-GT (GGT)												0.2785
		<= 3 x ULN	33	0.57 (0.23)	32	-4.77 (6.98)	14	0.41 (0.13)	13	14.07 (10.52)	-18.84 (-41.84, 4.16)	0.1059	-0.47 (-1.13, 0.18)	
		> 3 x ULN	95	0.52 (0.18)	94	-1.95 (4.60)	51	0.56 (0.21)	50	1.91 (6.32)	-3.86 (-19.28, 11.56)	0.6209	-0.09 (-0.43, 0.26)	
		Total Bilirubin I												0.9441
		<= 1 x ULN	108	0.47 (0.11)	106	-1.18 (4.33)	60	0.49 (0.14)	59	4.88 (5.76)	-6.06 (-20.14, 8.02)	0.3965	-0.14 (-0.45, 0.18)	
		> 1 x ULN	20	0.85 (0.24)	20	-17.79 (3.86)	5	0.96 (0.31)	4	-10.85 (9.57)	-6.94 (-28.80, 14.93)	0.5106	-0.38 (-1.46, 0.70)	
		Total Bilirubin II												0.3555
		< 0.6 x ULN	59	0.39 (0.07)	58	-7.94 (4.21)	32	0.38 (0.08)	31	6.65 (5.67)	-14.59 (-28.04, -1.15)	0.0338	-0.45 (-0.89, -0.01)	
		>= 0.6 x ULN	69	0.65 (0.19)	68	1.32 (6.41)	33	0.66 (0.19)	32	3.73 (9.35)	-2.41 (-25.05, 20.23)	0.8321	-0.05 (-0.47, 0.37)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Summary of mean values, absolute and relative changes from baseline of 5 Prime Nucleotidase by visit
Intention-to-treat

		Seladelpar 10 mg (N=128)				Placebo (N=65)			
		Value at Timepoint		Change from Baseline		Value at Timepoint		Change from Baseline	
Variable	Timepoint	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Change from baseline	Baseline	128	15.30 (11.30)	0	-	65	16.73 (10.60)	0	-
	Month 1	125	9.79 (7.94)	125	-5.60 (5.55)	62	14.31 (11.27)	62	-2.39 (6.92)
	Month 3	125	8.88 (7.65)	125	-6.54 (6.55)	62	13.45 (8.57)	62	-3.08 (6.43)
	Month 6	123	8.35 (6.73)	123	-7.03 (6.76)	60	13.38 (10.35)	60	-2.90 (6.02)
	Month 9	118	8.03 (6.77)	118	-7.37 (7.27)	57	11.65 (7.58)	57	-4.18 (7.14)
	Month 12	113	8.50 (8.26)	113	-7.00 (8.36)	57	11.74 (7.79)	57	-4.61 (7.59)
	Safety Follow-up	21	11.71 (11.38)	21	-3.70 (7.89)	7	21.57 (21.20)	7	1.10 (9.51)

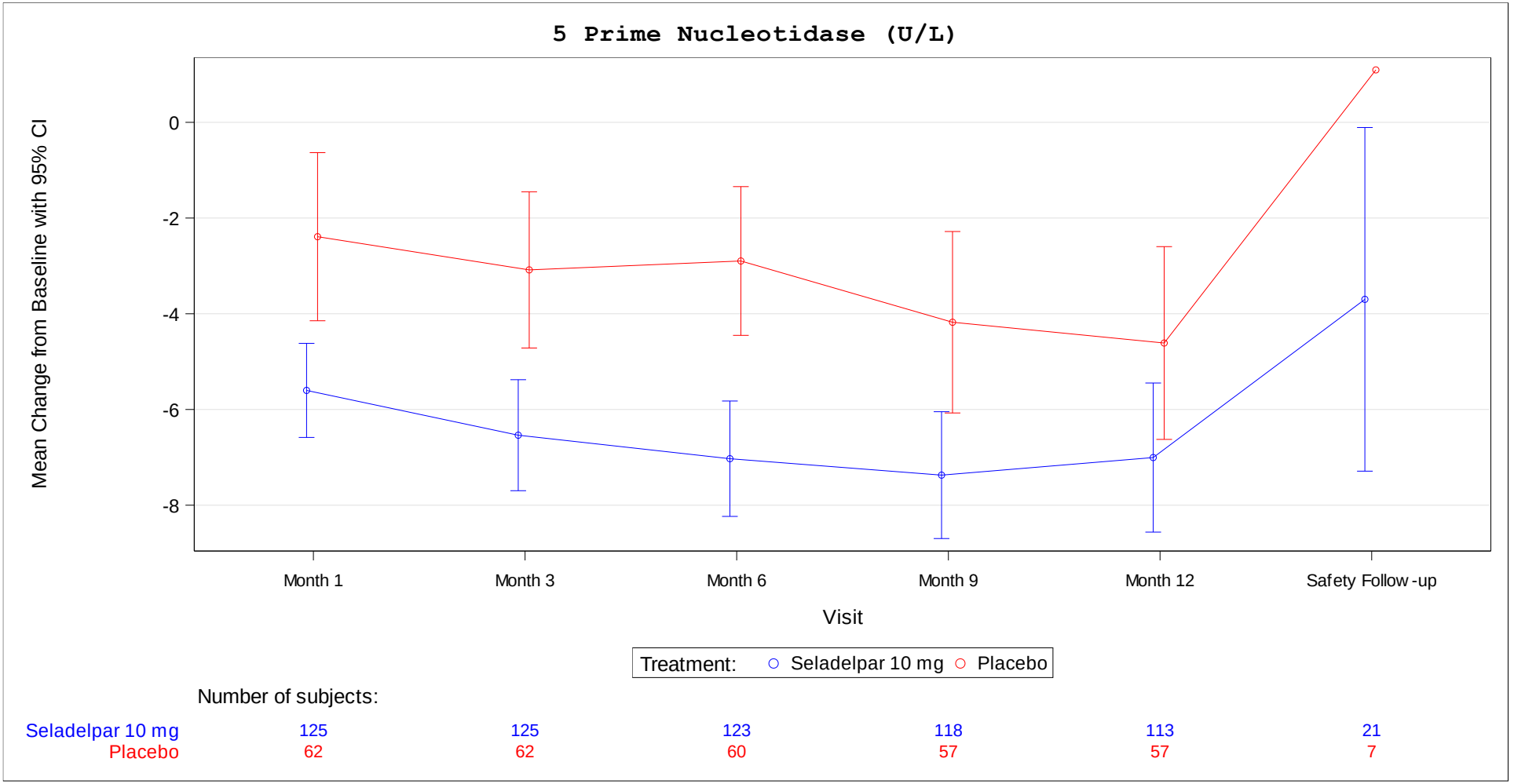
N describes number of patients with non-missing value at the respective timepoint.
N=Number of subjects included in the analysis, SD: Standard Deviation; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Summary of mean values, absolute and relative changes from baseline of 5 Prime Nucleotidase by visit
Intention-to-treat

		Seladelpar 10 mg (N=128)				Placebo (N=65)			
		Value at Timepoint		Change from Baseline		Value at Timepoint		Change from Baseline	
Variable	Timepoint	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Percent change from baseline	Baseline	128	15.30 (11.30)	0	-	65	16.73 (10.60)	0	-
	Month 1	125	9.79 (7.94)	125	-34.80 (16.94)	62	14.31 (11.27)	62	-11.62 (27.86)
	Month 3	125	8.88 (7.65)	125	-40.62 (19.31)	62	13.45 (8.57)	62	-14.18 (30.30)
	Month 6	123	8.35 (6.73)	123	-43.20 (20.48)	60	13.38 (10.35)	60	-16.17 (30.94)
	Month 9	118	8.03 (6.77)	118	-45.36 (24.54)	57	11.65 (7.58)	57	-20.36 (51.57)
	Month 12	113	8.50 (8.26)	113	-42.30 (36.66)	57	11.74 (7.79)	57	-22.87 (32.49)
	Safety Follow-up	21	11.71 (11.38)	21	-28.54 (36.16)	7	21.57 (21.20)	7	-9.61 (40.42)

N describes number of patients with non-missing value at the respective timepoint.
N=Number of subjects included in the analysis, SD: Standard Deviation; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Graphical summary of change from baseline of 5 Prime Nucleotidase by visit
Intention-to-treat



Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of absolute and relative changes from baseline of 5 Prime Nucleotidase by visit
Intention-to-treat

		Seladelpar 10 mg (N=128)		Placebo (N=65)		Difference of		
Score	Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)
Change from baseline	Month 1	126	-5.74 (0.47)	63	-2.13 (0.65)	-3.61 (-5.11, -2.11)	<.0001	-0.68 (-0.99, -0.37)
	Month 3	126	-6.66 (0.53)	63	-2.31 (0.73)	-4.35 (-6.05, -2.66)	<.0001	-0.74 (-1.05, -0.43)
	Month 6	126	-7.15 (0.45)	63	-2.39 (0.63)	-4.76 (-6.19, -3.32)	<.0001	-0.94 (-1.25, -0.62)
	Month 9	126	-7.34 (0.52)	63	-3.86 (0.72)	-3.48 (-5.15, -1.81)	<.0001	-0.60 (-0.91, -0.29)
	Month 12	126	-7.11 (0.62)	63	-4.04 (0.86)	-3.08 (-5.10, -1.06)	0.0031	-0.45 (-0.75, -0.14)

(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
N=Number of subjects included in the analysis, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of absolute and relative changes from baseline of 5 Prime Nucleotidase by visit
Intention-to-treat

		Seladelpar 10 mg (N=128)		Placebo (N=65)		Difference of		
Score	Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)
Percent change from baseline	Month 1	126	-34.32 (2.07)	63	-10.49 (2.84)	-23.83 (-30.27, -17.39)	<.0001	-1.03 (-1.35, -0.71)
	Month 3	126	-40.08 (2.31)	63	-12.02 (3.18)	-28.06 (-35.39, -20.72)	<.0001	-1.09 (-1.41, -0.77)
	Month 6	126	-42.71 (2.37)	63	-14.14 (3.30)	-28.57 (-36.18, -20.97)	<.0001	-1.07 (-1.40, -0.75)
	Month 9	126	-43.24 (3.61)	63	-17.82 (5.11)	-25.42 (-37.52, -13.32)	<.0001	-0.62 (-0.93, -0.32)
	Month 12	126	-42.29 (3.37)	63	-20.82 (4.71)	-21.47 (-32.61, -10.33)	0.0002	-0.57 (-0.88, -0.26)

(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
N=Number of subjects included in the analysis, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of absolute and relative changes from baseline of 5 Prime Nucleotidase at month 6 and 12 - Subgroup analysis
Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
			Baseline		Change from BL		Baseline		Change from BL					
Variable	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
Change from baseline	Month 6	Age at screening												0.2412
		< 65 years	99	15.14 (10.16)	97	-7.00 (0.58)	53	17.05 (10.52)	51	-2.54 (0.78)	-4.46 (-6.27, -2.65)	<.0001	-0.79 (-1.14, -0.44)	
		>= 65 years	29	15.84 (14.75)	29	-7.72 (0.58)	12	15.31 (11.31)	12	-1.71 (0.95)	-6.01 (-7.96, -4.05)	<.0001	-1.86 (-2.66, -1.07)	
		Age at PBC diagnosis												0.3215
		< 50 years	61	16.76 (11.24)	59	-7.19 (0.89)	32	18.33 (11.95)	30	-3.18 (1.26)	-4.02 (-6.98, -1.06)	0.0086	-0.58 (-1.03, -0.13)	
		>= 50 years	67	13.97 (11.28)	67	-6.86 (0.49)	33	15.17 (9.01)	33	-1.18 (0.69)	-5.68 (-7.26, -4.10)	<.0001	-1.40 (-1.87, -0.94)	
		Sex												NE
		female	123	15.57 (11.43)	121	-7.23 (0.48)	60	16.30 (10.42)	58	-2.24 (0.68)	-4.98 (-6.52, -3.44)	<.0001	-0.95 (-1.28, -0.62)	
		male	5	8.60 (3.70)	5	NE	5	21.87 (12.60)	5	NE	NE		NE	
		Race												
		white	114	15.54 (11.63)	113		56	17.31 (11.16)	54					
		black	2	28.67 (7.07)	2		2	11.67 (9.43)	2					
		asian	7	11.81 (5.36)	7		4	15.33 (4.12)	4					
		other	5	9.40 (4.63)	4		3	11.03 (3.23)	3					
		Region												0.2764
		North America	50	15.11 (12.05)	49	-7.34 (0.78)	13	17.98 (11.84)	12	-3.29 (1.47)	-4.05 (-7.20, -0.90)	0.0130	-0.74 (-1.39, -0.10)	
		Europe	39	15.95 (12.86)	39	-7.53 (0.83)	24	16.89 (10.40)	23	-1.14 (1.09)	-6.40 (-9.00, -3.79)	<.0001	-1.21 (-1.77, -0.65)	
		Rest-of-World	39	14.89 (8.58)	38	-6.57 (0.86)	28	16.00 (10.51)	28	-2.94 (1.01)	-3.63 (-6.23, -1.03)	0.0070	-0.67 (-1.18, -0.17)	
		Cirrhosis												0.5821
		yes	18	16.78 (9.37)	18	-7.03 (0.92)	9	19.52 (9.27)	9	-3.18 (1.31)	-3.85 (-7.04, -0.66)	0.0203	-0.96 (-1.80, -0.11)	
		no	110	15.06 (11.61)	108	-7.23 (0.48)	56	16.28 (10.80)	54	-2.43 (0.67)	-4.80 (-6.36, -3.24)	<.0001	-0.96 (-1.30, -0.61)	
		UDCA												<.0001
		UDCA Use	120	14.09 (9.58)	118	-6.51 (0.48)	62	16.17 (10.37)	60	-2.36 (0.65)	-4.14 (-5.63, -2.66)	<.0001	-0.80 (-1.12, -0.48)	
		UDCA Intolerance	8	33.50 (18.85)	8	-16.08 (1.64)	3	28.22 (10.30)	3	8.22 (3.03)	-24.30 (-33.44, -15.17)	0.0014	-4.65 (-7.41, -1.88)	
		Prior Use of OCA and/or Fibrates												0.4346
		yes	20	18.72 (13.62)	18	-7.85 (1.22)	13	19.96 (11.35)	12	-4.49 (1.53)	-3.35 (-7.35, 0.65)	0.0965	-0.62 (-1.37, 0.13)	
		no	108	14.67 (10.78)	108	-7.06 (0.49)	52	15.92 (10.36)	51	-2.08 (0.69)	-4.98 (-6.53, -3.44)	<.0001	-0.99 (-1.34, -0.64)	
		Therapy												<.0001
		Monotherapy (SEL)	8	33.50 (18.85)	8	-17.48 (1.21)	4	33.50 (13.49)	4	4.80 (2.05)	-22.28 (-29.55, -15.02)	0.0019	-5.66 (-8.67, -2.65)	
		Combinationtherapy (SEL + UDCA)	120	14.09 (9.58)	118	-6.38 (0.46)	61	15.63 (9.52)	59	-2.61 (0.63)	-3.77 (-5.18, -2.35)	<.0001	-0.76 (-1.09, -0.44)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of absolute and relative changes from baseline of 5 Prime Nucleotidase at month 6 and 12 - Subgroup analysis
Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
			Baseline		Change from BL		Baseline		Change from BL					
Variable	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
Change from baseline	Month 6	Stratification variable: Baseline Pruritus NRS												0.3262
		< 4	79	14.18 (12.17)	79	-7.12 (0.53)	42	15.21 (10.61)	41	-3.01 (0.69)	-4.11 (-5.68, -2.54)	<.0001	-0.89 (-1.28, -0.50)	
		>= 4	49	17.10 (9.59)	47	-7.65 (0.84)	23	19.50 (10.22)	22	-1.86 (1.28)	-5.79 (-8.83, -2.75)	0.0004	-0.98 (-1.52, -0.45)	
		Stratification variable: Baseline ALP Level												0.0553
		< 350 U/L	93	11.43 (5.59)	92	-5.35 (0.38)	47	13.31 (7.64)	45	-1.55 (0.54)	-3.81 (-5.10, -2.52)	<.0001	-1.03 (-1.41, -0.65)	
		>= 350 U/L	35	25.59 (15.58)	34	-12.07 (1.24)	18	25.64 (12.18)	18	-3.94 (1.76)	-8.13 (-12.51, -3.74)	0.0006	-1.09 (-1.71, -0.48)	
		Gamma-GT (GGT)												0.0091
		<= 3 x ULN	33	8.36 (3.45)	32	-2.85 (0.34)	14	8.45 (2.48)	13	-0.20 (0.47)	-2.65 (-3.61, -1.69)	<.0001	-1.39 (-2.10, -0.68)	
		> 3 x ULN	95	17.71 (12.07)	94	-8.33 (0.57)	51	19.00 (10.85)	50	-2.94 (0.78)	-5.40 (-7.25, -3.54)	<.0001	-0.97 (-1.33, -0.61)	
		Total Bilirubin I												<.0001
		<= 1 x ULN	108	14.37 (10.34)	106	-6.84 (0.51)	60	16.53 (10.36)	59	-2.44 (0.67)	-4.40 (-5.97, -2.83)	<.0001	-0.84 (-1.17, -0.50)	
		> 1 x ULN	20	20.35 (14.83)	20	-9.22 (0.75)	5	19.08 (14.36)	4	4.85 (2.01)	-14.07 (-18.53, -9.61)	<.0001	-3.92 (-5.54, -2.30)	
		Total Bilirubin II												0.0337
		< 0.6 x ULN	59	12.54 (7.78)	58	-5.85 (0.79)	32	16.60 (12.30)	31	-2.47 (1.05)	-3.39 (-5.68, -1.09)	0.0043	-0.56 (-1.01, -0.12)	
		>= 0.6 x ULN	69	17.66 (13.22)	68	-8.27 (0.49)	33	16.85 (8.84)	32	-1.84 (0.72)	-6.43 (-8.13, -4.73)	<.0001	-1.58 (-2.06, -1.11)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of absolute and relative changes from baseline of 5 Prime Nucleotidase at month 6 and 12 - Subgroup analysis
Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
			Baseline		Change from BL		Baseline		Change from BL					
Variable	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
Change from baseline	Month 12	Age at screening												0.3297
		< 65 years	99	15.14 (10.16)	97	-6.88 (0.79)	53	17.05 (10.52)	51	-4.18 (1.09)	-2.70 (-5.28, -0.12)	0.0405	-0.35 (-0.69, -0.01)	
		>= 65 years	29	15.84 (14.75)	29	-7.98 (0.80)	12	15.31 (11.31)	12	-3.50 (1.14)	-4.48 (-7.07, -1.88)	0.0013	-1.04 (-1.76, -0.33)	
		Age at PBC diagnosis												0.6823
		< 50 years	61	16.76 (11.24)	59	-7.07 (1.22)	32	18.33 (11.95)	30	-4.30 (1.73)	-2.78 (-6.93, 1.38)	0.1866	-0.29 (-0.73, 0.15)	
		>= 50 years	67	13.97 (11.28)	67	-6.94 (0.68)	33	15.17 (9.01)	33	-3.20 (0.93)	-3.74 (-5.96, -1.52)	0.0012	-0.68 (-1.11, -0.25)	
		Sex												NE
		female	123	15.57 (11.43)	121	-7.16 (0.65)	60	16.30 (10.42)	58	-3.91 (0.93)	-3.25 (-5.43, -1.07)	0.0038	-0.45 (-0.77, -0.14)	
		male	5	8.60 (3.70)	5	NE	5	21.87 (12.60)	5	NE	NE		NE	
		Race												
		white	114	15.54 (11.63)	113		56	17.31 (11.16)	54					
		black	2	28.67 (7.07)	2		2	11.67 (9.43)	2					
		asian	7	11.81 (5.36)	7		4	15.33 (4.12)	4					
		other	5	9.40 (4.63)	4		3	11.03 (3.23)	3					
		Region												0.2759
		North America	50	15.11 (12.05)	49	-6.92 (1.15)	13	17.98 (11.84)	12	-4.00 (2.36)	-2.92 (-8.06, 2.21)	0.2590	-0.36 (-0.99, 0.28)	
		Europe	39	15.95 (12.86)	39	-7.00 (0.99)	24	16.89 (10.40)	23	-1.84 (1.29)	-5.16 (-8.32, -2.00)	0.0020	-0.82 (-1.36, -0.28)	
		Rest-of-World	39	14.89 (8.58)	38	-7.29 (0.89)	28	16.00 (10.51)	28	-5.42 (1.02)	-1.87 (-4.53, 0.79)	0.1650	-0.34 (-0.83, 0.15)	
		Cirrhosis												0.6712
		yes	18	16.78 (9.37)	18	-6.18 (1.47)	9	19.52 (9.27)	9	-4.36 (2.29)	-1.82 (-7.44, 3.81)	0.5070	-0.27 (-1.08, 0.53)	
		no	110	15.06 (11.61)	108	-7.24 (0.62)	56	16.28 (10.80)	54	-4.21 (0.86)	-3.04 (-5.08, -1.00)	0.0038	-0.47 (-0.80, -0.14)	
		UDCA												0.1523
		UDCA Use	120	14.09 (9.58)	118	-6.48 (0.63)	62	16.17 (10.37)	60	-3.87 (0.87)	-2.62 (-4.66, -0.57)	0.0124	-0.38 (-0.69, -0.07)	
		UDCA Intolerance	8	33.50 (18.85)	8	-15.71 (4.77)	3	28.22 (10.30)	3	1.49 (8.95)	-17.19 (-40.20, 5.81)	0.1248	-1.13 (-2.58, 0.33)	
		Prior Use of OCA and/or Fibrates												0.4656
		yes	20	18.72 (13.62)	18	-8.39 (2.44)	13	19.96 (11.35)	12	-2.73 (3.03)	-5.66 (-13.69, 2.36)	0.1578	-0.53 (-1.27, 0.21)	
		no	108	14.67 (10.78)	108	-6.89 (0.60)	52	15.92 (10.36)	51	-4.15 (0.85)	-2.74 (-4.71, -0.78)	0.0067	-0.44 (-0.78, -0.11)	
		Therapy												0.8879
		Monotherapy (SEL)	8	33.50 (18.85)	8	-17.11 (6.13)	4	33.50 (13.49)	4	-15.50 (9.49)	-1.61 (-27.00, 23.79)	0.8899	-0.08 (-1.28, 1.12)	
		Combinationtherapy (SEL + UDCA)	120	14.09 (9.58)	118	-6.34 (0.60)	61	15.63 (9.52)	59	-3.13 (0.83)	-3.20 (-5.14, -1.27)	0.0014	-0.49 (-0.81, -0.18)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
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N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of absolute and relative changes from baseline of 5 Prime Nucleotidase at month 6 and 12 - Subgroup analysis
Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
			Baseline		Change from BL		Baseline		Change from BL					
Variable	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
Change from baseline	Month 12	Stratification variable: Baseline Pruritus NRS												0.2023
		< 4	79	14.18 (12.17)	79	-6.70 (0.74)	42	15.21 (10.61)	41	-4.64 (1.00)	-2.05 (-4.41, 0.31)	0.0873	-0.31 (-0.69, 0.07)	
		>= 4	49	17.10 (9.59)	47	-8.53 (1.06)	23	19.50 (10.22)	22	-3.63 (1.58)	-4.90 (-8.70, -1.10)	0.0126	-0.66 (-1.18, -0.15)	
		Stratification variable: Baseline ALP Level												0.6066
		< 350 U/L	93	11.43 (5.59)	92	-5.05 (0.54)	47	13.31 (7.64)	45	-1.91 (0.78)	-3.15 (-5.00, -1.30)	0.0010	-0.60 (-0.97, -0.24)	
		>= 350 U/L	35	25.59 (15.58)	34	-12.93 (1.61)	18	25.64 (12.18)	18	-8.32 (2.15)	-4.61 (-10.09, 0.87)	0.0960	-0.49 (-1.07, 0.09)	
		Gamma-GT (GGT)												0.3254
		<= 3 x ULN	33	8.36 (3.45)	32	-3.05 (0.41)	14	8.45 (2.48)	13	-1.09 (0.59)	-1.96 (-3.25, -0.67)	0.0037	-0.85 (-1.52, -0.18)	
		> 3 x ULN	95	17.71 (12.07)	94	-8.21 (0.79)	51	19.00 (10.85)	50	-4.80 (1.08)	-3.40 (-6.02, -0.78)	0.0114	-0.44 (-0.79, -0.09)	
		Total Bilirubin I												0.0135
		<= 1 x ULN	108	14.37 (10.34)	106	-6.65 (0.65)	60	16.53 (10.36)	59	-4.14 (0.85)	-2.51 (-4.54, -0.48)	0.0158	-0.38 (-0.70, -0.06)	
		> 1 x ULN	20	20.35 (14.83)	20	-9.80 (1.43)	5	19.08 (14.36)	4	2.47 (3.55)	-12.27 (-20.19, -4.34)	0.0041	-1.82 (-3.04, -0.61)	
		Total Bilirubin II												0.0495
		< 0.6 x ULN	59	12.54 (7.78)	58	-5.74 (0.90)	32	16.60 (12.30)	31	-4.59 (1.22)	-1.15 (-3.91, 1.61)	0.4078	-0.17 (-0.60, 0.27)	
		>= 0.6 x ULN	69	17.66 (13.22)	68	-8.29 (0.79)	33	16.85 (8.84)	32	-3.32 (1.12)	-4.97 (-7.68, -2.26)	0.0005	-0.77 (-1.20, -0.33)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
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p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
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Mixed Effects Model (MMRM) analysis of absolute and relative changes from baseline of 5 Prime Nucleotidase at month 6 and 12 - Subgroup analysis
Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
			Baseline		Change from BL		Baseline		Change from BL					
Variable	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
Percent change from baseline	Month 6	Age at screening												0.4069
		< 65 years	99	15.14 (10.16)	97	-42.37 (2.89)	53	17.05 (10.52)	51	-14.88 (3.90)	-27.49 (-36.64, -18.33)	<.0001	-0.97 (-1.33, -0.61)	
		>= 65 years	29	15.84 (14.75)	29	-43.29 (3.76)	12	15.31 (11.31)	12	-9.22 (6.02)	-34.07 (-47.13, -21.02)	<.0001	-1.64 (-2.40, -0.87)	
		Age at PBC diagnosis												0.3222
		< 50 years	61	16.76 (11.24)	59	-41.42 (3.74)	32	18.33 (11.95)	30	-16.60 (5.24)	-24.81 (-37.26, -12.37)	0.0002	-0.86 (-1.31, -0.40)	
		>= 50 years	67	13.97 (11.28)	67	-43.65 (3.05)	33	15.17 (9.01)	33	-10.98 (4.21)	-32.67 (-42.37, -22.97)	<.0001	-1.31 (-1.77, -0.86)	
		Sex												NE
		female	123	15.57 (11.43)	121	-43.35 (2.43)	60	16.30 (10.42)	58	-13.16 (3.45)	-30.19 (-38.11, -22.26)	<.0001	-1.13 (-1.47, -0.80)	
		male	5	8.60 (3.70)	5	NE	5	21.87 (12.60)	5	NE	NE		NE	
		Race												
		white	114	15.54 (11.63)	113		56	17.31 (11.16)	54					
		black	2	28.67 (7.07)	2		2	11.67 (9.43)	2					
		asian	7	11.81 (5.36)	7		4	15.33 (4.12)	4					
		other	5	9.40 (4.63)	4		3	11.03 (3.23)	3					
		Region												0.1059
		North America	50	15.11 (12.05)	49	-41.54 (4.49)	13	17.98 (11.84)	12	-20.13 (8.34)	-21.41 (-39.25, -3.57)	0.0195	-0.68 (-1.33, -0.04)	
		Europe	39	15.95 (12.86)	39	-46.47 (4.11)	24	16.89 (10.40)	23	-6.46 (5.46)	-40.01 (-53.01, -27.00)	<.0001	-1.53 (-2.11, -0.94)	
		Rest-of-World	39	14.89 (8.58)	38	-41.26 (3.62)	28	16.00 (10.51)	28	-17.36 (4.24)	-23.90 (-34.72, -13.08)	<.0001	-1.06 (-1.58, -0.53)	
		Cirrhosis												0.7880
		yes	18	16.78 (9.37)	18	-38.90 (6.72)	9	19.52 (9.27)	9	-12.81 (9.51)	-26.09 (-49.83, -2.35)	0.0329	-0.89 (-1.73, -0.05)	
		no	110	15.06 (11.61)	108	-43.58 (2.57)	56	16.28 (10.80)	54	-14.24 (3.56)	-29.34 (-37.55, -21.12)	<.0001	-1.10 (-1.45, -0.75)	
		UDCA												0.1191
		UDCA Use	120	14.09 (9.58)	118	-42.38 (2.50)	62	16.17 (10.37)	60	-14.55 (3.44)	-27.83 (-35.74, -19.92)	<.0001	-1.03 (-1.36, -0.70)	
		UDCA Intolerance	8	33.50 (18.85)	8	-48.65 (6.74)	3	28.22 (10.30)	3	3.70 (13.81)	-52.35 (-88.74, -15.96)	0.0118	-2.37 (-4.18, -0.55)	
		Prior Use of OCA and/or Fibrates												0.2909
		yes	20	18.72 (13.62)	18	-35.88 (8.09)	13	19.96 (11.35)	12	-20.00 (10.03)	-15.88 (-42.04, 10.28)	0.2239	-0.45 (-1.19, 0.29)	
		no	108	14.67 (10.78)	108	-44.31 (2.32)	52	15.92 (10.36)	51	-14.37 (3.29)	-29.94 (-37.43, -22.45)	<.0001	-1.25 (-1.61, -0.89)	
		Therapy												0.0182
		Monotherapy (SEL)	8	33.50 (18.85)	8	-49.11 (6.19)	4	33.50 (13.49)	4	6.98 (9.80)	-56.09 (-83.53, -28.65)	0.0019	-2.85 (-4.69, -1.01)	
		Combinationtherapy (SEL + UDCA)	120	14.09 (9.58)	118	-42.24 (2.49)	61	15.63 (9.52)	59	-15.11 (3.44)	-27.13 (-35.02, -19.24)	<.0001	-1.01 (-1.34, -0.68)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of absolute and relative changes from baseline of 5 Prime Nucleotidase at month 6 and 12 - Subgroup analysis
Intention-to-treat

Variable	Timepoint	Subgroup Level	Seladelpar 10 mg (N=128) Baseline N	Seladelpar 10 mg (N=128) Baseline Mean (SD)	Seladelpar 10 mg (N=128) Change from BL N	Seladelpar 10 mg (N=128) Change from BL LSMean (SE)	Placebo (N=65) Baseline N	Placebo (N=65) Baseline Mean (SD)	Placebo (N=65) Change from BL N	Placebo (N=65) Change from BL LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
Percent change from baseline	Month 6	Stratification variable: Baseline Pruritus NRS												0.7218
		< 4	79	14.18 (12.17)	79	-43.61 (3.21)	42	15.21 (10.61)	41	-16.24 (4.19)	-27.36 (-36.96, -17.76)	<.0001	-0.97 (-1.37, -0.57)	
		>= 4	49	17.10 (9.59)	47	-43.12 (3.41)	23	19.50 (10.22)	22	-12.97 (5.19)	-30.15 (-42.46, -17.84)	<.0001	-1.26 (-1.81, -0.71)	
		Stratification variable: Baseline ALP Level												0.8537
		< 350 U/L	93	11.43 (5.59)	92	-42.45 (2.75)	47	13.31 (7.64)	45	-13.27 (3.90)	-29.18 (-38.43, -19.94)	<.0001	-1.10 (-1.48, -0.72)	
		>= 350 U/L	35	25.59 (15.58)	34	-46.86 (3.69)	18	25.64 (12.18)	18	-16.21 (5.27)	-30.65 (-43.63, -17.67)	<.0001	-1.39 (-2.02, -0.75)	
		Gamma-GT (GGT)												0.5768
		<= 3 x ULN	33	8.36 (3.45)	32	-33.31 (4.26)	14	8.45 (2.48)	13	-0.99 (6.08)	-32.32 (-45.27, -19.38)	<.0001	-1.35 (-2.06, -0.64)	
		> 3 x ULN	95	17.71 (12.07)	94	-43.78 (2.79)	51	19.00 (10.85)	50	-15.86 (3.82)	-27.91 (-37.02, -18.81)	<.0001	-1.03 (-1.39, -0.66)	
		Total Bilirubin I												0.0646
		<= 1 x ULN	108	14.37 (10.34)	106	-42.15 (2.72)	60	16.53 (10.36)	59	-14.77 (3.56)	-27.38 (-35.65, -19.11)	<.0001	-0.98 (-1.32, -0.65)	
		> 1 x ULN	20	20.35 (14.83)	20	-46.31 (3.62)	5	19.08 (14.36)	4	1.30 (9.46)	-47.61 (-69.20, -26.03)	0.0003	-2.77 (-4.14, -1.40)	
		Total Bilirubin II												0.6749
		< 0.6 x ULN	59	12.54 (7.78)	58	-41.16 (4.17)	32	16.60 (12.30)	31	-13.84 (5.53)	-27.32 (-39.38, -15.26)	<.0001	-0.86 (-1.32, -0.41)	
		>= 0.6 x ULN	69	17.66 (13.22)	68	-44.53 (2.85)	33	16.85 (8.84)	32	-13.91 (4.17)	-30.62 (-40.54, -20.70)	<.0001	-1.29 (-1.75, -0.83)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of absolute and relative changes from baseline of 5 Prime Nucleotidase at month 6 and 12 - Subgroup analysis
Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
			Baseline		Change from BL		Baseline		Change from BL					
Variable	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
Percent change from baseline	Month 12	Age at screening												0.7950
		< 65 years	99	15.14 (10.16)	97	-41.02 (4.11)	53	17.05 (10.52)	51	-20.04 (5.69)	-20.99 (-34.57, -7.40)	0.0027	-0.52 (-0.86, -0.17)	
		>= 65 years	29	15.84 (14.75)	29	-46.42 (5.03)	12	15.31 (11.31)	12	-22.65 (7.12)	-23.77 (-40.43, -7.10)	0.0065	-0.88 (-1.58, -0.18)	
		Age at PBC diagnosis												0.8217
		< 50 years	61	16.76 (11.24)	59	-40.72 (4.54)	32	18.33 (11.95)	30	-17.48 (6.45)	-23.25 (-38.62, -7.87)	0.0035	-0.66 (-1.11, -0.21)	
		>= 50 years	67	13.97 (11.28)	67	-43.83 (4.95)	33	15.17 (9.01)	33	-23.13 (6.84)	-20.70 (-37.10, -4.29)	0.0140	-0.51 (-0.93, -0.09)	
		Sex												NE
		female	123	15.57 (11.43)	121	-42.41 (3.49)	60	16.30 (10.42)	58	-20.38 (4.96)	-22.03 (-33.71, -10.34)	0.0003	-0.57 (-0.89, -0.26)	
		male	5	8.60 (3.70)	5	NE	5	21.87 (12.60)	5	NE	NE		NE	
		Race												
		white	114	15.54 (11.63)	113		56	17.31 (11.16)	54					
		black	2	28.67 (7.07)	2		2	11.67 (9.43)	2					
		asian	7	11.81 (5.36)	7		4	15.33 (4.12)	4					
		other	5	9.40 (4.63)	4		3	11.03 (3.23)	3					
		Region												0.2794
		North America	50	15.11 (12.05)	49	-40.75 (7.42)	13	17.98 (11.84)	12	-11.96 (15.17)	-28.79 (-62.00, 4.41)	0.0879	-0.55 (-1.19, 0.09)	
		Europe	39	15.95 (12.86)	39	-40.74 (5.35)	24	16.89 (10.40)	23	-9.46 (6.93)	-31.28 (-48.28, -14.28)	0.0005	-0.93 (-1.47, -0.38)	
		Rest-of-World	39	14.89 (8.58)	38	-46.36 (3.91)	28	16.00 (10.51)	28	-30.70 (4.45)	-15.66 (-27.16, -4.15)	0.0085	-0.65 (-1.15, -0.15)	
		Cirrhosis												0.5136
		yes	18	16.78 (9.37)	18	-38.84 (6.52)	9	19.52 (9.27)	9	-25.81 (9.94)	-13.03 (-37.23, 11.16)	0.2746	-0.45 (-1.26, 0.37)	
		no	110	15.06 (11.61)	108	-42.80 (3.71)	56	16.28 (10.80)	54	-21.18 (5.13)	-21.62 (-33.82, -9.42)	0.0006	-0.56 (-0.89, -0.23)	
		UDCA												0.7412
		UDCA Use	120	14.09 (9.58)	118	-41.71 (3.56)	62	16.17 (10.37)	60	-21.20 (4.89)	-20.51 (-32.11, -8.91)	0.0006	-0.53 (-0.85, -0.22)	
		UDCA Intolerance	8	33.50 (18.85)	8	-51.88 (11.21)	3	28.22 (10.30)	3	-22.80 (22.72)	-29.08 (-90.91, 32.76)	0.2936	-0.79 (-2.18, 0.60)	
		Prior Use of OCA and/or Fibrates												0.7628
		yes	20	18.72 (13.62)	18	-31.54 (15.57)	13	19.96 (11.35)	12	-4.40 (19.22)	-27.15 (-77.80, 23.50)	0.2811	-0.40 (-1.14, 0.34)	
		no	108	14.67 (10.78)	108	-44.46 (2.72)	52	15.92 (10.36)	51	-24.89 (3.86)	-19.57 (-28.51, -10.63)	<.0001	-0.70 (-1.04, -0.35)	
		Therapy												0.6389
		Monotherapy (SEL)	8	33.50 (18.85)	8	-52.35 (13.08)	4	33.50 (13.49)	4	-42.48 (20.35)	-9.86 (-66.89, 47.16)	0.6955	-0.24 (-1.44, 0.97)	
		Combinationtherapy (SEL + UDCA)	120	14.09 (9.58)	118	-41.57 (3.56)	61	15.63 (9.52)	59	-20.02 (4.92)	-21.55 (-33.19, -9.90)	0.0003	-0.56 (-0.88, -0.24)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
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N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of absolute and relative changes from baseline of 5 Prime Nucleotidase at month 6 and 12 - Subgroup analysis
Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
			Baseline		Change from BL		Baseline		Change from BL					
Variable	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
Percent change from baseline	Month 12	Stratification variable: Baseline Pruritus NRS												0.6257
		< 4	79	14.18 (12.17)	79	-41.93 (4.71)	42	15.21 (10.61)	41	-22.15 (6.33)	-19.78 (-34.83, -4.73)	0.0105	-0.47 (-0.86, -0.09)	
		>= 4	49	17.10 (9.59)	47	-46.03 (4.23)	23	19.50 (10.22)	22	-21.03 (6.29)	-25.00 (-40.11, -9.90)	0.0016	-0.85 (-1.37, -0.32)	
		Stratification variable: Baseline ALP Level												0.6878
		< 350 U/L	93	11.43 (5.59)	92	-40.87 (4.15)	47	13.31 (7.64)	45	-16.63 (5.98)	-24.24 (-38.52, -9.97)	0.0010	-0.60 (-0.97, -0.24)	
		>= 350 U/L	35	25.59 (15.58)	34	-49.69 (4.81)	18	25.64 (12.18)	18	-29.76 (6.35)	-19.93 (-36.02, -3.84)	0.0165	-0.71 (-1.30, -0.12)	
		Gamma-GT (GGT)												0.8515
		<= 3 x ULN	33	8.36 (3.45)	32	-37.53 (4.48)	14	8.45 (2.48)	13	-14.28 (6.35)	-23.25 (-37.05, -9.44)	0.0015	-0.93 (-1.60, -0.25)	
		> 3 x ULN	95	17.71 (12.07)	94	-41.70 (4.25)	51	19.00 (10.85)	50	-20.29 (5.80)	-21.40 (-35.47, -7.34)	0.0031	-0.52 (-0.87, -0.17)	
		Total Bilirubin I												0.1908
		<= 1 x ULN	108	14.37 (10.34)	106	-40.46 (3.81)	60	16.53 (10.36)	59	-21.48 (5.01)	-18.98 (-31.01, -6.95)	0.0022	-0.48 (-0.81, -0.16)	
		> 1 x ULN	20	20.35 (14.83)	20	-52.56 (5.36)	5	19.08 (14.36)	4	-12.51 (13.86)	-40.05 (-71.41, -8.68)	0.0153	-1.58 (-2.76, -0.40)	
		Total Bilirubin II												0.7470
		< 0.6 x ULN	59	12.54 (7.78)	58	-40.56 (4.59)	32	16.60 (12.30)	31	-19.80 (6.22)	-20.75 (-34.64, -6.87)	0.0038	-0.59 (-1.04, -0.15)	
		>= 0.6 x ULN	69	17.66 (13.22)	68	-44.45 (5.09)	33	16.85 (8.84)	32	-20.05 (7.32)	-24.40 (-42.05, -6.75)	0.0073	-0.58 (-1.01, -0.15)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Number and Proportion of subjects with PBC Hospitalization Event
Intention-to-treat

Timepoint		Seladelpar 10 mg	Placebo
During study	Number of subjects with reponse, n/N (%)	6/128 (4.7)	3/ 65 (4.6)
	Number of missing values imputed as Non-Response	0	0
	Stratified Analysis Seladelpar 10 mg vs. Placebo		
	Relative Risk (95% CI)	1.06 (0.27, 4.17)	
	p-value	0.9384	
	Odds Ratio (95% CI)	1.06 (0.25, 4.47)	
	p-value	0.9379	
	Risk Difference (95% CI)	0.00 (-0.06, 0.06)	
	p-value	0.9373	
	Unstratified Analysis Seladelpar 10 mg vs. Placebo		
	Relative Risk (95% CI)	1.02 (0.26, 3.93)	
	p-value	0.9821	
	Odds Ratio (95% CI)	1.02 (0.25, 4.20)	
	p-value	0.9821	
	Peto Odds Ratio (95% CI)	1.02 (0.25, 4.17)	
	p-value	0.9821	
	Risk Difference (95% CI)	0.00 (-0.06, 0.06)	
	p-value	0.9820	

RR, OR and RD estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
Stratification factors: Baseline ALP level: < 350 U/L and >= 350 U/L; baseline pruritus NRS: < 4 and >= 4.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Number and Proportion of subjects with PBC Hospitalization Event - Subgroup analysis
Intention-to-treat

Timepoint	Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	OR (95% CI); p-Value	RD (95% CI); p-Value	Interaction p-Value
During study	Age at screening						
	< 65 years	3/ 99 (3.0)	3/ 53 (5.7)				
	>= 65 years	3/ 29 (10.3)	0/ 12 (0.0)				
	Age at PBC diagnosis						
	< 50 years	2/ 61 (3.3)	2/ 32 (6.3)				
	>= 50 years	4/ 67 (6.0)	1/ 33 (3.0)				
	Sex						
	female	6/ 123 (4.9)	2/ 60 (3.3)				
	male	0/ 5 (0.0)	1/ 5 (20.0)				
	Race						
	white	6/ 114 (5.3)	3/ 56 (5.4)				
	black	0/ 2 (0.0)	0/ 2 (0.0)				
	asian	0/ 7 (0.0)	0/ 4 (0.0)				
	other	0/ 5 (0.0)	0/ 3 (0.0)				
	Region						
	North America	3/ 50 (6.0)	0/ 13 (0.0)				
	Europe	1/ 39 (2.6)	2/ 24 (8.3)				
	Rest-of-World	2/ 39 (5.1)	1/ 28 (3.6)				
	Cirrhosis						
	yes	1/ 18 (5.6)	1/ 9 (11.1)				
	no	5/ 110 (4.5)	2/ 56 (3.6)				
	UDCA						
	UDCA Use	5/ 120 (4.2)	3/ 62 (4.8)				
	UDCA Intolerance	1/ 8 (12.5)	0/ 3 (0.0)				
	Prior Use of OCA and/or Fibrates						
	yes	2/ 20 (10.0)	0/ 13 (0.0)				
	no	4/ 108 (3.7)	3/ 52 (5.8)				
	Therapy						
	Monotherapy (SEL)	1/ 8 (12.5)	1/ 4 (25.0)				
	Combinationtherapy (SEL + UDCA)	5/ 120 (4.2)	2/ 61 (3.3)				
	Stratification variable: Baseline Pruritus NRS						
	< 4	4/ 79 (5.1)	2/ 42 (4.8)				
	>= 4	2/ 49 (4.1)	1/ 23 (4.3)				
	Stratification variable: Baseline ALP Level						
	< 350 U/L	4/ 93 (4.3)	1/ 47 (2.1)				
	>= 350 U/L	2/ 35 (5.7)	2/ 18 (11.1)				

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of subjects with event; N=Number of patients included in the analysis; CI=Confidence Interval; OR=Odds Ratio; RR=Relative Risk; RD=Risk Difference; NE=Not estimable

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Number and Proportion of subjects with PBC Hospitalization Event - Subgroup analysis
Intention-to-treat

Timepoint	Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	Seladelpar 10 mg vs. Placebo OR (95% CI); p-Value	Seladelpar 10 mg vs. Placebo RD (95% CI); p-Value	Interaction p-Value
During study	Gamma-GT (GGT)						
	<= 3.2 x ULN	2/ 38 (5.3)	0/ 18 (0.0)				
	> 3.2 x ULN	4/ 90 (4.4)	3/ 47 (6.4)				
	Total Bilirubin I						
	<= 1 x ULN	6/ 108 (5.6)	2/ 60 (3.3)				
	> 1 x ULN	0/ 20 (0.0)	1/ 5 (20.0)				
	Total Bilirubin II						
	< 0.6 x ULN	4/ 59 (6.8)	2/ 32 (6.3)				
	>= 0.6 x ULN	2/ 69 (2.9)	1/ 33 (3.0)				

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of subjects with event; N=Number of patients included in the analysis; CI=Confidence Interval; OR=Odds Ratio; RR=Relative Risk; RD=Risk Difference; NE=Not estimable

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Completion rates of Pruritus NRS (weekly averages) by visit
Intention-to-treat

Timepoint	Seladelpar 10 mg (N=128) n/ N	Seladelpar 10 mg (N=128) Completion	Placebo (N=65) n/ N	Placebo (N=65) Completion
Baseline	128/ 128	100.0%	65/ 65	100.0%
Month 1	127/ 128	99.22%	64/ 65	98.46%
Month 3	124/ 128	96.88%	63/ 65	96.92%
Month 6	121/ 128	94.53%	61/ 65	93.85%
Month 9	108/ 128	84.38%	56/ 65	86.15%
Month 12	105/ 128	82.03%	48/ 65	73.85%

n describes number of patients with non-missing value at the respective timepoint.
N defines number of patients still alive at beginning of respective visit window.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Number and Proportion of subjects with Pruritus NRS improvement of >= 4 points at 6 and 12 months
Intention-to-treat

Timepoint		Seladelpar 10 mg	Placebo
Month 6	Number of subjects with reponse, n/N (%)	14/128 (10.9)	4/ 65 (6.2)
	Number of missing values imputed as Non-Response	7	4
	Stratified Analysis Seladelpar 10 mg vs. Placebo		
	Relative Risk (95% CI)	1.65 (0.61, 4.47)	
	p-value	0.3280	
	Odds Ratio (95% CI)	1.90 (0.55, 6.59)	
	p-value	0.3115	
	Risk Difference (95% CI)	0.04 (-0.03, 0.11)	
	p-value	0.2727	
	Unstratified Analysis Seladelpar 10 mg vs. Placebo		
	Relative Risk (95% CI)	1.78 (0.61, 5.18)	
	p-value	0.2923	
	Odds Ratio (95% CI)	1.87 (0.59, 5.94)	
	p-value	0.2865	
	Peto Odds Ratio (95% CI)	1.76 (0.63, 4.89)	
	p-value	0.2814	
	Risk Difference (95% CI)	0.05 (-0.03, 0.13)	
	p-value	0.2389	

RR, OR and RD estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
Stratification factors: Baseline ALP level: < 350 U/L and >= 350 U/L; baseline pruritus NRS: < 4 and >= 4.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Number and Proportion of subjects with Pruritus NRS improvement of >= 4 points at 6 and 12 months
Intention-to-treat

Timepoint		Seladelpar 10 mg	Placebo
Month 12	Number of subjects with reponse, n/N (%)	15/128 (11.7)	2/ 65 (3.1)
	Number of missing values imputed as Non-Response	23	17
	Stratified Analysis Seladelpar 10 mg vs. Placebo		
	Relative Risk (95% CI)	3.50 (0.88, 14.01)	
	p-value	0.0764	
	Odds Ratio (95% CI)	4.64 (0.96, 22.48)	
	p-value	0.0563	
	Risk Difference (95% CI)	0.08 (0.01, 0.14)	
	p-value	0.0169	
	Unstratified Analysis Seladelpar 10 mg vs. Placebo		
	Relative Risk (95% CI)	3.81 (0.90, 16.15)	
	p-value	0.0697	
	Odds Ratio (95% CI)	4.18 (0.93, 18.88)	
	p-value	0.0628	
	Peto Odds Ratio (95% CI)	2.92 (1.02, 8.34)	
	p-value	0.0458	
	Risk Difference (95% CI)	0.09 (0.02, 0.16)	
	p-value	0.0152	

RR, OR and RD estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
Stratification factors: Baseline ALP level: < 350 U/L and >= 350 U/L; baseline pruritus NRS: < 4 and >= 4.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Number and Proportion of subjects with Pruritus NRS improvement of >= 4 points at 6 and 12 months - Subgroup analysis
Intention-to-treat

Timepoint	Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	Seladelpar 10 mg vs. Placebo OR (95% CI); p-Value	Seladelpar 10 mg vs. Placebo RD (95% CI); p-Value	Interaction p-Value
Month 6	Age at screening						0.8630
	< 65 years	13/ 99 (13.1)	4/ 53 (7.5)	1.74 (0.60, 5.07); p=0.3103	1.85 (0.57, 5.99); p=0.3038	0.06 (-0.04, 0.15); p=0.2611	
	>= 65 years	1/ 29 (3.4)	0/ 12 (0.0)	1.30 (0.06, 29.85); p=0.8697	1.32 (0.05, 34.58); p=0.8693	0.03 (-0.03, 0.10); p=0.3088	
	Age at PBC diagnosis						0.1602
	< 50 years	9/ 61 (14.8)	1/ 32 (3.1)	4.72 (0.63, 35.63); p=0.1323	5.37 (0.65, 44.40); p=0.1192	0.12 (0.01, 0.22); p=0.0340	
	>= 50 years	5/ 67 (7.5)	3/ 33 (9.1)	0.82 (0.21, 3.23); p=0.7776	0.81 (0.18, 3.60); p=0.7781	-0.02 (-0.13, 0.10); p=0.7842	
	Sex						0.6944
	female	13/ 123 (10.6)	4/ 60 (6.7)	1.59 (0.54, 4.66); p=0.4018	1.65 (0.52, 5.31); p=0.3973	0.04 (-0.04, 0.12); p=0.3584	
	male	1/ 5 (20.0)	0/ 5 (0.0)	3.00 (0.15, 59.89); p=0.4720	3.67 (0.12, 113.73); p=0.4584	0.20 (-0.15, 0.55); p=0.2636	
	Race						
	white	11/ 114 (9.6)	3/ 56 (5.4)				
	black	1/ 2 (50.0)	0/ 2 (0.0)				
	asian	1/ 7 (14.3)	0/ 4 (0.0)				
	other	1/ 5 (20.0)	1/ 3 (33.3)				
	Region						
	North America	5/ 50 (10.0)	2/ 13 (15.4)				
	Europe	4/ 39 (10.3)	1/ 24 (4.2)				
	Rest-of-World	5/ 39 (12.8)	1/ 28 (3.6)				
	Cirrhosis						0.3188
	yes	1/ 18 (5.6)	1/ 9 (11.1)	0.50 (0.04, 7.10); p=0.6087	0.47 (0.03, 8.52); p=0.6100	-0.06 (-0.29, 0.18); p=0.6374	
	no	13/ 110 (11.8)	3/ 56 (5.4)	2.21 (0.66, 7.42); p=0.2013	2.37 (0.65, 8.68); p=0.1935	0.06 (-0.02, 0.15); p=0.1333	
	UDCA						0.3973
	UDCA Use	12/ 120 (10.0)	3/ 62 (4.8)	2.07 (0.61, 7.05); p=0.2464	2.19 (0.59, 8.05); p=0.2401	0.05 (-0.02, 0.13); p=0.1816	
	UDCA Intolerance	2/ 8 (25.0)	1/ 3 (33.3)	0.75 (0.10, 5.54); p=0.7780	0.67 (0.04, 11.94); p=0.7830	-0.08 (-0.70, 0.53); p=0.7896	
	Prior Use of OCA and/or Fibrates						0.5063
	yes	5/ 20 (25.0)	1/ 13 (7.7)	3.25 (0.43, 24.75); p=0.2552	4.00 (0.41, 39.00); p=0.2328	0.17 (-0.07, 0.41); p=0.1553	
	no	9/ 108 (8.3)	3/ 52 (5.8)	1.44 (0.41, 5.11); p=0.5686	1.48 (0.38, 5.73); p=0.5662	0.03 (-0.06, 0.11); p=0.5402	
	Therapy						0.5645
	Monotherapy (SEL)	2/ 8 (25.0)	1/ 4 (25.0)	1.00 (0.13, 8.00); p=1.0000	1.00 (0.06, 15.99); p=1.0000	0.00 (-0.52, 0.52); p=1.0000	
	Combinationtherapy (SEL + UDCA)	12/ 120 (10.0)	3/ 61 (4.9)	2.03 (0.60, 6.94); p=0.2570	2.15 (0.58, 7.92); p=0.2507	0.05 (-0.03, 0.13); p=0.1919	
	Stratification variable: Baseline Pruritus NRS						NE
	< 4	0/ 79 (0.0)	0/ 42 (0.0)	NE	NE	NE	
	>= 4	14/ 49 (28.6)	4/ 23 (17.4)	1.64 (0.61, 4.44); p=0.3280	1.90 (0.55, 6.59); p=0.3118	0.11 (-0.09, 0.31); p=0.2732	
	Stratification variable: Baseline ALP Level						0.5001
	< 350 U/L	8/ 93 (8.6)	3/ 47 (6.4)	1.35 (0.37, 4.85); p=0.6477	1.38 (0.35, 5.46); p=0.6461	0.02 (-0.07, 0.11); p=0.6296	
	>= 350 U/L	6/ 35 (17.1)	1/ 18 (5.6)	3.09 (0.40, 23.71); p=0.2788	3.52 (0.39, 31.74); p=0.2625	0.12 (-0.05, 0.28); p=0.1653	

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of subjects with event; N=Number of patients included in the analysis; CI=Confidence Interval; OR=Odds Ratio; RR=Relative Risk; RD=Risk Difference; NE=Not estimable

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Number and Proportion of subjects with Pruritus NRS improvement of >= 4 points at 6 and 12 months - Subgroup analysis
Intention-to-treat

Timepoint	Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	Seladelpar 10 mg vs. Placebo OR (95% CI); p-Value	Seladelpar 10 mg vs. Placebo RD (95% CI); p-Value	Interaction p-Value
Month 6	Gamma-GT (GGT)						0.5559
	<= 3.2 x ULN	2/ 38 (5.3)	1/ 18 (5.6)	0.95 (0.09, 9.78); p=0.9638	0.94 (0.08, 11.15); p=0.9638	-0.00 (-0.13, 0.12); p=0.9641	
	> 3.2 x ULN	12/ 90 (13.3)	3/ 47 (6.4)	2.09 (0.62, 7.04); p=0.2347	2.26 (0.60, 8.43); p=0.2262	0.07 (-0.03, 0.17); p=0.1692	
	Total Bilirubin I						0.4117
	<= 1 x ULN	11/ 108 (10.2)	3/ 60 (5.0)	2.04 (0.59, 7.02); p=0.2596	2.15 (0.58, 8.05); p=0.2536	0.05 (-0.03, 0.13); p=0.2002	
	> 1 x ULN	3/ 20 (15.0)	1/ 5 (20.0)	0.75 (0.10, 5.77); p=0.7822	0.71 (0.06, 8.70); p=0.7858	-0.05 (-0.43, 0.33); p=0.7985	
	Total Bilirubin II						0.1341
	< 0.6 x ULN	4/ 59 (6.8)	3/ 32 (9.4)	0.72 (0.17, 3.03); p=0.6577	0.70 (0.15, 3.36); p=0.6586	-0.03 (-0.15, 0.09); p=0.6707	
	>= 0.6 x ULN	10/ 69 (14.5)	1/ 33 (3.0)	4.78 (0.64, 35.81); p=0.1276	5.42 (0.66, 44.30); p=0.1146	0.11 (0.01, 0.22); p=0.0270	

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of subjects with event; N=Number of patients included in the analysis; CI=Confidence Interval; OR=Odds Ratio; RR=Relative Risk; RD=Risk Difference; NE=Not estimable

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Number and Proportion of subjects with Pruritus NRS improvement of >= 4 points at 6 and 12 months - Subgroup analysis
Intention-to-treat

Timepoint	Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	Seladelpar 10 mg vs. Placebo OR (95% CI); p-Value	Seladelpar 10 mg vs. Placebo RD (95% CI); p-Value	Interaction p-Value
Month 12	Age at screening						0.0903
	< 65 years	14/ 99 (14.1)	1/ 53 (1.9)	7.49 (1.01, 55.44); p=0.0485	8.56 (1.09, 67.06); p=0.0408	0.12 (0.04, 0.20); p=0.0020	
	>= 65 years	1/ 29 (3.4)	1/ 12 (8.3)	0.41 (0.03, 6.09); p=0.5201	0.39 (0.02, 6.85); p=0.5217	-0.05 (-0.22, 0.12); p=0.5731	
	Age at PBC diagnosis						
	< 50 years	9/ 61 (14.8)	0/ 32 (0.0)				
	>= 50 years	6/ 67 (9.0)	2/ 33 (6.1)				
	Sex						0.9392
	female	14/ 123 (11.4)	2/ 60 (3.3)	3.41 (0.80, 14.54); p=0.0967	3.72 (0.82, 16.95); p=0.0890	0.08 (0.01, 0.15); p=0.0289	
	male	1/ 5 (20.0)	0/ 5 (0.0)	3.00 (0.15, 59.89); p=0.4720	3.67 (0.12, 113.73); p=0.4584	0.20 (-0.15, 0.55); p=0.2636	
	Race						
	white	12/ 114 (10.5)	2/ 56 (3.6)				
	black	1/ 2 (50.0)	0/ 2 (0.0)				
	asian	1/ 7 (14.3)	0/ 4 (0.0)				
	other	1/ 5 (20.0)	0/ 3 (0.0)				
	Region						
	North America	5/ 50 (10.0)	0/ 13 (0.0)				
	Europe	5/ 39 (12.8)	2/ 24 (8.3)				
	Rest-of-World	5/ 39 (12.8)	0/ 28 (0.0)				
	Cirrhosis						0.6416
	yes	1/ 18 (5.6)	0/ 9 (0.0)	1.58 (0.07, 35.32); p=0.7733	1.63 (0.06, 44.01); p=0.7718	0.06 (-0.05, 0.16); p=0.3035	
	no	14/ 110 (12.7)	2/ 56 (3.6)	3.56 (0.84, 15.14); p=0.0850	3.94 (0.86, 17.98); p=0.0769	0.09 (0.01, 0.17); p=0.0231	
	UDCA						0.7975
	UDCA Use	13/ 120 (10.8)	2/ 62 (3.2)	3.36 (0.78, 14.41); p=0.1031	3.64 (0.80, 16.70); p=0.0958	0.08 (0.01, 0.15); p=0.0355	
	UDCA Intolerance	2/ 8 (25.0)	0/ 3 (0.0)	2.22 (0.14, 36.49); p=0.5760	2.69 (0.10, 73.20); p=0.5567	0.25 (-0.05, 0.55); p=0.1025	
	Prior Use of OCA and/or Fibrates						0.7884
	yes	5/ 20 (25.0)	1/ 13 (7.7)	3.25 (0.43, 24.75); p=0.2552	4.00 (0.41, 39.00); p=0.2328	0.17 (-0.07, 0.41); p=0.1553	
	no	10/ 108 (9.3)	1/ 52 (1.9)	4.81 (0.63, 36.62); p=0.1289	5.20 (0.65, 41.79); p=0.1207	0.07 (0.01, 0.14); p=0.0298	
	Therapy						0.9150
	Monotherapy (SEL)	2/ 8 (25.0)	0/ 4 (0.0)	2.78 (0.16, 47.20); p=0.4796	3.46 (0.13, 90.68); p=0.4561	0.25 (-0.05, 0.55); p=0.1025	
	Combinationtherapy (SEL + UDCA)	13/ 120 (10.8)	2/ 61 (3.3)	3.30 (0.77, 14.18); p=0.1078	3.58 (0.78, 16.42); p=0.1003	0.08 (0.00, 0.15); p=0.0379	
	Stratification variable: Baseline Pruritus NRS						NE
	< 4	0/ 79 (0.0)	0/ 42 (0.0)	NE	NE	NE	
	>= 4	15/ 49 (30.6)	2/ 23 (8.7)	3.52 (0.88, 14.13); p=0.0759	4.63 (0.96, 22.32); p=0.0560	0.22 (0.05, 0.39); p=0.0130	
	Stratification variable: Baseline ALP Level						
	< 350 U/L	8/ 93 (8.6)	1/ 47 (2.1)				
	>= 350 U/L	7/ 35 (20.0)	1/ 18 (5.6)				

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of subjects with event; N=Number of patients included in the analysis; CI=Confidence Interval; OR=Odds Ratio; RR=Relative Risk; RD=Risk Difference; NE=Not estimable

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Number and Proportion of subjects with Pruritus NRS improvement of >= 4 points at 6 and 12 months - Subgroup analysis
Intention-to-treat

Timepoint	Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	Seladelpar 10 mg vs. Placebo OR (95% CI); p-Value	Seladelpar 10 mg vs. Placebo RD (95% CI); p-Value	Interaction p-Value
Month 12	Gamma-GT (GGT)						0.9593
	<= 3.2 x ULN	3/ 38 (7.9)	0/ 18 (0.0)	3.41 (0.19, 62.73); p=0.4090	3.65 (0.18, 74.45); p=0.4003	0.08 (-0.01, 0.16); p=0.0711	
	> 3.2 x ULN	12/ 90 (13.3)	2/ 47 (4.3)	3.13 (0.73, 13.42); p=0.1239	3.46 (0.74, 16.17); p=0.1143	0.09 (-0.00, 0.18); p=0.0503	
	Total Bilirubin I						0.7527
	<= 1 x ULN	12/ 108 (11.1)	2/ 60 (3.3)	3.33 (0.77, 14.40); p=0.1068	3.63 (0.78, 16.77); p=0.0994	0.08 (0.00, 0.15); p=0.0412	
	> 1 x ULN	3/ 20 (15.0)	0/ 5 (0.0)	2.00 (0.12, 33.58); p=0.6301	2.20 (0.10, 49.54); p=0.6197	0.15 (-0.01, 0.31); p=0.0603	
	Total Bilirubin II						0.1593
	< 0.6 x ULN	4/ 59 (6.8)	2/ 32 (6.3)	1.08 (0.21, 5.60); p=0.9226	1.09 (0.19, 6.31); p=0.9226	0.01 (-0.10, 0.11); p=0.9217	
	>= 0.6 x ULN	11/ 69 (15.9)	0/ 33 (0.0)	11.17 (0.68, 184.01); p=0.0913	13.17 (0.75, 230.70); p=0.0776	0.16 (0.07, 0.25); p=0.0003	

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of subjects with event; N=Number of patients included in the analysis; CI=Confidence Interval; OR=Odds Ratio; RR=Relative Risk; RD=Risk Difference; NE=Not estimable

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Summary of mean values and change from baseline of Pruritus NRS (weekly averages) by visit
Intention-to-treat

	Seladelpar 10 mg (N=128)				Placebo (N=65)			
	Value at Timepoint		Change from Baseline		Value at Timepoint		Change from Baseline	
Timepoint	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	128	3.03 (2.81)	0	-	65	3.02 (2.96)	0	-
Month 1	127	2.17 (2.26)	127	-0.82 (1.52)	64	2.88 (2.71)	64	-0.12 (1.25)
Month 3	124	1.87 (2.17)	124	-1.11 (1.95)	63	2.47 (2.45)	63	-0.53 (1.59)
Month 6	121	1.62 (1.88)	121	-1.36 (2.07)	61	2.44 (2.35)	61	-0.42 (1.80)
Month 9	108	1.46 (1.98)	108	-1.35 (2.31)	56	2.56 (2.54)	56	-0.46 (1.97)
Month 12	105	1.55 (1.94)	105	-1.48 (2.26)	48	2.21 (2.43)	48	-0.55 (1.81)

N describes number of patients with non-missing value at the respective timepoint.
N=Number of subjects included in the analysis, SD: Standard Deviation; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of change from baseline of Pruritus NRS (weekly averages) by visit
Intention-to-treat

Visit	Seladelpar 10 mg (N=128)		Placebo (N=65)		Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)
	N	LSMean (SE)	N	LSMean (SE)			
Month 1	127	-0.80 (0.12)	64	-0.10 (0.16)	-0.70 (-1.07, -0.33)	0.0003	-0.53 (-0.84, -0.23)
Month 3	127	-1.09 (0.14)	64	-0.52 (0.19)	-0.57 (-1.02, -0.13)	0.0117	-0.37 (-0.67, -0.07)
Month 6	127	-1.33 (0.14)	64	-0.42 (0.19)	-0.90 (-1.35, -0.45)	0.0001	-0.58 (-0.89, -0.28)
Month 9	127	-1.42 (0.17)	64	-0.40 (0.23)	-1.02 (-1.56, -0.47)	0.0003	-0.55 (-0.85, -0.24)
Month 12	127	-1.35 (0.16)	64	-0.52 (0.22)	-0.83 (-1.35, -0.31)	0.0018	-0.47 (-0.78, -0.17)

(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variable (baseline ALP level), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
N=Number of subjects included in the analysis, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of change from baseline of Pruritus NRS (weekly averages) at month 6 and 12 - Subgroup analysis
Intention-to-treat

		Seladelpar 10 mg (N=128)				Placebo (N=65)							
	Subgroup	Baseline		Change from BL		Baseline		Change from BL		Difference of			Interaction
Timepoint	Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value
Month 6	Age at screening												0.4617
	< 65 years	99	3.14 (2.81)	98	-1.46 (0.16)	53	3.07 (2.98)	52	-0.62 (0.21)	-0.84 (-1.34, -0.34)	0.0011	-0.55 (-0.89, -0.20)	
	>= 65 years	29	2.68 (2.82)	29	-0.86 (0.28)	12	2.80 (2.99)	12	0.39 (0.43)	-1.25 (-2.25, -0.25)	0.0154	-0.82 (-1.52, -0.12)	
	Age at PBC diagnosis												0.1905
	< 50 years	61	3.27 (2.96)	60	-1.52 (0.19)	32	3.03 (2.80)	31	-0.28 (0.26)	-1.23 (-1.86, -0.60)	0.0002	-0.84 (-1.29, -0.39)	
	>= 50 years	67	2.82 (2.66)	67	-1.19 (0.21)	33	3.01 (3.15)	33	-0.55 (0.28)	-0.63 (-1.29, 0.02)	0.0562	-0.38 (-0.80, 0.04)	
	Sex												NE
	female	123	3.05 (2.79)	122	-1.35 (0.14)	60	3.09 (3.00)	59	-0.48 (0.20)	-0.87 (-1.34, -0.40)	0.0004	-0.55 (-0.87, -0.24)	
	male	5	2.51 (3.37)	5	NE	5	2.17 (2.53)	5	NE	NE		NE	
	Race												
	white	114	3.00 (2.81)	114		56	3.08 (2.95)	55					
	black	2	5.22 (2.19)	2		2	1.41 (1.99)	2					
	asian	7	1.92 (1.95)	7		4	2.00 (3.03)	4					
	other	5	4.49 (3.61)	4		3	4.37 (4.13)	3					
	Region												0.5035
	North America	50	2.89 (2.69)	50	-1.26 (0.22)	13	3.07 (2.93)	13	-0.79 (0.41)	-0.48 (-1.36, 0.40)	0.2818	-0.30 (-0.92, 0.31)	
	Europe	39	3.03 (2.70)	39	-1.48 (0.27)	24	3.52 (2.85)	23	-0.50 (0.35)	-0.99 (-1.86, -0.11)	0.0277	-0.58 (-1.10, -0.05)	
	Rest-of-World	39	3.22 (3.10)	38	-1.33 (0.24)	28	2.57 (3.10)	28	-0.20 (0.27)	-1.13 (-1.83, -0.42)	0.0021	-0.76 (-1.27, -0.26)	
	Cirrhosis												0.5467
	yes	18	3.57 (2.93)	18	-1.44 (0.40)	9	3.80 (2.89)	9	-0.91 (0.56)	-0.53 (-1.92, 0.86)	0.4408	-0.30 (-1.11, 0.50)	
	no	110	2.94 (2.79)	109	-1.29 (0.15)	56	2.89 (2.98)	55	-0.33 (0.20)	-0.96 (-1.43, -0.49)	<.0001	-0.63 (-0.96, -0.30)	
	UDCA												NE
	UDCA Use	120	2.99 (2.78)	119	-1.31 (0.15)	62	3.02 (2.91)	61	-0.35 (0.20)	-0.96 (-1.42, -0.49)	<.0001	-0.61 (-0.92, -0.29)	
	UDCA Intolerance	8	3.72 (3.29)	8	NE	3	3.10 (4.73)	3	NE	NE		NE	
	Prior Use of OCA and/or Fibrates												0.3835
	yes	20	4.23 (3.23)	19	-1.90 (0.48)	13	3.94 (3.14)	12	-0.41 (0.59)	-1.49 (-3.06, 0.09)	0.0629	-0.70 (-1.44, 0.05)	
	no	108	2.81 (2.68)	108	-1.23 (0.14)	52	2.79 (2.90)	52	-0.44 (0.20)	-0.79 (-1.26, -0.33)	0.0010	-0.53 (-0.87, -0.20)	
	Therapy												0.4882
	Monotherapy (SEL)	8	3.72 (3.29)	8	-1.55 (0.54)	4	2.47 (4.06)	4	-1.29 (0.80)	-0.27 (-2.67, 2.13)	0.7909	-0.16 (-1.36, 1.04)	
	Combinationtherapy (SEL + UDCA)	120	2.99 (2.78)	119	-1.32 (0.15)	61	3.06 (2.92)	60	-0.36 (0.20)	-0.96 (-1.43, -0.49)	<.0001	-0.60 (-0.92, -0.29)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variable (baseline ALP level), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of change from baseline of Pruritus NRS (weekly averages) at month 6 and 12 - Subgroup analysis
Intention-to-treat

		Seladelpar 10 mg (N=128)				Placebo (N=65)							
		Baseline		Change from BL		Baseline		Change from BL					
Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
Month 6	Stratification variable: Baseline Pruritus NRS												0.1519
	< 4	79	1.11 (1.34)	79	-0.27 (0.13)	42	1.04 (1.12)	42	0.36 (0.17)	-0.63 (-1.02, -0.23)	0.0021	-0.55 (-0.93, -0.17)	
	>= 4	49	6.13 (1.42)	48	-3.15 (0.28)	23	6.63 (1.44)	22	-1.74 (0.42)	-1.41 (-2.42, -0.40)	0.0072	-0.71 (-1.23, -0.19)	
	Stratification variable: Baseline ALP Level												0.7227
	< 350 U/L	93	2.54 (2.59)	93	-1.14 (0.15)	47	2.71 (2.87)	46	-0.30 (0.21)	-0.85 (-1.36, -0.34)	0.0013	-0.59 (-0.95, -0.23)	
	>= 350 U/L	35	4.35 (2.96)	34	-1.82 (0.29)	18	3.82 (3.13)	18	-0.78 (0.40)	-1.04 (-2.03, -0.06)	0.0385	-0.61 (-1.20, -0.03)	
	Gamma-GT (GGT)												0.5490
	<= 3 x ULN	33	2.62 (2.70)	33	-0.60 (0.31)	14	1.54 (1.68)	13	0.62 (0.42)	-1.22 (-2.13, -0.31)	0.0096	-0.71 (-1.37, -0.05)	
	> 3 x ULN	95	3.17 (2.84)	94	-1.51 (0.16)	51	3.43 (3.11)	51	-0.60 (0.22)	-0.91 (-1.44, -0.38)	0.0009	-0.58 (-0.93, -0.23)	
	Total Bilirubin I												0.3014
	<= 1 x ULN	108	2.93 (2.77)	107	-1.30 (0.15)	60	2.97 (2.91)	59	-0.31 (0.19)	-1.00 (-1.45, -0.54)	<.0001	-0.65 (-0.98, -0.33)	
	> 1 x ULN	20	3.59 (2.99)	20	-1.36 (0.56)	5	3.61 (3.87)	5	-1.80 (1.25)	0.44 (-2.88, 3.75)	0.7595	0.17 (-0.82, 1.15)	
	Total Bilirubin II												0.4101
	< 0.6 x ULN	59	2.32 (2.48)	58	-0.92 (0.20)	32	2.99 (2.91)	31	-0.20 (0.26)	-0.72 (-1.32, -0.12)	0.0194	-0.49 (-0.93, -0.05)	
	>= 0.6 x ULN	69	3.64 (2.94)	69	-1.57 (0.20)	33	3.05 (3.05)	33	-0.47 (0.28)	-1.10 (-1.78, -0.42)	0.0018	-0.66 (-1.09, -0.24)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variable (baseline ALP level), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
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p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of change from baseline of Pruritus NRS (weekly averages) at month 6 and 12 - Subgroup analysis
Intention-to-treat

		Seladelpar 10 mg (N=128)				Placebo (N=65)							
	Subgroup	Baseline		Change from BL		Baseline		Change from BL		Difference of			Interaction
Timepoint	Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value
Month 12	Age at screening												0.4898
	< 65 years	99	3.14 (2.81)	98	-1.46 (0.18)	53	3.07 (2.98)	52	-0.69 (0.24)	-0.78 (-1.36, -0.19)	0.0096	-0.44 (-0.78, -0.10)	
	>= 65 years	29	2.68 (2.82)	29	-0.96 (0.31)	12	2.80 (2.99)	12	0.24 (0.48)	-1.21 (-2.32, -0.09)	0.0352	-0.71 (-1.40, -0.02)	
	Age at PBC diagnosis												0.5763
	< 50 years	61	3.27 (2.96)	60	-1.59 (0.21)	32	3.03 (2.80)	31	-0.59 (0.29)	-1.00 (-1.71, -0.30)	0.0057	-0.62 (-1.06, -0.18)	
	>= 50 years	67	2.82 (2.66)	67	-1.17 (0.24)	33	3.01 (3.15)	33	-0.45 (0.32)	-0.71 (-1.48, 0.06)	0.0685	-0.37 (-0.79, 0.05)	
	Sex												NE
	female	123	3.05 (2.79)	122	-1.39 (0.16)	60	3.09 (3.00)	59	-0.58 (0.23)	-0.81 (-1.34, -0.27)	0.0033	-0.46 (-0.77, -0.14)	
	male	5	2.51 (3.37)	5	NE	5	2.17 (2.53)	5	NE	NE		NE	
	Race												
	white	114	3.00 (2.81)	114		56	3.08 (2.95)	55					
	black	2	5.22 (2.19)	2		2	1.41 (1.99)	2					
	asian	7	1.92 (1.95)	7		4	2.00 (3.03)	4					
	other	5	4.49 (3.61)	4		3	4.37 (4.13)	3					
	Region												0.2411
	North America	50	2.89 (2.69)	50	-1.14 (0.28)	13	3.07 (2.93)	13	-1.16 (0.63)	0.02 (-1.33, 1.38)	0.9738	0.01 (-0.60, 0.62)	
	Europe	39	3.03 (2.70)	39	-1.53 (0.27)	24	3.52 (2.85)	23	-0.66 (0.35)	-0.87 (-1.74, -0.00)	0.0489	-0.51 (-1.03, 0.01)	
	Rest-of-World	39	3.22 (3.10)	38	-1.50 (0.26)	28	2.57 (3.10)	28	-0.21 (0.31)	-1.29 (-2.08, -0.50)	0.0018	-0.79 (-1.29, -0.28)	
	Cirrhosis												0.9704
	yes	18	3.57 (2.93)	18	-1.53 (0.34)	9	3.80 (2.89)	9	-0.69 (0.50)	-0.84 (-2.08, 0.39)	0.1713	-0.55 (-1.37, 0.26)	
	no	110	2.94 (2.79)	109	-1.30 (0.17)	56	2.89 (2.98)	55	-0.48 (0.24)	-0.82 (-1.39, -0.25)	0.0051	-0.45 (-0.78, -0.13)	
	UDCA												NE
	UDCA Use	120	2.99 (2.78)	119	-1.37 (0.16)	62	3.02 (2.91)	61	-0.47 (0.22)	-0.90 (-1.42, -0.37)	0.0009	-0.51 (-0.83, -0.20)	
	UDCA Intolerance	8	3.72 (3.29)	8	NE	3	3.10 (4.73)	3	NE	NE		NE	
	Prior Use of OCA and/or Fibrates												0.7289
	yes	20	4.23 (3.23)	19	-2.10 (0.49)	13	3.94 (3.14)	12	-0.99 (0.59)	-1.11 (-2.69, 0.48)	0.1606	-0.52 (-1.25, 0.22)	
	no	108	2.81 (2.68)	108	-1.23 (0.16)	52	2.79 (2.90)	52	-0.40 (0.24)	-0.83 (-1.38, -0.27)	0.0037	-0.48 (-0.82, -0.14)	
	Therapy												0.4854
	Monotherapy (SEL)	8	3.72 (3.29)	8	-1.16 (0.82)	4	2.47 (4.06)	4	-1.29 (1.20)	0.14 (-3.24, 3.52)	0.9270	0.05 (-1.15, 1.25)	
	Combinationtherapy (SEL + UDCA)	120	2.99 (2.78)	119	-1.38 (0.16)	61	3.06 (2.92)	60	-0.48 (0.22)	-0.89 (-1.42, -0.36)	0.0010	-0.51 (-0.82, -0.19)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variable (baseline ALP level), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of change from baseline of Pruritus NRS (weekly averages) at month 6 and 12 - Subgroup analysis
Intention-to-treat

		Seladelpar 10 mg (N=128)				Placebo (N=65)							
		Baseline		Change from BL		Baseline		Change from BL					
Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
Month 12	Stratification variable: Baseline Pruritus NRS												0.0256
	< 4	79	1.11 (1.34)	79	-0.24 (0.15)	42	1.04 (1.12)	42	0.10 (0.20)	-0.33 (-0.79, 0.13)	0.1527	-0.26 (-0.63, 0.12)	
	>= 4	49	6.13 (1.42)	48	-3.27 (0.33)	23	6.63 (1.44)	22	-1.50 (0.50)	-1.77 (-2.97, -0.57)	0.0045	-0.76 (-1.28, -0.24)	
	Stratification variable: Baseline ALP Level												0.2398
	< 350 U/L	93	2.54 (2.59)	93	-1.14 (0.17)	47	2.71 (2.87)	46	-0.55 (0.25)	-0.60 (-1.20, 0.01)	0.0537	-0.35 (-0.71, 0.00)	
	>= 350 U/L	35	4.35 (2.96)	34	-1.92 (0.31)	18	3.82 (3.13)	18	-0.60 (0.43)	-1.31 (-2.38, -0.25)	0.0165	-0.71 (-1.30, -0.13)	
	Gamma-GT (GGT)												0.7060
	<= 3 x ULN	33	2.62 (2.70)	33	-0.81 (0.30)	14	1.54 (1.68)	13	-0.08 (0.41)	-0.73 (-1.61, 0.16)	0.1037	-0.43 (-1.08, 0.22)	
	> 3 x ULN	95	3.17 (2.84)	94	-1.47 (0.19)	51	3.43 (3.11)	51	-0.53 (0.27)	-0.93 (-1.58, -0.29)	0.0051	-0.49 (-0.84, -0.14)	
	Total Bilirubin I												0.1978
	<= 1 x ULN	108	2.93 (2.77)	107	-1.26 (0.18)	60	2.97 (2.91)	59	-0.52 (0.23)	-0.74 (-1.30, -0.19)	0.0091	-0.41 (-0.73, -0.09)	
	> 1 x ULN	20	3.59 (2.99)	20	-1.64 (0.36)	5	3.61 (3.87)	5	0.29 (0.80)	-1.93 (-4.09, 0.23)	0.0713	-1.13 (-2.17, -0.09)	
	Total Bilirubin II												0.0120
	< 0.6 x ULN	59	2.32 (2.48)	58	-0.89 (0.21)	32	2.99 (2.91)	31	-0.70 (0.28)	-0.19 (-0.86, 0.48)	0.5744	-0.12 (-0.55, 0.32)	
	>= 0.6 x ULN	69	3.64 (2.94)	69	-1.60 (0.22)	33	3.05 (3.05)	33	-0.13 (0.32)	-1.47 (-2.24, -0.71)	0.0002	-0.79 (-1.22, -0.36)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variable (baseline ALP level), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
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p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Completion rates of 5-D Itch Scale by visit
Intention-to-treat

Score	Timepoint	Seladelpar 10 mg (N=128) n/ N	Seladelpar 10 mg (N=128) Completion	Placebo (N=65) n/ N	Placebo (N=65) Completion
ITCH5D-Duration	Baseline	128/ 128	100.0%	65/ 65	100.0%
	Month 1	127/ 128	99.22%	64/ 65	98.46%
	Month 3	126/ 128	98.44%	64/ 65	98.46%
	Month 6	123/ 128	96.09%	61/ 65	93.85%
	Month 9	115/ 128	89.84%	57/ 65	87.69%
	Month 12	96/ 128	75.00%	46/ 65	70.77%

n describes number of patients with non-missing value at the respective timepoint.
N defines number of patients still alive at beginning of respective visit window.

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RESPONSE - Seladelpar 10 mg vs Placebo
Completion rates of 5-D Itch Scale by visit
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		Seladelpar 10 mg (N=128)			Placebo (N=65)		
Score	Timepoint	n/	N	Completion	n/	N	Completion
ITCH5D-Degree	Baseline	128/	128	100.0%	65/	65	100.0%
	Month 1	127/	128	99.22%	64/	65	98.46%
	Month 3	126/	128	98.44%	64/	65	98.46%
	Month 6	123/	128	96.09%	61/	65	93.85%
	Month 9	115/	128	89.84%	57/	65	87.69%
	Month 12	96/	128	75.00%	46/	65	70.77%

n describes number of patients with non-missing value at the respective timepoint.
N defines number of patients still alive at beginning of respective visit window.

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		Seladelpar 10 mg (N=128)			Placebo (N=65)		
Score	Timepoint	n/	N	Completion	n/	N	Completion
ITCH5D-Direction	Baseline	128/	128	100.0%	65/	65	100.0%
	Month 1	127/	128	99.22%	64/	65	98.46%
	Month 3	126/	128	98.44%	64/	65	98.46%
	Month 6	123/	128	96.09%	61/	65	93.85%
	Month 9	115/	128	89.84%	57/	65	87.69%
	Month 12	96/	128	75.00%	46/	65	70.77%

n describes number of patients with non-missing value at the respective timepoint.
N defines number of patients still alive at beginning of respective visit window.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Completion rates of 5-D Itch Scale by visit
Intention-to-treat

Score	Timepoint	Seladelpar 10 mg (N=128) n/ N	Seladelpar 10 mg (N=128) Completion	Placebo (N=65) n/ N	Placebo (N=65) Completion
ITCH5D-Distribution Total	Baseline	128/ 128	100.0%	65/ 65	100.0%
	Month 1	127/ 128	99.22%	64/ 65	98.46%
	Month 3	126/ 128	98.44%	64/ 65	98.46%
	Month 6	123/ 128	96.09%	61/ 65	93.85%
	Month 9	115/ 128	89.84%	57/ 65	87.69%
	Month 12	96/ 128	75.00%	46/ 65	70.77%

n describes number of patients with non-missing value at the respective timepoint.
N defines number of patients still alive at beginning of respective visit window.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Completion rates of 5-D Itch Scale by visit
Intention-to-treat

Score	Timepoint	Seladelpar 10 mg (N=128) n/ N	Seladelpar 10 mg (N=128) Completion	Placebo (N=65) n/ N	Placebo (N=65) Completion
ITCH5D-Highest Disability	Baseline	128/ 128	100.0%	65/ 65	100.0%
	Month 1	127/ 128	99.22%	64/ 65	98.46%
	Month 3	126/ 128	98.44%	64/ 65	98.46%
	Month 6	123/ 128	96.09%	61/ 65	93.85%
	Month 9	115/ 128	89.84%	57/ 65	87.69%
	Month 12	96/ 128	75.00%	46/ 65	70.77%

n describes number of patients with non-missing value at the respective timepoint.
N defines number of patients still alive at beginning of respective visit window.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Completion rates of 5-D Itch Scale by visit
Intention-to-treat

Score	Timepoint	Seladelpar 10 mg (N=128) n/ N	Seladelpar 10 mg (N=128) Completion	Placebo (N=65) n/ N	Placebo (N=65) Completion
ITCH5D-Modified Total Score	Baseline	128/ 128	100.0%	65/ 65	100.0%
	Month 1	127/ 128	99.22%	64/ 65	98.46%
	Month 3	126/ 128	98.44%	64/ 65	98.46%
	Month 6	123/ 128	96.09%	61/ 65	93.85%
	Month 9	115/ 128	89.84%	57/ 65	87.69%
	Month 12	96/ 128	75.00%	46/ 65	70.77%

n describes number of patients with non-missing value at the respective timepoint.
N defines number of patients still alive at beginning of respective visit window.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Completion rates of 5-D Itch Scale by visit
Intention-to-treat

Score	Timepoint	Seladelpar 10 mg (N=128) n/ N	Seladelpar 10 mg (N=128) Completion	Placebo (N=65) n/ N	Placebo (N=65) Completion
ITCH5D-Total Score	Baseline	128/ 128	100.0%	65/ 65	100.0%
	Month 1	127/ 128	99.22%	64/ 65	98.46%
	Month 3	126/ 128	98.44%	64/ 65	98.46%
	Month 6	123/ 128	96.09%	61/ 65	93.85%
	Month 9	115/ 128	89.84%	57/ 65	87.69%
	Month 12	96/ 128	75.00%	46/ 65	70.77%

n describes number of patients with non-missing value at the respective timepoint.
N defines number of patients still alive at beginning of respective visit window.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Summary of mean values and change from baseline of 5-D Itch Scale by visit
Intention-to-treat

		Seladelpar 10 mg (N=128)				Placebo (N=65)			
		Value at Timepoint		Change from Baseline		Value at Timepoint		Change from Baseline	
Score	Timepoint	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
ITCH5D-Duration	Baseline	128	1.59 (1.11)	128	0.00 (0.00)	65	1.56 (1.08)	65	0.00 (0.00)
	Month 1	127	1.38 (0.85)	127	-0.22 (0.85)	64	1.44 (0.89)	64	-0.13 (0.90)
	Month 3	126	1.37 (0.87)	126	-0.23 (0.96)	64	1.52 (1.07)	64	-0.05 (1.26)
	Month 6	123	1.24 (0.75)	123	-0.33 (0.89)	61	1.38 (0.78)	61	-0.13 (1.08)
	Month 9	115	1.25 (0.88)	115	-0.30 (0.95)	57	1.33 (0.66)	57	-0.19 (0.90)
	Month 12	96	1.16 (0.59)	96	-0.34 (0.89)	46	1.54 (0.98)	46	-0.02 (1.18)

N describes number of patients with non-missing value at the respective timepoint.
N=Number of subjects included in the analysis, SD: Standard Deviation; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Summary of mean values and change from baseline of 5-D Itch Scale by visit
Intention-to-treat

		Seladelpar 10 mg (N=128)				Placebo (N=65)			
		Value at Timepoint		Change from Baseline		Value at Timepoint		Change from Baseline	
Score	Timepoint	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
ITCH5D-Degree	Baseline	128	2.26 (1.04)	128	0.00 (0.00)	65	2.24 (0.99)	65	0.00 (0.00)
	Month 1	127	2.09 (0.88)	127	-0.16 (0.62)	64	2.25 (1.05)	64	0.04 (0.60)
	Month 3	126	2.06 (0.87)	126	-0.20 (0.87)	64	2.19 (1.02)	64	-0.03 (0.75)
	Month 6	123	1.83 (0.80)	123	-0.41 (0.83)	61	2.13 (0.92)	61	-0.04 (0.78)
	Month 9	115	1.69 (0.77)	115	-0.53 (0.89)	57	2.14 (0.95)	57	-0.06 (0.75)
	Month 12	96	1.71 (0.81)	96	-0.49 (0.90)	46	2.04 (0.84)	46	-0.09 (0.77)

N describes number of patients with non-missing value at the respective timepoint.
N=Number of subjects included in the analysis, SD: Standard Deviation; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Summary of mean values and change from baseline of 5-D Itch Scale by visit
Intention-to-treat

		Seladelpar 10 mg (N=128)				Placebo (N=65)			
		Value at Timepoint		Change from Baseline		Value at Timepoint		Change from Baseline	
Score	Timepoint	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
ITCH5D-Direction	Baseline	128	3.35 (1.09)	128	0.00 (0.00)	65	3.13 (1.16)	65	0.00 (0.00)
	Month 1	127	2.98 (1.20)	127	-0.36 (1.16)	64	3.19 (1.07)	64	0.06 (1.15)
	Month 3	126	2.83 (1.23)	126	-0.52 (1.46)	64	3.05 (1.19)	64	-0.08 (1.54)
	Month 6	123	2.73 (1.27)	123	-0.63 (1.39)	61	2.93 (1.28)	61	-0.18 (1.33)
	Month 9	115	2.56 (1.30)	115	-0.80 (1.56)	57	2.61 (1.22)	57	-0.52 (1.27)
	Month 12	96	2.64 (1.35)	96	-0.68 (1.54)	46	3.04 (1.25)	46	-0.03 (1.43)

N describes number of patients with non-missing value at the respective timepoint.
N=Number of subjects included in the analysis, SD: Standard Deviation; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Summary of mean values and change from baseline of 5-D Itch Scale by visit
Intention-to-treat

		Seladelpar 10 mg (N=128)				Placebo (N=65)			
		Value at Timepoint		Change from Baseline		Value at Timepoint		Change from Baseline	
Score	Timepoint	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
ITCH5D-Distribution Total	Baseline	128	2.16 (1.29)	128	0.00 (0.00)	65	2.08 (1.20)	65	0.00 (0.00)
	Month 1	127	2.09 (1.24)	127	-0.07 (0.74)	64	2.08 (1.26)	64	0.03 (0.59)
	Month 3	126	2.04 (1.30)	126	-0.12 (0.96)	64	2.08 (1.31)	64	0.03 (0.78)
	Month 6	123	1.90 (1.24)	123	-0.24 (1.02)	61	2.13 (1.26)	61	0.18 (0.83)
	Month 9	115	1.86 (1.29)	115	-0.26 (1.08)	57	2.00 (1.31)	57	0.04 (0.87)
	Month 12	96	1.76 (1.19)	96	-0.31 (1.02)	46	1.98 (1.22)	46	0.04 (0.67)

N describes number of patients with non-missing value at the respective timepoint.
N=Number of subjects included in the analysis, SD: Standard Deviation; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Summary of mean values and change from baseline of 5-D Itch Scale by visit
Intention-to-treat

		Seladelpar 10 mg (N=128)				Placebo (N=65)			
		Value at Timepoint		Change from Baseline		Value at Timepoint		Change from Baseline	
Score	Timepoint	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
ITCH5D-Highest Disability	Baseline	128	2.27 (1.37)	128	0.00 (0.00)	65	2.22 (1.24)	65	0.00 (0.00)
	Month 1	127	1.97 (1.19)	127	-0.31 (0.76)	64	2.16 (1.26)	64	-0.03 (0.80)
	Month 3	126	1.97 (1.19)	126	-0.32 (1.27)	64	1.97 (1.15)	64	-0.22 (0.84)
	Month 6	123	1.69 (0.97)	123	-0.57 (1.08)	61	2.07 (1.36)	61	-0.07 (1.04)
	Month 9	115	1.61 (0.97)	115	-0.62 (1.12)	57	2.04 (1.28)	57	-0.14 (0.85)
	Month 12	96	1.57 (0.96)	96	-0.63 (1.16)	46	2.09 (1.35)	46	-0.07 (1.05)

N describes number of patients with non-missing value at the respective timepoint.
N=Number of subjects included in the analysis, SD: Standard Deviation; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Summary of mean values and change from baseline of 5-D Itch Scale by visit
Intention-to-treat

		Seladelpar 10 mg (N=128)				Placebo (N=65)			
		Value at Timepoint		Change from Baseline		Value at Timepoint		Change from Baseline	
Score	Timepoint	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
ITCH5D-Modified Total Score	Baseline	128	8.28 (4.24)	128	0.00 (0.00)	65	8.10 (3.96)	65	0.00 (0.00)
	Month 1	127	7.54 (3.50)	127	-0.77 (2.13)	64	7.92 (3.75)	64	-0.09 (1.79)
	Month 3	126	7.44 (3.50)	126	-0.86 (3.22)	64	7.75 (3.87)	64	-0.26 (2.59)
	Month 6	123	6.67 (3.16)	123	-1.55 (2.96)	61	7.70 (3.63)	61	-0.06 (2.77)
	Month 9	115	6.41 (3.20)	115	-1.71 (3.17)	57	7.51 (3.67)	57	-0.36 (2.52)
	Month 12	96	6.20 (2.95)	96	-1.77 (3.15)	46	7.65 (3.70)	46	-0.13 (2.65)

N describes number of patients with non-missing value at the respective timepoint.
N=Number of subjects included in the analysis, SD: Standard Deviation; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Summary of mean values and change from baseline of 5-D Itch Scale by visit
Intention-to-treat

		Seladelpar 10 mg (N=128)				Placebo (N=65)			
		Value at Timepoint		Change from Baseline		Value at Timepoint		Change from Baseline	
Score	Timepoint	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
ITCH5D-Total Score	Baseline	128	11.63 (4.85)	128	0.00 (0.00)	65	11.23 (4.65)	65	0.00 (0.00)
	Month 1	127	10.51 (3.98)	127	-1.13 (2.89)	64	11.11 (4.10)	64	-0.03 (2.26)
	Month 3	126	10.26 (4.07)	126	-1.38 (4.26)	64	10.80 (4.44)	64	-0.34 (3.42)
	Month 6	123	9.40 (3.83)	123	-2.18 (3.87)	61	10.64 (4.39)	61	-0.24 (3.49)
	Month 9	115	8.97 (3.83)	115	-2.50 (4.24)	57	10.12 (4.39)	57	-0.88 (3.26)
	Month 12	96	8.83 (3.68)	96	-2.45 (4.16)	46	10.70 (4.38)	46	-0.16 (3.68)

N describes number of patients with non-missing value at the respective timepoint.
N=Number of subjects included in the analysis, SD: Standard Deviation; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of change from baseline of 5-D Itch Scale by visit
Intention-to-treat

		Seladelpar 10 mg (N=128)		Placebo (N=65)		Difference of		
Score	Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)
ITCH5D-Duration	Month 1	128	-0.16 (0.06)	64	-0.08 (0.09)	-0.08 (-0.28, 0.12)	0.4390	-0.11 (-0.41, 0.19)
	Month 3	128	-0.18 (0.08)	64	-0.01 (0.11)	-0.17 (-0.42, 0.08)	0.1777	-0.20 (-0.50, 0.10)
	Month 6	128	-0.28 (0.06)	64	-0.10 (0.09)	-0.18 (-0.39, 0.02)	0.0731	-0.26 (-0.56, 0.04)
	Month 9	128	-0.25 (0.07)	64	-0.15 (0.09)	-0.10 (-0.32, 0.12)	0.3575	-0.13 (-0.44, 0.17)
	Month 12	128	-0.32 (0.07)	64	0.08 (0.10)	-0.40 (-0.63, -0.16)	0.0011	-0.49 (-0.79, -0.19)

(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
N=Number of subjects included in the analysis, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of change from baseline of 5-D Itch Scale by visit
Intention-to-treat

Score	Visit	Seladelpar 10 mg (N=128) N	Seladelpar 10 mg (N=128) LSMean (SE)	Placebo (N=65) N	Placebo (N=65) LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)
ITCH5D-Degree	Month 1	128	-0.14 (0.05)	64	0.05 (0.07)	-0.19 (-0.36, -0.03)	0.0233	-0.32 (-0.62, -0.02)
	Month 3	128	-0.17 (0.07)	64	-0.01 (0.09)	-0.16 (-0.37, 0.06)	0.1469	-0.21 (-0.51, 0.09)
	Month 6	128	-0.38 (0.06)	64	-0.02 (0.09)	-0.35 (-0.56, -0.15)	0.0008	-0.49 (-0.80, -0.19)
	Month 9	128	-0.47 (0.07)	64	-0.04 (0.09)	-0.43 (-0.65, -0.22)	0.0001	-0.57 (-0.87, -0.26)
	Month 12	128	-0.42 (0.07)	64	-0.05 (0.10)	-0.38 (-0.61, -0.15)	0.0016	-0.47 (-0.77, -0.16)

(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
N=Number of subjects included in the analysis, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of change from baseline of 5-D Itch Scale by visit
Intention-to-treat

		Seladelpar 10 mg (N=128)		Placebo (N=65)		Difference of		
Score	Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)
ITCH5D-Direction	Month 1	128	-0.36 (0.09)	64	-0.07 (0.13)	-0.29 (-0.60, 0.01)	0.0599	-0.27 (-0.58, 0.03)
	Month 3	128	-0.51 (0.11)	64	-0.21 (0.15)	-0.30 (-0.66, 0.06)	0.1007	-0.24 (-0.54, 0.06)
	Month 6	128	-0.62 (0.11)	64	-0.31 (0.15)	-0.31 (-0.68, 0.06)	0.0981	-0.25 (-0.55, 0.06)
	Month 9	128	-0.77 (0.12)	64	-0.61 (0.16)	-0.16 (-0.54, 0.23)	0.4273	-0.12 (-0.42, 0.18)
	Month 12	128	-0.64 (0.13)	64	-0.17 (0.18)	-0.47 (-0.90, -0.04)	0.0340	-0.32 (-0.62, -0.02)

(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
N=Number of subjects included in the analysis, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of change from baseline of 5-D Itch Scale by visit
Intention-to-treat

Score	Visit	Seladelpar 10 mg (N=128) N	Seladelpar 10 mg (N=128) LSMean (SE)	Placebo (N=65) N	Placebo (N=65) LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)
ITCH5D-Distribution Total	Month 1	128	-0.01 (0.07)	64	0.07 (0.09)	-0.08 (-0.28, 0.12)	0.4377	-0.11 (-0.41, 0.19)
	Month 3	128	-0.06 (0.08)	64	0.07 (0.11)	-0.13 (-0.39, 0.13)	0.3107	-0.15 (-0.45, 0.15)
	Month 6	128	-0.18 (0.08)	64	0.23 (0.12)	-0.41 (-0.68, -0.14)	0.0034	-0.43 (-0.73, -0.13)
	Month 9	128	-0.18 (0.09)	64	0.07 (0.13)	-0.25 (-0.55, 0.04)	0.0910	-0.25 (-0.55, 0.05)
	Month 12	128	-0.25 (0.09)	64	0.14 (0.12)	-0.38 (-0.67, -0.10)	0.0085	-0.39 (-0.69, -0.09)

(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
N=Number of subjects included in the analysis, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of change from baseline of 5-D Itch Scale by visit
Intention-to-treat

		Seladelpar 10 mg (N=128)		Placebo (N=65)		Difference of		
Score	Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)
ITCH5D-Highest Disability	Month 1	128	-0.26 (0.07)	64	-0.01 (0.09)	-0.25 (-0.47, -0.04)	0.0221	-0.33 (-0.63, -0.03)
	Month 3	128	-0.26 (0.09)	64	-0.20 (0.12)	-0.06 (-0.35, 0.23)	0.6612	-0.06 (-0.36, 0.24)
	Month 6	128	-0.52 (0.08)	64	-0.05 (0.11)	-0.47 (-0.73, -0.20)	0.0006	-0.50 (-0.81, -0.20)
	Month 9	128	-0.57 (0.08)	64	-0.12 (0.11)	-0.45 (-0.71, -0.19)	0.0009	-0.49 (-0.80, -0.19)
	Month 12	128	-0.55 (0.09)	64	0.05 (0.13)	-0.60 (-0.91, -0.29)	0.0002	-0.57 (-0.87, -0.26)

(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
N=Number of subjects included in the analysis, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of change from baseline of 5-D Itch Scale by visit
Intention-to-treat

		Seladelpar 10 mg (N=128)		Placebo (N=65)		Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)
Score	Visit	N	LSMean (SE)	N	LSMean (SE)			
ITCH5D-Modified Total Score	Month 1	128	-0.62 (0.17)	64	-0.02 (0.23)	-0.60 (-1.13, -0.07)	0.0269	-0.31 (-0.61, -0.01)
	Month 3	128	-0.71 (0.24)	64	-0.20 (0.33)	-0.52 (-1.30, 0.26)	0.1898	-0.19 (-0.49, 0.11)
	Month 6	128	-1.40 (0.23)	64	0.01 (0.31)	-1.41 (-2.14, -0.68)	0.0002	-0.55 (-0.86, -0.25)
	Month 9	128	-1.52 (0.24)	64	-0.28 (0.33)	-1.23 (-2.00, -0.47)	0.0018	-0.46 (-0.76, -0.16)
	Month 12	128	-1.59 (0.25)	64	0.19 (0.35)	-1.79 (-2.60, -0.97)	<.0001	-0.63 (-0.94, -0.33)

(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
N=Number of subjects included in the analysis, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of change from baseline of 5-D Itch Scale by visit
Intention-to-treat

		Seladelpar 10 mg (N=128)		Placebo (N=65)		Difference of		
Score	Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)
ITCH5D-Total Score	Month 1	128	-1.00 (0.23)	64	-0.07 (0.30)	-0.93 (-1.62, -0.24)	0.0086	-0.37 (-0.67, -0.07)
	Month 3	128	-1.24 (0.31)	64	-0.38 (0.43)	-0.86 (-1.87, 0.15)	0.0942	-0.24 (-0.55, 0.06)
	Month 6	128	-2.04 (0.30)	64	-0.27 (0.41)	-1.76 (-2.72, -0.81)	0.0003	-0.53 (-0.83, -0.22)
	Month 9	128	-2.30 (0.31)	64	-0.87 (0.43)	-1.43 (-2.44, -0.42)	0.0056	-0.41 (-0.71, -0.11)
	Month 12	128	-2.26 (0.33)	64	0.05 (0.46)	-2.31 (-3.40, -1.23)	<.0001	-0.62 (-0.93, -0.31)

(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
N=Number of subjects included in the analysis, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of change from baseline of 5-D Itch Scale at month 6 and 12 - Subgroup analysis
Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
			Baseline		Change from BL		Baseline		Change from BL					
Score	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
ITCH5D-Duration	Month 6	Age at screening												0.8680
		< 65 years	99	1.62 (1.11)	99	-0.31 (0.07)	53	1.63 (1.16)	52	-0.11 (0.10)	-0.20 (-0.44, 0.04)	0.1055	-0.27 (-0.60, 0.07)	
		>= 65 years	29	1.52 (1.13)	29	-0.23 (0.11)	12	1.29 (0.58)	12	-0.07 (0.17)	-0.16 (-0.54, 0.22)	0.4029	-0.26 (-0.93, 0.42)	
		Age at PBC diagnosis												0.8193
		< 50 years	61	1.73 (1.22)	61	-0.40 (0.10)	32	1.79 (1.31)	31	-0.18 (0.14)	-0.22 (-0.55, 0.12)	0.2012	-0.27 (-0.71, 0.16)	
		>= 50 years	67	1.47 (1.00)	67	-0.17 (0.08)	33	1.35 (0.76)	33	-0.00 (0.11)	-0.17 (-0.42, 0.09)	0.1996	-0.26 (-0.67, 0.16)	
		Sex												NE
		female	123	1.60 (1.12)	123	-0.28 (0.06)	60	1.58 (1.10)	59	-0.07 (0.09)	-0.21 (-0.42, 0.00)	0.0537	-0.29 (-0.60, 0.02)	
		male	5	1.40 (0.89)	5	NE	5	1.40 (0.89)	5	NE	NE		NE	
		Race												
		white	114	1.61 (1.11)	114		56	1.61 (1.14)	55					
		black	2	1.00 (0.00)	2		2	1.00 (0.00)	2					
		asian	7	1.00 (0.00)	7		4	1.13 (0.25)	4					
		other	5	2.20 (1.79)	5		3	1.67 (0.76)	3					
		Region												0.6272
		North America	50	1.47 (0.89)	50	-0.20 (0.09)	13	1.38 (0.68)	13	0.12 (0.16)	-0.32 (-0.65, 0.01)	0.0552	-0.53 (-1.14, 0.09)	
		Europe	39	1.50 (1.02)	39	-0.19 (0.13)	24	1.80 (1.35)	23	0.05 (0.18)	-0.25 (-0.69, 0.20)	0.2686	-0.29 (-0.81, 0.23)	
		Rest-of-World	39	1.85 (1.40)	39	-0.47 (0.10)	28	1.45 (0.96)	28	-0.36 (0.12)	-0.11 (-0.41, 0.19)	0.4544	-0.18 (-0.66, 0.31)	
		Cirrhosis												0.0854
		yes	18	2.14 (1.66)	18	-0.19 (0.31)	9	1.56 (0.77)	9	0.80 (0.42)	-1.00 (-2.10, 0.11)	0.0746	-0.75 (-1.58, 0.08)	
		no	110	1.50 (0.98)	110	-0.28 (0.05)	56	1.57 (1.12)	55	-0.21 (0.07)	-0.07 (-0.23, 0.09)	0.3889	-0.13 (-0.46, 0.19)	
		UDCA												NE
		UDCA Use	120	1.60 (1.12)	120	-0.28 (0.07)	62	1.59 (1.10)	61	-0.11 (0.09)	-0.17 (-0.38, 0.04)	0.1170	-0.23 (-0.54, 0.07)	
		UDCA Intolerance	8	1.56 (1.05)	8	NE	3	1.00 (0.00)	3	NE	NE		NE	
		Prior Use of OCA and/or Fibrates												0.5498
		yes	20	1.87 (1.23)	20	-0.38 (0.15)	13	1.74 (1.47)	12	-0.33 (0.19)	-0.06 (-0.54, 0.43)	0.8149	-0.08 (-0.80, 0.63)	
		no	108	1.54 (1.09)	108	-0.27 (0.07)	52	1.52 (0.97)	52	-0.06 (0.10)	-0.21 (-0.44, 0.01)	0.0611	-0.30 (-0.63, 0.04)	
		Therapy												NE
		Monotherapy (SEL)	8	1.56 (1.05)	8	NE	4	1.00 (0.00)	4	NE	NE		NE	
		Combinationtherapy (SEL + UDCA)	120	1.60 (1.12)	120	-0.28 (0.07)	61	1.60 (1.10)	60	-0.11 (0.09)	-0.17 (-0.38, 0.04)	0.1133	-0.24 (-0.55, 0.07)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of change from baseline of 5-D Itch Scale at month 6 and 12 - Subgroup analysis
Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
		Subgroup	Baseline		Change from BL		Baseline		Change from BL		Difference of			
Score	Timepoint	Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
ITCH5D-Duration	Month 6	Stratification variable: Baseline Pruritus NRS												0.0902
		< 4	79	1.08 (0.29)	79	-0.05 (0.03)	42	1.10 (0.35)	42	-0.01 (0.04)	-0.04 (-0.13, 0.06)	0.4780	-0.12 (-0.50, 0.25)	
		>= 4	49	2.43 (1.41)	49	-0.82 (0.15)	23	2.42 (1.40)	22	-0.30 (0.23)	-0.51 (-1.07, 0.04)	0.0692	-0.47 (-0.98, 0.04)	
		Stratification variable: Baseline ALP Level												0.1827
		< 350 U/L	93	1.46 (0.99)	93	-0.24 (0.06)	47	1.57 (1.12)	46	-0.18 (0.08)	-0.06 (-0.25, 0.12)	0.5114	-0.11 (-0.46, 0.24)	
		>= 350 U/L	35	1.94 (1.34)	35	-0.46 (0.16)	18	1.56 (1.00)	18	-0.01 (0.23)	-0.45 (-1.00, 0.10)	0.1092	-0.47 (-1.05, 0.10)	
		Gamma-GT (GGT)												0.5607
		<= 3 x ULN	33	1.57 (1.05)	33	-0.08 (0.11)	14	1.19 (0.43)	13	0.01 (0.15)	-0.09 (-0.37, 0.18)	0.4987	-0.15 (-0.79, 0.49)	
		> 3 x ULN	95	1.60 (1.14)	95	-0.31 (0.08)	51	1.67 (1.18)	51	-0.11 (0.11)	-0.20 (-0.46, 0.05)	0.1191	-0.27 (-0.61, 0.08)	
		Total Bilirubin I												0.9534
		<= 1 x ULN	108	1.53 (1.05)	108	-0.27 (0.06)	60	1.57 (1.11)	59	-0.08 (0.08)	-0.19 (-0.39, 0.00)	0.0550	-0.29 (-0.61, 0.02)	
		> 1 x ULN	20	1.93 (1.39)	20	-0.44 (0.22)	5	1.50 (0.50)	5	-0.22 (0.49)	-0.22 (-1.34, 0.90)	0.6823	-0.22 (-1.20, 0.77)	
		Total Bilirubin II												0.2488
		< 0.6 x ULN	59	1.30 (0.75)	59	-0.16 (0.06)	32	1.52 (1.06)	31	-0.07 (0.08)	-0.08 (-0.27, 0.10)	0.3739	-0.18 (-0.61, 0.26)	
		>= 0.6 x ULN	69	1.84 (1.30)	69	-0.40 (0.10)	33	1.61 (1.11)	33	-0.08 (0.15)	-0.32 (-0.68, 0.04)	0.0830	-0.36 (-0.78, 0.05)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
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p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of change from baseline of 5-D Itch Scale at month 6 and 12 - Subgroup analysis
Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
			Baseline		Change from BL		Baseline		Change from BL					
Score	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
ITCH5D-Duration	Month 12	Age at screening												0.0413
		< 65 years	99	1.62 (1.11)	99	-0.28 (0.08)	53	1.63 (1.16)	52	-0.06 (0.10)	-0.23 (-0.47, 0.02)	0.0722	-0.30 (-0.64, 0.04)	
		>= 65 years	29	1.52 (1.13)	29	-0.31 (0.17)	12	1.29 (0.58)	12	0.58 (0.26)	-0.89 (-1.50, -0.28)	0.0055	-0.94 (-1.65, -0.24)	
		Age at PBC diagnosis												0.2261
		< 50 years	61	1.73 (1.22)	61	-0.31 (0.12)	32	1.79 (1.31)	31	-0.09 (0.16)	-0.21 (-0.60, 0.18)	0.2854	-0.23 (-0.66, 0.20)	
		>= 50 years	67	1.47 (1.00)	67	-0.28 (0.10)	33	1.35 (0.76)	33	0.24 (0.14)	-0.52 (-0.84, -0.20)	0.0018	-0.66 (-1.09, -0.23)	
		Sex												NE
		female	123	1.60 (1.12)	123	-0.32 (0.07)	60	1.58 (1.10)	59	0.10 (0.11)	-0.43 (-0.68, -0.18)	0.0010	-0.51 (-0.83, -0.20)	
		male	5	1.40 (0.89)	5	NE	5	1.40 (0.89)	5	NE	NE		NE	
		Race												
		white	114	1.61 (1.11)	114		56	1.61 (1.14)	55					
		black	2	1.00 (0.00)	2		2	1.00 (0.00)	2					
		asian	7	1.00 (0.00)	7		4	1.13 (0.25)	4					
		other	5	2.20 (1.79)	5		3	1.67 (0.76)	3					
		Region												0.5316
		North America	50	1.47 (0.89)	50	-0.15 (0.12)	13	1.38 (0.68)	13	0.48 (0.24)	-0.63 (-1.16, -0.10)	0.0201	-0.73 (-1.36, -0.11)	
		Europe	39	1.50 (1.02)	39	-0.33 (0.10)	24	1.80 (1.35)	23	-0.04 (0.13)	-0.30 (-0.61, 0.02)	0.0668	-0.47 (-0.99, 0.05)	
		Rest-of-World	39	1.85 (1.40)	39	-0.39 (0.17)	28	1.45 (0.96)	28	0.04 (0.21)	-0.43 (-0.97, 0.11)	0.1150	-0.39 (-0.88, 0.10)	
		Cirrhosis												0.9829
		yes	18	2.14 (1.66)	18	-0.44 (0.28)	9	1.56 (0.77)	9	-0.07 (0.42)	-0.37 (-1.48, 0.74)	0.4875	-0.30 (-1.10, 0.51)	
		no	110	1.50 (0.98)	110	-0.28 (0.07)	56	1.57 (1.12)	55	0.10 (0.11)	-0.38 (-0.63, -0.13)	0.0029	-0.49 (-0.82, -0.16)	
		UDCA												NE
		UDCA Use	120	1.60 (1.12)	120	-0.35 (0.07)	62	1.59 (1.10)	61	0.07 (0.10)	-0.43 (-0.65, -0.20)	0.0003	-0.56 (-0.87, -0.25)	
		UDCA Intolerance	8	1.56 (1.05)	8	NE	3	1.00 (0.00)	3	NE	NE		NE	
		Prior Use of OCA and/or Fibrates												0.7045
		yes	20	1.87 (1.23)	20	-0.42 (0.17)	13	1.74 (1.47)	12	-0.14 (0.21)	-0.28 (-0.84, 0.28)	0.3087	-0.37 (-1.09, 0.36)	
		no	108	1.54 (1.09)	108	-0.29 (0.08)	52	1.52 (0.97)	52	0.10 (0.12)	-0.40 (-0.67, -0.13)	0.0045	-0.47 (-0.80, -0.14)	
		Therapy												NE
		Monotherapy (SEL)	8	1.56 (1.05)	8	NE	4	1.00 (0.00)	4	NE	NE		NE	
		Combinationtherapy (SEL + UDCA)	120	1.60 (1.12)	120	-0.36 (0.07)	61	1.60 (1.10)	60	0.08 (0.10)	-0.44 (-0.66, -0.21)	0.0002	-0.57 (-0.88, -0.25)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
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p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of change from baseline of 5-D Itch Scale at month 6 and 12 - Subgroup analysis
Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
		Subgroup	Baseline		Change from BL		Baseline		Change from BL		Difference of			Interaction
Score	Timepoint	Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value
ITCH5D-Duration	Month 12	Stratification variable: Baseline Pruritus NRS												0.0227
		< 4	79	1.08 (0.29)	79	-0.01 (0.08)	42	1.10 (0.35)	42	0.04 (0.11)	-0.05 (-0.32, 0.22)	0.7043	-0.07 (-0.45, 0.30)	
		>= 4	49	2.43 (1.41)	49	-0.99 (0.14)	23	2.42 (1.40)	22	-0.28 (0.21)	-0.71 (-1.22, -0.20)	0.0075	-0.70 (-1.21, -0.18)	
		Stratification variable: Baseline ALP Level												0.6740
		< 350 U/L	93	1.46 (0.99)	93	-0.24 (0.09)	47	1.57 (1.12)	46	0.16 (0.12)	-0.40 (-0.69, -0.11)	0.0077	-0.48 (-0.83, -0.12)	
		>= 350 U/L	35	1.94 (1.34)	35	-0.56 (0.10)	18	1.56 (1.00)	18	-0.26 (0.14)	-0.30 (-0.66, 0.06)	0.0955	-0.50 (-1.08, 0.08)	
		Gamma-GT (GGT)												0.7227
		<= 3 x ULN	33	1.57 (1.05)	33	-0.10 (0.14)	14	1.19 (0.43)	13	0.38 (0.19)	-0.48 (-0.87, -0.08)	0.0195	-0.62 (-1.28, 0.03)	
		> 3 x ULN	95	1.60 (1.14)	95	-0.34 (0.09)	51	1.67 (1.18)	51	0.05 (0.12)	-0.39 (-0.69, -0.09)	0.0106	-0.44 (-0.79, -0.10)	
		Total Bilirubin I												0.8925
		<= 1 x ULN	108	1.53 (1.05)	108	-0.24 (0.08)	60	1.57 (1.11)	59	0.13 (0.10)	-0.37 (-0.62, -0.12)	0.0046	-0.45 (-0.77, -0.13)	
		> 1 x ULN	20	1.93 (1.39)	20	-0.68 (0.21)	5	1.50 (0.50)	5	-0.39 (0.60)	-0.28 (-1.64, 1.07)	0.6631	-0.27 (-1.25, 0.71)	
		Total Bilirubin II												0.2933
		< 0.6 x ULN	59	1.30 (0.75)	59	-0.10 (0.08)	32	1.52 (1.06)	31	0.19 (0.11)	-0.29 (-0.55, -0.03)	0.0291	-0.47 (-0.91, -0.03)	
		>= 0.6 x ULN	69	1.84 (1.30)	69	-0.61 (0.11)	33	1.61 (1.11)	33	-0.07 (0.16)	-0.54 (-0.93, -0.15)	0.0078	-0.57 (-0.99, -0.14)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
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p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
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Gilead Sciences, Inc.
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Mixed Effects Model (MMRM) analysis of change from baseline of 5-D Itch Scale at month 6 and 12 - Subgroup analysis
Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
			Baseline		Change from BL		Baseline		Change from BL					
Score	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
ITCH5D-Degree	Month 6	Age at screening												0.6778
		< 65 years	99	2.32 (1.02)	99	-0.38 (0.08)	53	2.26 (1.03)	52	-0.04 (0.10)	-0.34 (-0.58, -0.09)	0.0067	-0.44 (-0.78, -0.11)	
		>= 65 years	29	2.05 (1.10)	29	-0.31 (0.12)	12	2.13 (0.83)	12	0.12 (0.18)	-0.43 (-0.83, -0.03)	0.0344	-0.67 (-1.36, 0.02)	
		Age at PBC diagnosis												0.5189
		< 50 years	61	2.34 (1.07)	61	-0.44 (0.09)	32	2.32 (1.04)	31	-0.16 (0.13)	-0.28 (-0.58, 0.02)	0.0684	-0.39 (-0.82, 0.05)	
		>= 50 years	67	2.18 (1.02)	67	-0.33 (0.09)	33	2.16 (0.95)	33	0.09 (0.12)	-0.41 (-0.70, -0.13)	0.0042	-0.56 (-0.99, -0.14)	
		Sex												NE
		female	123	2.28 (1.04)	123	-0.39 (0.06)	60	2.27 (1.00)	59	-0.06 (0.09)	-0.33 (-0.54, -0.12)	0.0020	-0.47 (-0.78, -0.15)	
		male	5	1.80 (1.04)	5	NE	5	1.80 (0.84)	5	NE	NE		NE	
		Race												
		white	114	2.25 (1.04)	114		56	2.26 (1.00)	55					
		black	2	3.17 (0.24)	2		2	1.50 (0.71)	2					
		asian	7	1.71 (0.81)	7		4	2.00 (0.91)	4					
		other	5	2.70 (1.40)	5		3	2.50 (1.32)	3					
		Region												0.3653
		North America	50	2.16 (0.91)	50	-0.36 (0.11)	13	2.21 (0.99)	13	-0.26 (0.20)	-0.11 (-0.51, 0.30)	0.6074	-0.14 (-0.75, 0.48)	
		Europe	39	2.29 (1.01)	39	-0.44 (0.10)	24	2.59 (0.97)	23	-0.03 (0.14)	-0.41 (-0.73, -0.08)	0.0163	-0.63 (-1.15, -0.10)	
		Rest-of-World	39	2.34 (1.23)	39	-0.35 (0.13)	28	1.95 (0.95)	28	0.12 (0.15)	-0.48 (-0.85, -0.10)	0.0135	-0.60 (-1.10, -0.10)	
		Cirrhosis												0.1669
		yes	18	2.56 (1.14)	18	-0.54 (0.17)	9	2.50 (1.09)	9	0.15 (0.22)	-0.68 (-1.26, -0.11)	0.0214	-0.94 (-1.79, -0.10)	
		no	110	2.21 (1.02)	110	-0.34 (0.07)	56	2.19 (0.98)	55	-0.07 (0.09)	-0.27 (-0.49, -0.05)	0.0153	-0.38 (-0.71, -0.05)	
		UDCA												NE
		UDCA Use	120	2.23 (1.04)	120	-0.35 (0.07)	62	2.24 (0.99)	61	0.00 (0.09)	-0.35 (-0.56, -0.14)	0.0011	-0.49 (-0.80, -0.17)	
		UDCA Intolerance	8	2.58 (1.16)	8	NE	3	2.22 (1.35)	3	NE	NE		NE	
		Prior Use of OCA and/or Fibrates												0.1330
		yes	20	2.52 (1.13)	20	-0.57 (0.16)	13	2.72 (0.97)	12	-0.55 (0.21)	-0.02 (-0.57, 0.52)	0.9349	-0.03 (-0.75, 0.69)	
		no	108	2.21 (1.02)	108	-0.34 (0.07)	52	2.12 (0.97)	52	0.11 (0.10)	-0.46 (-0.68, -0.23)	<.0001	-0.62 (-0.96, -0.29)	
		Therapy												NE
		Monotherapy (SEL)	8	2.58 (1.16)	8	NE	4	2.04 (1.16)	4	NE	NE		NE	
		Combinationtherapy (SEL + UDCA)	120	2.23 (1.04)	120	-0.35 (0.07)	61	2.25 (0.99)	60	-0.01 (0.09)	-0.34 (-0.56, -0.13)	0.0015	-0.48 (-0.79, -0.16)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of change from baseline of 5-D Itch Scale at month 6 and 12 - Subgroup analysis
Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
		Subgroup	Baseline		Change from BL		Baseline		Change from BL		Difference of			Interaction
Score	Timepoint	Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value
ITCH5D-Degree	Month 6	Stratification variable: Baseline Pruritus NRS												0.0560
		< 4	79	1.62 (0.67)	79	-0.13 (0.08)	42	1.63 (0.62)	42	0.09 (0.10)	-0.22 (-0.45, 0.02)	0.0744	-0.32 (-0.69, 0.06)	
		>= 4	49	3.28 (0.65)	49	-0.94 (0.10)	23	3.34 (0.42)	22	-0.31 (0.15)	-0.63 (-1.00, -0.27)	0.0010	-0.88 (-1.40, -0.35)	
		Stratification variable: Baseline ALP Level												0.1043
		< 350 U/L	93	2.05 (0.94)	93	-0.24 (0.08)	47	2.16 (0.99)	46	0.02 (0.11)	-0.26 (-0.50, -0.01)	0.0391	-0.35 (-0.71, 0.00)	
		>= 350 U/L	35	2.81 (1.12)	35	-0.68 (0.11)	18	2.44 (0.98)	18	-0.06 (0.15)	-0.62 (-1.00, -0.25)	0.0017	-0.96 (-1.56, -0.36)	
		Gamma-GT (GGT)												0.7140
		<= 3 x ULN	33	2.17 (0.93)	33	-0.21 (0.17)	14	1.83 (0.89)	13	0.24 (0.24)	-0.45 (-0.94, 0.04)	0.0708	-0.46 (-1.11, 0.19)	
		> 3 x ULN	95	2.29 (1.08)	95	-0.40 (0.07)	51	2.35 (1.00)	51	-0.05 (0.10)	-0.35 (-0.58, -0.12)	0.0030	-0.51 (-0.85, -0.16)	
		Total Bilirubin I												0.7122
		<= 1 x ULN	108	2.21 (1.03)	108	-0.37 (0.07)	60	2.23 (0.98)	59	0.00 (0.09)	-0.38 (-0.58, -0.17)	0.0005	-0.53 (-0.85, -0.21)	
		> 1 x ULN	20	2.53 (1.11)	20	-0.40 (0.18)	5	2.30 (1.25)	5	-0.21 (0.45)	-0.19 (-1.19, 0.80)	0.6912	-0.22 (-1.20, 0.76)	
		Total Bilirubin II												0.0138
		< 0.6 x ULN	59	2.05 (0.91)	59	-0.13 (0.09)	32	2.24 (1.06)	31	-0.03 (0.12)	-0.09 (-0.36, 0.17)	0.4851	-0.14 (-0.57, 0.30)	
		>= 0.6 x ULN	69	2.43 (1.12)	69	-0.51 (0.09)	33	2.23 (0.94)	33	0.09 (0.13)	-0.60 (-0.91, -0.29)	0.0002	-0.79 (-1.22, -0.36)	

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p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
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Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
		Subgroup	Baseline		Change from BL		Baseline		Change from BL		Difference of			Interaction
Score	Timepoint	Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value
ITCH5D-Degree	Month 12	Age at screening												0.7635
		< 65 years	99	2.32 (1.02)	99	-0.50 (0.08)	53	2.26 (1.03)	52	-0.14 (0.11)	-0.36 (-0.62, -0.09)	0.0101	-0.43 (-0.77, -0.09)	
		>= 65 years	29	2.05 (1.10)	29	-0.11 (0.13)	12	2.13 (0.83)	12	0.32 (0.20)	-0.43 (-0.88, 0.01)	0.0571	-0.60 (-1.29, 0.08)	
		Age at PBC diagnosis												0.6583
		< 50 years	61	2.34 (1.07)	61	-0.55 (0.10)	32	2.32 (1.04)	31	-0.13 (0.14)	-0.42 (-0.76, -0.08)	0.0155	-0.52 (-0.96, -0.09)	
		>= 50 years	67	2.18 (1.02)	67	-0.31 (0.10)	33	2.16 (0.95)	33	0.01 (0.14)	-0.32 (-0.64, 0.01)	0.0540	-0.38 (-0.81, 0.04)	
		Sex												NE
		female	123	2.28 (1.04)	123	-0.44 (0.07)	60	2.27 (1.00)	59	-0.07 (0.10)	-0.37 (-0.61, -0.13)	0.0031	-0.46 (-0.77, -0.14)	
		male	5	1.80 (1.04)	5	NE	5	1.80 (0.84)	5	NE	NE		NE	
		Race												
		white	114	2.25 (1.04)	114		56	2.26 (1.00)	55					
		black	2	3.17 (0.24)	2		2	1.50 (0.71)	2					
		asian	7	1.71 (0.81)	7		4	2.00 (0.91)	4					
		other	5	2.70 (1.40)	5		3	2.50 (1.32)	3					
		Region												0.2027
		North America	50	2.16 (0.91)	50	-0.32 (0.14)	13	2.21 (0.99)	13	0.06 (0.28)	-0.38 (-0.99, 0.24)	0.2229	-0.37 (-0.98, 0.25)	
		Europe	39	2.29 (1.01)	39	-0.40 (0.11)	24	2.59 (0.97)	23	-0.20 (0.15)	-0.20 (-0.57, 0.16)	0.2678	-0.28 (-0.80, 0.23)	
		Rest-of-World	39	2.34 (1.23)	39	-0.54 (0.12)	28	1.95 (0.95)	28	0.12 (0.14)	-0.66 (-1.03, -0.29)	0.0007	-0.85 (-1.36, -0.34)	
		Cirrhosis												0.7134
		yes	18	2.56 (1.14)	18	-0.61 (0.23)	9	2.50 (1.09)	9	-0.40 (0.31)	-0.21 (-1.03, 0.61)	0.5984	-0.21 (-1.02, 0.59)	
		no	110	2.21 (1.02)	110	-0.38 (0.08)	56	2.19 (0.98)	55	-0.02 (0.11)	-0.36 (-0.61, -0.11)	0.0044	-0.46 (-0.78, -0.13)	
		UDCA												NE
		UDCA Use	120	2.23 (1.04)	120	-0.43 (0.07)	62	2.24 (0.99)	61	-0.02 (0.10)	-0.40 (-0.64, -0.17)	0.0008	-0.51 (-0.82, -0.19)	
		UDCA Intolerance	8	2.58 (1.16)	8	NE	3	2.22 (1.35)	3	NE	NE		NE	
		Prior Use of OCA and/or Fibrates												0.4325
		yes	20	2.52 (1.13)	20	-0.71 (0.16)	13	2.72 (0.97)	12	-0.47 (0.19)	-0.23 (-0.76, 0.29)	0.3635	-0.33 (-1.05, 0.39)	
		no	108	2.21 (1.02)	108	-0.38 (0.08)	52	2.12 (0.97)	52	0.08 (0.11)	-0.46 (-0.72, -0.20)	0.0007	-0.55 (-0.89, -0.21)	
		Therapy												NE
		Monotherapy (SEL)	8	2.58 (1.16)	8	NE	4	2.04 (1.16)	4	NE	NE		NE	
		Combinationtherapy (SEL + UDCA)	120	2.23 (1.04)	120	-0.43 (0.07)	61	2.25 (0.99)	60	-0.04 (0.10)	-0.39 (-0.63, -0.16)	0.0011	-0.50 (-0.81, -0.18)	

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Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
		Subgroup	Baseline		Change from BL		Baseline		Change from BL		Difference of			Interaction
Score	Timepoint	Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value
ITCH5D-Degree	Month 12	Stratification variable: Baseline Pruritus NRS												0.3169
		< 4	79	1.62 (0.67)	79	-0.15 (0.08)	42	1.63 (0.62)	42	0.18 (0.11)	-0.33 (-0.59, -0.07)	0.0139	-0.45 (-0.83, -0.07)	
		>= 4	49	3.28 (0.65)	49	-1.08 (0.12)	23	3.34 (0.42)	22	-0.50 (0.17)	-0.58 (-0.99, -0.16)	0.0070	-0.70 (-1.22, -0.19)	
		Stratification variable: Baseline ALP Level												0.7701
		< 350 U/L	93	2.05 (0.94)	93	-0.29 (0.08)	47	2.16 (0.99)	46	0.06 (0.12)	-0.35 (-0.63, -0.07)	0.0137	-0.43 (-0.79, -0.07)	
		>= 350 U/L	35	2.81 (1.12)	35	-0.70 (0.12)	18	2.44 (0.98)	18	-0.27 (0.18)	-0.43 (-0.87, 0.01)	0.0556	-0.57 (-1.15, 0.01)	
		Gamma-GT (GGT)												0.2886
		<= 3 x ULN	33	2.17 (0.93)	33	-0.27 (0.17)	14	1.83 (0.89)	13	0.36 (0.24)	-0.62 (-1.11, -0.13)	0.0146	-0.63 (-1.29, 0.02)	
		> 3 x ULN	95	2.29 (1.08)	95	-0.43 (0.08)	51	2.35 (1.00)	51	-0.11 (0.11)	-0.33 (-0.60, -0.05)	0.0189	-0.40 (-0.75, -0.06)	
		Total Bilirubin I												0.3889
		<= 1 x ULN	108	2.21 (1.03)	108	-0.38 (0.08)	60	2.23 (0.98)	59	-0.03 (0.11)	-0.34 (-0.59, -0.09)	0.0075	-0.41 (-0.73, -0.09)	
		> 1 x ULN	20	2.53 (1.11)	20	-0.62 (0.15)	5	2.30 (1.25)	5	0.13 (0.43)	-0.75 (-1.68, 0.18)	0.1088	-0.99 (-2.01, 0.04)	
		Total Bilirubin II												0.0382
		< 0.6 x ULN	59	2.05 (0.91)	59	-0.13 (0.11)	32	2.24 (1.06)	31	-0.01 (0.15)	-0.12 (-0.47, 0.22)	0.4797	-0.14 (-0.58, 0.29)	
		>= 0.6 x ULN	69	2.43 (1.12)	69	-0.61 (0.09)	33	2.23 (0.94)	33	-0.00 (0.13)	-0.61 (-0.93, -0.29)	0.0003	-0.79 (-1.22, -0.36)	

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			Baseline		Change from BL		Baseline		Change from BL					
Score	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
ITCH5D-Direction	Month 6	Age at screening												0.7033
		< 65 years	99	3.40 (1.02)	99	-0.66 (0.13)	53	3.16 (1.16)	52	-0.31 (0.18)	-0.34 (-0.77, 0.08)	0.1114	-0.27 (-0.60, 0.07)	
		>= 65 years	29	3.15 (1.30)	29	-0.49 (0.23)	12	3.00 (1.22)	12	-0.31 (0.34)	-0.18 (-0.95, 0.59)	0.6433	-0.14 (-0.82, 0.53)	
		Age at PBC diagnosis												0.9834
		< 50 years	61	3.39 (1.09)	61	-0.61 (0.16)	32	3.14 (1.19)	31	-0.30 (0.23)	-0.31 (-0.86, 0.24)	0.2642	-0.24 (-0.68, 0.19)	
		>= 50 years	67	3.31 (1.10)	67	-0.60 (0.16)	33	3.12 (1.16)	33	-0.30 (0.21)	-0.30 (-0.80, 0.20)	0.2321	-0.24 (-0.66, 0.18)	
		Sex												NE
		female	123	3.32 (1.11)	123	-0.64 (0.11)	60	3.16 (1.16)	59	-0.29 (0.16)	-0.35 (-0.73, 0.04)	0.0756	-0.27 (-0.59, 0.04)	
		male	5	4.00 (0.00)	5	NE	5	2.73 (1.30)	5	NE	NE		NE	
		Race												
		white	114	3.33 (1.09)	114		56	3.19 (1.15)	55					
		black	2	4.33 (0.47)	2		2	2.75 (0.35)	2					
		asian	7	3.07 (1.43)	7		4	2.63 (1.38)	4					
		other	5	3.70 (0.67)	5		3	2.83 (1.76)	3					
		Region												0.4531
		North America	50	3.44 (1.16)	50	-0.78 (0.19)	13	3.26 (1.06)	13	-0.83 (0.34)	0.05 (-0.68, 0.79)	0.8893	0.04 (-0.57, 0.65)	
		Europe	39	3.53 (0.84)	39	-0.63 (0.21)	24	3.46 (0.94)	23	-0.34 (0.29)	-0.28 (-0.99, 0.42)	0.4231	-0.21 (-0.72, 0.31)	
		Rest-of-World	39	3.04 (1.19)	39	-0.57 (0.19)	28	2.79 (1.32)	28	-0.04 (0.22)	-0.53 (-1.11, 0.04)	0.0671	-0.44 (-0.94, 0.05)	
		Cirrhosis												0.2455
		yes	18	3.42 (1.22)	18	-0.76 (0.31)	9	3.39 (1.11)	9	0.10 (0.44)	-0.86 (-1.96, 0.24)	0.1197	-0.64 (-1.46, 0.18)	
		no	110	3.33 (1.08)	110	-0.57 (0.12)	56	3.09 (1.18)	55	-0.37 (0.17)	-0.20 (-0.59, 0.19)	0.3170	-0.16 (-0.48, 0.17)	
		UDCA												NE
		UDCA Use	120	3.36 (1.07)	120	-0.61 (0.12)	62	3.12 (1.14)	61	-0.30 (0.16)	-0.31 (-0.69, 0.07)	0.1050	-0.25 (-0.56, 0.06)	
		UDCA Intolerance	8	3.15 (1.46)	8	NE	3	3.22 (1.95)	3	NE	NE		NE	
		Prior Use of OCA and/or Fibrates												0.0217
		yes	20	3.23 (1.31)	20	-0.26 (0.29)	13	3.32 (1.20)	12	-0.86 (0.36)	0.61 (-0.34, 1.55)	0.1990	0.47 (-0.26, 1.19)	
		no	108	3.37 (1.05)	108	-0.69 (0.12)	52	3.08 (1.16)	52	-0.15 (0.17)	-0.55 (-0.94, -0.15)	0.0070	-0.44 (-0.77, -0.11)	
		Therapy												NE
		Monotherapy (SEL)	8	3.15 (1.46)	8	NE	4	3.42 (1.64)	4	NE	NE		NE	
		Combinationtherapy (SEL + UDCA)	120	3.36 (1.07)	120	-0.60 (0.12)	61	3.11 (1.14)	60	-0.30 (0.16)	-0.30 (-0.68, 0.08)	0.1165	-0.24 (-0.55, 0.07)	

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(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of change from baseline of 5-D Itch Scale at month 6 and 12 - Subgroup analysis
Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
		Subgroup	Baseline		Change from BL		Baseline		Change from BL		Difference of			Interaction
Score	Timepoint	Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value
ITCH5D-Direction	Month 6	Stratification variable: Baseline Pruritus NRS												0.2721
		< 4	79	2.98 (1.18)	79	-0.16 (0.16)	42	2.65 (1.15)	42	0.04 (0.21)	-0.19 (-0.68, 0.29)	0.4313	-0.14 (-0.51, 0.23)	
		>= 4	49	3.94 (0.57)	49	-1.23 (0.15)	23	4.01 (0.49)	22	-0.64 (0.22)	-0.59 (-1.12, -0.06)	0.0308	-0.56 (-1.07, -0.05)	
		Stratification variable: Baseline ALP Level												0.4028
		< 350 U/L	93	3.32 (1.09)	93	-0.64 (0.13)	47	3.13 (1.18)	46	-0.42 (0.18)	-0.21 (-0.64, 0.21)	0.3181	-0.17 (-0.53, 0.18)	
		>= 350 U/L	35	3.42 (1.11)	35	-0.63 (0.22)	18	3.11 (1.17)	18	-0.05 (0.31)	-0.58 (-1.33, 0.18)	0.1324	-0.44 (-1.02, 0.13)	
		Gamma-GT (GGT)												0.8940
		<= 3 x ULN	33	3.31 (0.98)	33	-0.20 (0.27)	14	2.68 (1.01)	13	0.10 (0.39)	-0.30 (-1.13, 0.53)	0.4684	-0.19 (-0.84, 0.45)	
		> 3 x ULN	95	3.36 (1.13)	95	-0.69 (0.13)	51	3.25 (1.18)	51	-0.32 (0.17)	-0.36 (-0.78, 0.05)	0.0856	-0.29 (-0.64, 0.05)	
		Total Bilirubin I												0.9802
		<= 1 x ULN	108	3.29 (1.12)	108	-0.62 (0.12)	60	3.12 (1.15)	59	-0.27 (0.16)	-0.35 (-0.73, 0.03)	0.0717	-0.28 (-0.60, 0.04)	
		> 1 x ULN	20	3.65 (0.91)	20	-0.63 (0.33)	5	3.20 (1.44)	5	-0.26 (0.82)	-0.37 (-2.22, 1.48)	0.6789	-0.23 (-1.22, 0.75)	
		Total Bilirubin II												0.3244
		< 0.6 x ULN	59	3.15 (1.12)	59	-0.47 (0.17)	32	3.13 (1.18)	31	-0.33 (0.22)	-0.13 (-0.65, 0.38)	0.6058	-0.10 (-0.54, 0.33)	
		>= 0.6 x ULN	69	3.51 (1.04)	69	-0.71 (0.16)	33	3.13 (1.17)	33	-0.20 (0.23)	-0.51 (-1.05, 0.04)	0.0672	-0.39 (-0.81, 0.03)	

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BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
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RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of change from baseline of 5-D Itch Scale at month 6 and 12 - Subgroup analysis
Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
			Baseline		Change from BL		Baseline		Change from BL					
Score	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
ITCH5D-Direction	Month 12	Age at screening												0.7839
		< 65 years	99	3.40 (1.02)	99	-0.75 (0.15)	53	3.16 (1.16)	52	-0.23 (0.21)	-0.52 (-1.03, -0.01)	0.0459	-0.34 (-0.68, -0.00)	
		>= 65 years	29	3.15 (1.30)	29	-0.28 (0.24)	12	3.00 (1.22)	12	0.11 (0.36)	-0.39 (-1.20, 0.42)	0.3380	-0.30 (-0.98, 0.37)	
		Age at PBC diagnosis												0.8660
		< 50 years	61	3.39 (1.09)	61	-0.63 (0.19)	32	3.14 (1.19)	31	-0.14 (0.27)	-0.49 (-1.15, 0.16)	0.1375	-0.33 (-0.76, 0.11)	
		>= 50 years	67	3.31 (1.10)	67	-0.60 (0.17)	33	3.12 (1.16)	33	-0.18 (0.24)	-0.42 (-0.99, 0.15)	0.1467	-0.30 (-0.71, 0.12)	
		Sex												NE
		female	123	3.32 (1.11)	123	-0.65 (0.13)	60	3.16 (1.16)	59	-0.17 (0.19)	-0.48 (-0.94, -0.03)	0.0366	-0.33 (-0.64, -0.01)	
		male	5	4.00 (0.00)	5	NE	5	2.73 (1.30)	5	NE	NE		NE	
		Race												
		white	114	3.33 (1.09)	114		56	3.19 (1.15)	55					
		black	2	4.33 (0.47)	2		2	2.75 (0.35)	2					
		asian	7	3.07 (1.43)	7		4	2.63 (1.38)	4					
		other	5	3.70 (0.67)	5		3	2.83 (1.76)	3					
		Region												0.2674
		North America	50	3.44 (1.16)	50	-0.78 (0.24)	13	3.26 (1.06)	13	-0.12 (0.50)	-0.66 (-1.73, 0.41)	0.2195	-0.38 (-1.00, 0.23)	
		Europe	39	3.53 (0.84)	39	-0.46 (0.22)	24	3.46 (0.94)	23	-0.35 (0.29)	-0.11 (-0.84, 0.62)	0.7538	-0.08 (-0.60, 0.43)	
		Rest-of-World	39	3.04 (1.19)	39	-0.78 (0.22)	28	2.79 (1.32)	28	0.13 (0.26)	-0.91 (-1.59, -0.24)	0.0090	-0.65 (-1.15, -0.16)	
		Cirrhosis												0.6873
		yes	18	3.42 (1.22)	18	-0.92 (0.28)	9	3.39 (1.11)	9	-0.67 (0.43)	-0.25 (-1.37, 0.87)	0.6416	-0.20 (-1.00, 0.60)	
		no	110	3.33 (1.08)	110	-0.61 (0.14)	56	3.09 (1.18)	55	-0.13 (0.20)	-0.48 (-0.95, -0.02)	0.0420	-0.33 (-0.65, -0.00)	
		UDCA												NE
		UDCA Use	120	3.36 (1.07)	120	-0.66 (0.13)	62	3.12 (1.14)	61	-0.15 (0.18)	-0.51 (-0.95, -0.07)	0.0227	-0.35 (-0.66, -0.04)	
		UDCA Intolerance	8	3.15 (1.46)	8	NE	3	3.22 (1.95)	3	NE	NE		NE	
		Prior Use of OCA and/or Fibrates												0.0414
		yes	20	3.23 (1.31)	20	-0.36 (0.35)	13	3.32 (1.20)	12	-0.84 (0.42)	0.48 (-0.64, 1.60)	0.3849	0.31 (-0.41, 1.03)	
		no	108	3.37 (1.05)	108	-0.71 (0.13)	52	3.08 (1.16)	52	0.02 (0.20)	-0.73 (-1.19, -0.27)	0.0022	-0.52 (-0.85, -0.18)	
		Therapy												NE
		Monotherapy (SEL)	8	3.15 (1.46)	8	NE	4	3.42 (1.64)	4	NE	NE		NE	
		Combinationtherapy (SEL + UDCA)	120	3.36 (1.07)	120	-0.66 (0.13)	61	3.11 (1.14)	60	-0.15 (0.19)	-0.50 (-0.95, -0.06)	0.0264	-0.34 (-0.66, -0.03)	

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Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
		Subgroup	Baseline		Change from BL		Baseline		Change from BL		Difference of			Interaction
Score	Timepoint	Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value
ITCH5D-Direction	Month 12	Stratification variable: Baseline Pruritus NRS												0.9460
		< 4	79	2.98 (1.18)	79	-0.13 (0.17)	42	2.65 (1.15)	42	0.32 (0.23)	-0.44 (-0.99, 0.10)	0.1095	-0.29 (-0.67, 0.08)	
		>= 4	49	3.94 (0.57)	49	-1.28 (0.20)	23	4.01 (0.49)	22	-0.87 (0.30)	-0.41 (-1.14, 0.31)	0.2564	-0.29 (-0.80, 0.22)	
		Stratification variable: Baseline ALP Level												0.5320
		< 350 U/L	93	3.32 (1.09)	93	-0.77 (0.15)	47	3.13 (1.18)	46	-0.26 (0.22)	-0.51 (-1.03, 0.01)	0.0547	-0.34 (-0.70, 0.01)	
		>= 350 U/L	35	3.42 (1.11)	35	-0.29 (0.21)	18	3.11 (1.17)	18	-0.06 (0.30)	-0.23 (-0.97, 0.51)	0.5361	-0.18 (-0.75, 0.39)	
		Gamma-GT (GGT)												0.1853
		<= 3 x ULN	33	3.31 (0.98)	33	-0.46 (0.29)	14	2.68 (1.01)	13	0.53 (0.41)	-0.99 (-1.87, -0.12)	0.0274	-0.61 (-1.26, 0.05)	
		> 3 x ULN	95	3.36 (1.13)	95	-0.61 (0.15)	51	3.25 (1.18)	51	-0.28 (0.20)	-0.33 (-0.82, 0.16)	0.1871	-0.23 (-0.57, 0.11)	
		Total Bilirubin I												0.6868
		<= 1 x ULN	108	3.29 (1.12)	108	-0.59 (0.15)	60	3.12 (1.15)	59	-0.13 (0.19)	-0.45 (-0.92, 0.01)	0.0574	-0.30 (-0.62, 0.02)	
		> 1 x ULN	20	3.65 (0.91)	20	-0.93 (0.22)	5	3.20 (1.44)	5	-0.21 (0.58)	-0.72 (-2.00, 0.56)	0.2546	-0.67 (-1.67, 0.33)	
		Total Bilirubin II												0.3416
		< 0.6 x ULN	59	3.15 (1.12)	59	-0.47 (0.20)	32	3.13 (1.18)	31	-0.19 (0.27)	-0.28 (-0.90, 0.34)	0.3745	-0.18 (-0.62, 0.25)	
		>= 0.6 x ULN	69	3.51 (1.04)	69	-0.78 (0.18)	33	3.13 (1.17)	33	-0.08 (0.25)	-0.70 (-1.31, -0.08)	0.0262	-0.47 (-0.89, -0.05)	

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Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
		Subgroup	Baseline		Change from BL		Baseline		Change from BL		Difference of			Interaction
Score	Timepoint	Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value
ITCH5D-Distributi on Total	Month 6	Age at screening												0.3845
		< 65 years	99	2.20 (1.32)	99	-0.22 (0.09)	53	2.17 (1.25)	52	0.15 (0.13)	-0.37 (-0.67, -0.07)	0.0166	-0.40 (-0.73, -0.06)	
		>= 65 years	29	2.00 (1.20)	29	-0.06 (0.19)	12	1.67 (0.89)	12	0.62 (0.29)	-0.68 (-1.34, -0.02)	0.0424	-0.66 (-1.35, 0.03)	
		Age at PBC diagnosis												0.1900
		< 50 years	61	2.28 (1.42)	61	-0.23 (0.13)	32	2.44 (1.32)	31	0.02 (0.18)	-0.25 (-0.67, 0.18)	0.2506	-0.25 (-0.68, 0.19)	
		>= 50 years	67	2.04 (1.16)	67	-0.15 (0.11)	33	1.73 (0.98)	33	0.46 (0.15)	-0.61 (-0.97, -0.25)	0.0010	-0.66 (-1.09, -0.24)	
		Sex												NE
		female	123	2.19 (1.30)	123	-0.20 (0.09)	60	2.12 (1.22)	59	0.23 (0.12)	-0.43 (-0.72, -0.14)	0.0037	-0.44 (-0.76, -0.13)	
		male	5	1.40 (0.55)	5	NE	5	1.60 (0.89)	5	NE	NE		NE	
		Race												
		white	114	2.18 (1.29)	114		56	2.04 (1.17)	55					
		black	2	3.50 (0.71)	2		2	1.50 (0.71)	2					
		asian	7	1.43 (0.79)	7		4	2.50 (1.29)	4					
		other	5	2.00 (1.73)	5		3	2.67 (2.08)	3					
		Region												0.8215
		North America	50	2.16 (1.13)	50	-0.12 (0.17)	13	2.00 (1.15)	13	0.19 (0.31)	-0.32 (-0.98, 0.34)	0.3420	-0.27 (-0.88, 0.34)	
		Europe	39	2.08 (1.29)	39	-0.17 (0.15)	24	2.21 (1.25)	23	0.26 (0.19)	-0.43 (-0.90, 0.04)	0.0746	-0.46 (-0.98, 0.06)	
		Rest-of-World	39	2.23 (1.49)	39	-0.30 (0.13)	28	2.00 (1.22)	28	0.25 (0.15)	-0.54 (-0.92, -0.17)	0.0052	-0.68 (-1.18, -0.18)	
		Cirrhosis												0.0897
		yes	18	2.67 (1.61)	18	-0.08 (0.25)	9	2.44 (1.01)	9	0.99 (0.35)	-1.07 (-1.98, -0.16)	0.0224	-0.98 (-1.83, -0.13)	
		no	110	2.07 (1.22)	110	-0.18 (0.09)	56	2.02 (1.23)	55	0.11 (0.12)	-0.29 (-0.56, -0.01)	0.0412	-0.32 (-0.65, 0.00)	
		UDCA												NE
		UDCA Use	120	2.14 (1.30)	120	-0.15 (0.09)	62	2.13 (1.21)	61	0.24 (0.12)	-0.39 (-0.66, -0.12)	0.0055	-0.42 (-0.73, -0.11)	
		UDCA Intolerance	8	2.38 (1.06)	8	NE	3	1.00 (0.00)	3	NE	NE		NE	
		Prior Use of OCA and/or Fibrates												0.5669
		yes	20	2.55 (1.39)	20	-0.33 (0.24)	13	2.23 (1.30)	12	-0.10 (0.31)	-0.22 (-1.03, 0.58)	0.5749	-0.20 (-0.92, 0.52)	
		no	108	2.08 (1.26)	108	-0.16 (0.09)	52	2.04 (1.19)	52	0.31 (0.13)	-0.46 (-0.75, -0.17)	0.0019	-0.49 (-0.83, -0.16)	
		Therapy												NE
		Monotherapy (SEL)	8	2.38 (1.06)	8	NE	4	1.00 (0.00)	4	NE	NE		NE	
		Combinationtherapy (SEL + UDCA)	120	2.14 (1.30)	120	-0.16 (0.09)	61	2.15 (1.21)	60	0.22 (0.12)	-0.38 (-0.65, -0.10)	0.0072	-0.41 (-0.72, -0.09)	

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			Seladelpar 10 mg (N=128)				Placebo (N=65)							
			Baseline		Change from BL		Baseline		Change from BL					
Score	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
ITCH5D-Distributi on Total	Month 6	Stratification variable: Baseline Pruritus NRS												0.0510
		< 4	79	1.57 (0.93)	79	-0.01 (0.10)	42	1.50 (0.77)	42	0.18 (0.13)	-0.19 (-0.49, 0.11)	0.2188	-0.22 (-0.59, 0.16)	
		>= 4	49	3.10 (1.23)	49	-0.57 (0.15)	23	3.13 (1.14)	22	0.24 (0.23)	-0.80 (-1.35, -0.25)	0.0049	-0.74 (-1.25, -0.22)	
		Stratification variable: Baseline ALP Level												0.3047
		< 350 U/L	93	1.90 (1.15)	93	-0.22 (0.09)	47	2.04 (1.22)	46	0.09 (0.12)	-0.31 (-0.59, -0.03)	0.0308	-0.37 (-0.73, -0.02)	
		>= 350 U/L	35	2.83 (1.40)	35	-0.24 (0.20)	18	2.17 (1.20)	18	0.46 (0.29)	-0.70 (-1.40, 0.01)	0.0522	-0.57 (-1.15, 0.01)	
		Gamma-GT (GGT)												0.4116
		<= 3 x ULN	33	2.09 (1.31)	33	-0.40 (0.21)	14	1.86 (1.29)	13	-0.23 (0.30)	-0.17 (-0.79, 0.46)	0.5941	-0.14 (-0.78, 0.50)	
		> 3 x ULN	95	2.18 (1.29)	95	-0.19 (0.09)	51	2.14 (1.18)	51	0.26 (0.13)	-0.45 (-0.76, -0.15)	0.0041	-0.49 (-0.84, -0.15)	
		Total Bilirubin I												0.8684
		<= 1 x ULN	108	2.06 (1.21)	108	-0.19 (0.10)	60	2.07 (1.21)	59	0.21 (0.12)	-0.40 (-0.69, -0.10)	0.0085	-0.40 (-0.72, -0.08)	
		> 1 x ULN	20	2.70 (1.59)	20	-0.19 (0.16)	5	2.20 (1.30)	5	0.28 (0.42)	-0.47 (-1.38, 0.44)	0.2977	-0.61 (-1.60, 0.39)	
		Total Bilirubin II												0.0080
		< 0.6 x ULN	59	1.81 (1.14)	59	-0.07 (0.12)	32	2.13 (1.31)	31	0.01 (0.16)	-0.08 (-0.44, 0.28)	0.6732	-0.08 (-0.52, 0.35)	
		>= 0.6 x ULN	69	2.45 (1.35)	69	-0.29 (0.11)	33	2.03 (1.10)	33	0.49 (0.16)	-0.78 (-1.16, -0.39)	0.0001	-0.83 (-1.26, -0.40)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of change from baseline of 5-D Itch Scale at month 6 and 12 - Subgroup analysis
Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
		Subgroup	Baseline		Change from BL		Baseline		Change from BL		Difference of			Interaction
Score	Timepoint	Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value
ITCH5D-Distributi on Total	Month 12	Age at screening												0.5797
		< 65 years	99	2.20 (1.32)	99	-0.29 (0.10)	53	2.17 (1.25)	52	0.10 (0.13)	-0.39 (-0.70, -0.07)	0.0165	-0.40 (-0.74, -0.06)	
		>= 65 years	29	2.00 (1.20)	29	-0.17 (0.19)	12	1.67 (0.89)	12	0.41 (0.28)	-0.58 (-1.22, 0.06)	0.0725	-0.58 (-1.26, 0.11)	
		Age at PBC diagnosis												0.7404
		< 50 years	61	2.28 (1.42)	61	-0.25 (0.13)	32	2.44 (1.32)	31	0.23 (0.18)	-0.49 (-0.92, -0.05)	0.0298	-0.47 (-0.91, -0.04)	
		>= 50 years	67	2.04 (1.16)	67	-0.28 (0.12)	33	1.73 (0.98)	33	0.11 (0.16)	-0.39 (-0.76, -0.02)	0.0390	-0.42 (-0.84, 0.00)	
		Sex												NE
		female	123	2.19 (1.30)	123	-0.26 (0.09)	60	2.12 (1.22)	59	0.20 (0.13)	-0.46 (-0.76, -0.16)	0.0030	-0.46 (-0.77, -0.14)	
		male	5	1.40 (0.55)	5	NE	5	1.60 (0.89)	5	NE	NE		NE	
		Race												
		white	114	2.18 (1.29)	114		56	2.04 (1.17)	55					
		black	2	3.50 (0.71)	2		2	1.50 (0.71)	2					
		asian	7	1.43 (0.79)	7		4	2.50 (1.29)	4					
		other	5	2.00 (1.73)	5		3	2.67 (2.08)	3					
		Region												0.7182
		North America	50	2.16 (1.13)	50	-0.16 (0.19)	13	2.00 (1.15)	13	-0.00 (0.38)	-0.16 (-0.98, 0.65)	0.6902	-0.12 (-0.73, 0.49)	
		Europe	39	2.08 (1.29)	39	-0.32 (0.14)	24	2.21 (1.25)	23	0.08 (0.18)	-0.40 (-0.84, 0.04)	0.0738	-0.46 (-0.98, 0.06)	
		Rest-of-World	39	2.23 (1.49)	39	-0.30 (0.12)	28	2.00 (1.22)	28	0.22 (0.15)	-0.51 (-0.88, -0.15)	0.0061	-0.66 (-1.16, -0.16)	
		Cirrhosis												0.7862
		yes	18	2.67 (1.61)	18	-0.36 (0.33)	9	2.44 (1.01)	9	0.15 (0.49)	-0.51 (-1.83, 0.81)	0.4180	-0.34 (-1.15, 0.46)	
		no	110	2.07 (1.22)	110	-0.20 (0.09)	56	2.02 (1.23)	55	0.13 (0.12)	-0.34 (-0.63, -0.05)	0.0220	-0.36 (-0.69, -0.04)	
		UDCA												NE
		UDCA Use	120	2.14 (1.30)	120	-0.26 (0.09)	62	2.13 (1.21)	61	0.15 (0.12)	-0.42 (-0.69, -0.14)	0.0035	-0.44 (-0.75, -0.13)	
		UDCA Intolerance	8	2.38 (1.06)	8	NE	3	1.00 (0.00)	3	NE	NE		NE	
		Prior Use of OCA and/or Fibrates												0.8204
		yes	20	2.55 (1.39)	20	-0.40 (0.28)	13	2.23 (1.30)	12	-0.10 (0.32)	-0.30 (-1.20, 0.60)	0.4869	-0.25 (-0.96, 0.47)	
		no	108	2.08 (1.26)	108	-0.20 (0.10)	52	2.04 (1.19)	52	0.20 (0.14)	-0.40 (-0.72, -0.09)	0.0124	-0.41 (-0.74, -0.07)	
		Therapy												NE
		Monotherapy (SEL)	8	2.38 (1.06)	8	NE	4	1.00 (0.00)	4	NE	NE		NE	
		Combinationtherapy (SEL + UDCA)	120	2.14 (1.30)	120	-0.27 (0.09)	61	2.15 (1.21)	60	0.16 (0.12)	-0.42 (-0.70, -0.14)	0.0033	-0.45 (-0.76, -0.13)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
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p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of change from baseline of 5-D Itch Scale at month 6 and 12 - Subgroup analysis
Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
		Subgroup	Baseline		Change from BL		Baseline		Change from BL		Difference of			Interaction
Score	Timepoint	Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value
ITCH5D-Distributi on Total	Month 12	Stratification variable: Baseline Pruritus NRS												0.0025
		< 4	79	1.57 (0.93)	79	0.01 (0.10)	42	1.50 (0.77)	42	0.03 (0.14)	-0.02 (-0.34, 0.30)	0.9022	-0.02 (-0.40, 0.35)	
		>= 4	49	3.10 (1.23)	49	-0.79 (0.16)	23	3.13 (1.14)	22	0.24 (0.24)	-1.03 (-1.61, -0.44)	0.0009	-0.89 (-1.41, -0.36)	
		Stratification variable: Baseline ALP Level												0.2826
		< 350 U/L	93	1.90 (1.15)	93	-0.26 (0.10)	47	2.04 (1.22)	46	0.02 (0.14)	-0.27 (-0.60, 0.06)	0.1031	-0.29 (-0.64, 0.07)	
		>= 350 U/L	35	2.83 (1.40)	35	-0.37 (0.18)	18	2.17 (1.20)	18	0.29 (0.26)	-0.66 (-1.30, -0.02)	0.0450	-0.60 (-1.18, -0.02)	
		Gamma-GT (GGT)												0.3591
		<= 3 x ULN	33	2.09 (1.31)	33	-0.33 (0.22)	14	1.86 (1.29)	13	-0.22 (0.31)	-0.11 (-0.76, 0.55)	0.7389	-0.09 (-0.73, 0.55)	
		> 3 x ULN	95	2.18 (1.29)	95	-0.31 (0.10)	51	2.14 (1.18)	51	0.13 (0.14)	-0.44 (-0.77, -0.11)	0.0092	-0.45 (-0.79, -0.11)	
		Total Bilirubin I												0.6537
		<= 1 x ULN	108	2.06 (1.21)	108	-0.22 (0.10)	60	2.07 (1.21)	59	0.12 (0.13)	-0.35 (-0.65, -0.04)	0.0252	-0.34 (-0.66, -0.02)	
		> 1 x ULN	20	2.70 (1.59)	20	-0.44 (0.19)	5	2.20 (1.30)	5	0.17 (0.52)	-0.60 (-1.73, 0.52)	0.2805	-0.65 (-1.64, 0.35)	
		Total Bilirubin II												0.0730
		< 0.6 x ULN	59	1.81 (1.14)	59	-0.04 (0.13)	32	2.13 (1.31)	31	0.12 (0.18)	-0.17 (-0.58, 0.25)	0.4246	-0.16 (-0.60, 0.27)	
		>= 0.6 x ULN	69	2.45 (1.35)	69	-0.46 (0.11)	33	2.03 (1.10)	33	0.21 (0.16)	-0.67 (-1.05, -0.29)	0.0007	-0.73 (-1.15, -0.30)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
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Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
			Baseline		Change from BL		Baseline		Change from BL					
Score	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
ITCH5D-Highest Disability	Month 6	Age at screening												0.4233
		< 65 years	99	2.38 (1.40)	99	-0.62 (0.09)	53	2.27 (1.25)	52	-0.19 (0.12)	-0.43 (-0.72, -0.15)	0.0034	-0.49 (-0.83, -0.15)	
		>= 65 years	29	1.90 (1.18)	29	-0.14 (0.19)	12	2.00 (1.21)	12	0.58 (0.29)	-0.72 (-1.38, -0.06)	0.0345	-0.70 (-1.39, -0.01)	
		Age at PBC diagnosis												0.1778
		< 50 years	61	2.40 (1.47)	61	-0.68 (0.12)	32	2.32 (1.22)	31	-0.02 (0.17)	-0.66 (-1.05, -0.26)	0.0014	-0.71 (-1.15, -0.26)	
		>= 50 years	67	2.16 (1.26)	67	-0.39 (0.11)	33	2.12 (1.27)	33	-0.10 (0.15)	-0.30 (-0.66, 0.07)	0.1072	-0.32 (-0.74, 0.10)	
		Sex												NE
		female	123	2.30 (1.36)	123	-0.54 (0.08)	60	2.27 (1.26)	59	-0.12 (0.11)	-0.42 (-0.68, -0.16)	0.0019	-0.48 (-0.79, -0.16)	
		male	5	1.60 (1.34)	5	NE	5	1.60 (0.89)	5	NE	NE		NE	
		Race												
		white	114	2.28 (1.35)	114		56	2.19 (1.25)	55					
		black	2	3.50 (0.71)	2		2	1.75 (1.06)	2					
		asian	7	1.43 (1.13)	7		4	2.63 (1.38)	4					
		other	5	2.90 (1.75)	5		3	2.50 (1.32)	3					
		Region												0.4389
		North America	50	2.16 (1.23)	50	-0.46 (0.14)	13	2.23 (1.13)	13	-0.18 (0.25)	-0.28 (-0.81, 0.25)	0.2884	-0.29 (-0.90, 0.33)	
		Europe	39	2.51 (1.44)	39	-0.61 (0.15)	24	2.53 (1.30)	23	-0.23 (0.20)	-0.38 (-0.86, 0.10)	0.1202	-0.40 (-0.92, 0.12)	
		Rest-of-World	39	2.18 (1.46)	39	-0.54 (0.15)	28	1.95 (1.21)	28	0.15 (0.17)	-0.69 (-1.12, -0.25)	0.0025	-0.75 (-1.25, -0.25)	
		Cirrhosis												0.5624
		yes	18	2.35 (1.50)	18	-0.23 (0.29)	9	2.44 (0.95)	9	0.47 (0.40)	-0.70 (-1.73, 0.34)	0.1723	-0.56 (-1.37, 0.26)	
		no	110	2.26 (1.35)	110	-0.56 (0.08)	56	2.18 (1.28)	55	-0.15 (0.12)	-0.40 (-0.67, -0.13)	0.0037	-0.46 (-0.79, -0.13)	
		UDCA												NE
		UDCA Use	120	2.26 (1.38)	120	-0.50 (0.09)	62	2.23 (1.23)	61	-0.02 (0.12)	-0.48 (-0.75, -0.20)	0.0007	-0.51 (-0.82, -0.20)	
		UDCA Intolerance	8	2.44 (1.11)	8	NE	3	2.00 (1.73)	3	NE	NE		NE	
		Prior Use of OCA and/or Fibrates												0.1476
		yes	20	2.59 (1.37)	20	-0.73 (0.20)	13	2.76 (1.30)	12	-0.67 (0.26)	-0.05 (-0.73, 0.62)	0.8754	-0.06 (-0.77, 0.66)	
		no	108	2.21 (1.36)	108	-0.48 (0.09)	52	2.09 (1.20)	52	0.10 (0.13)	-0.57 (-0.86, -0.28)	0.0001	-0.62 (-0.95, -0.28)	
		Therapy												NE
		Monotherapy (SEL)	8	2.44 (1.11)	8	NE	4	1.75 (1.50)	4	NE	NE		NE	
		Combinationtherapy (SEL + UDCA)	120	2.26 (1.38)	120	-0.50 (0.09)	61	2.25 (1.23)	60	-0.02 (0.12)	-0.48 (-0.76, -0.21)	0.0007	-0.51 (-0.83, -0.20)	

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			Seladelpar 10 mg (N=128)				Placebo (N=65)							
		Subgroup	Baseline		Change from BL		Baseline		Change from BL		Difference of			Interaction
Score	Timepoint	Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value
ITCH5D-Highest Disability	Month 6	Stratification variable: Baseline Pruritus NRS												0.0147
		< 4	79	1.51 (0.85)	79	-0.18 (0.09)	42	1.51 (0.78)	42	0.02 (0.11)	-0.20 (-0.46, 0.07)	0.1463	-0.26 (-0.63, 0.12)	
		>= 4	49	3.50 (1.12)	49	-1.21 (0.16)	23	3.51 (0.80)	22	-0.24 (0.24)	-0.97 (-1.55, -0.40)	0.0012	-0.85 (-1.38, -0.33)	
		Stratification variable: Baseline ALP Level												0.4548
		< 350 U/L	93	1.99 (1.21)	93	-0.38 (0.09)	47	2.17 (1.20)	46	0.03 (0.13)	-0.41 (-0.71, -0.11)	0.0085	-0.46 (-0.81, -0.10)	
		>= 350 U/L	35	3.04 (1.48)	35	-0.90 (0.16)	18	2.36 (1.36)	18	-0.25 (0.23)	-0.65 (-1.21, -0.09)	0.0247	-0.67 (-1.25, -0.09)	
		Gamma-GT (GGT)												0.2411
		<= 3 x ULN	33	2.11 (1.29)	33	-0.01 (0.19)	14	1.99 (1.18)	13	0.19 (0.26)	-0.20 (-0.71, 0.30)	0.4224	-0.19 (-0.83, 0.45)	
		> 3 x ULN	95	2.33 (1.39)	95	-0.58 (0.10)	51	2.28 (1.26)	51	-0.02 (0.13)	-0.55 (-0.87, -0.24)	0.0008	-0.58 (-0.93, -0.24)	
		Total Bilirubin I												0.6420
		<= 1 x ULN	108	2.25 (1.32)	108	-0.57 (0.09)	60	2.23 (1.26)	59	-0.07 (0.12)	-0.50 (-0.78, -0.22)	0.0005	-0.54 (-0.86, -0.21)	
		> 1 x ULN	20	2.41 (1.61)	20	-0.42 (0.22)	5	2.10 (1.08)	5	-0.18 (0.49)	-0.24 (-1.36, 0.87)	0.6554	-0.24 (-1.22, 0.75)	
		Total Bilirubin II												0.0493
		< 0.6 x ULN	59	2.05 (1.18)	59	-0.40 (0.11)	32	2.20 (1.23)	31	-0.21 (0.14)	-0.20 (-0.54, 0.14)	0.2472	-0.23 (-0.67, 0.20)	
		>= 0.6 x ULN	69	2.47 (1.48)	69	-0.58 (0.12)	33	2.24 (1.27)	33	0.14 (0.17)	-0.72 (-1.12, -0.32)	0.0006	-0.73 (-1.16, -0.31)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
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Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of change from baseline of 5-D Itch Scale at month 6 and 12 - Subgroup analysis
Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
			Baseline		Change from BL		Baseline		Change from BL					
Score	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
ITCH5D-Highest Disability	Month 12	Age at screening												0.5524
		< 65 years	99	2.38 (1.40)	99	-0.63 (0.11)	53	2.27 (1.25)	52	0.04 (0.16)	-0.67 (-1.05, -0.30)	0.0006	-0.59 (-0.93, -0.25)	
		>= 65 years	29	1.90 (1.18)	29	-0.22 (0.15)	12	2.00 (1.21)	12	0.27 (0.22)	-0.49 (-0.99, 0.01)	0.0537	-0.61 (-1.30, 0.08)	
		Age at PBC diagnosis												0.4611
		< 50 years	61	2.40 (1.47)	61	-0.64 (0.15)	32	2.32 (1.22)	31	0.08 (0.21)	-0.73 (-1.22, -0.23)	0.0046	-0.63 (-1.07, -0.19)	
		>= 50 years	67	2.16 (1.26)	67	-0.47 (0.12)	33	2.12 (1.27)	33	0.02 (0.17)	-0.49 (-0.88, -0.10)	0.0149	-0.50 (-0.92, -0.08)	
		Sex												NE
		female	123	2.30 (1.36)	123	-0.55 (0.09)	60	2.27 (1.26)	59	-0.05 (0.13)	-0.50 (-0.81, -0.19)	0.0019	-0.48 (-0.80, -0.17)	
		male	5	1.60 (1.34)	5	NE	5	1.60 (0.89)	5	NE	NE		NE	
		Race												
		white	114	2.28 (1.35)	114		56	2.19 (1.25)	55					
		black	2	3.50 (0.71)	2		2	1.75 (1.06)	2					
		asian	7	1.43 (1.13)	7		4	2.63 (1.38)	4					
		other	5	2.90 (1.75)	5		3	2.50 (1.32)	3					
		Region												0.1973
		North America	50	2.16 (1.23)	50	-0.63 (0.18)	13	2.23 (1.13)	13	0.48 (0.39)	-1.12 (-1.95, -0.28)	0.0103	-0.83 (-1.46, -0.20)	
		Europe	39	2.51 (1.44)	39	-0.48 (0.16)	24	2.53 (1.30)	23	-0.18 (0.21)	-0.29 (-0.81, 0.22)	0.2564	-0.29 (-0.81, 0.23)	
		Rest-of-World	39	2.18 (1.46)	39	-0.63 (0.14)	28	1.95 (1.21)	28	0.09 (0.17)	-0.72 (-1.14, -0.29)	0.0013	-0.80 (-1.31, -0.30)	
		Cirrhosis												0.8873
		yes	18	2.35 (1.50)	18	-0.34 (0.29)	9	2.44 (0.95)	9	0.30 (0.40)	-0.64 (-1.69, 0.42)	0.2144	-0.51 (-1.32, 0.31)	
		no	110	2.26 (1.35)	110	-0.55 (0.10)	56	2.18 (1.28)	55	0.01 (0.14)	-0.56 (-0.90, -0.23)	0.0011	-0.53 (-0.86, -0.20)	
		UDCA												NE
		UDCA Use	120	2.26 (1.38)	120	-0.56 (0.09)	62	2.23 (1.23)	61	0.06 (0.13)	-0.62 (-0.92, -0.32)	<.0001	-0.61 (-0.92, -0.30)	
		UDCA Intolerance	8	2.44 (1.11)	8	NE	3	2.00 (1.73)	3	NE	NE		NE	
		Prior Use of OCA and/or Fibrates												0.1788
		yes	20	2.59 (1.37)	20	-0.61 (0.30)	13	2.76 (1.30)	12	-0.52 (0.33)	-0.09 (-1.03, 0.85)	0.8419	-0.07 (-0.79, 0.65)	
		no	108	2.21 (1.36)	108	-0.53 (0.10)	52	2.09 (1.20)	52	0.20 (0.14)	-0.73 (-1.06, -0.40)	<.0001	-0.70 (-1.04, -0.36)	
		Therapy												NE
		Monotherapy (SEL)	8	2.44 (1.11)	8	NE	4	1.75 (1.50)	4	NE	NE		NE	
		Combinationtherapy (SEL + UDCA)	120	2.26 (1.38)	120	-0.56 (0.09)	61	2.25 (1.23)	60	0.07 (0.13)	-0.63 (-0.93, -0.32)	<.0001	-0.62 (-0.93, -0.30)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

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Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
		Subgroup	Baseline		Change from BL		Baseline		Change from BL		Difference of			Interaction
Score	Timepoint	Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value
ITCH5D-Highest Disability	Month 12	Stratification variable: Baseline Pruritus NRS												0.1777
		< 4	79	1.51 (0.85)	79	-0.18 (0.10)	42	1.51 (0.78)	42	0.28 (0.14)	-0.46 (-0.80, -0.12)	0.0080	-0.49 (-0.87, -0.11)	
		>= 4	49	3.50 (1.12)	49	-1.34 (0.17)	23	3.51 (0.80)	22	-0.41 (0.25)	-0.93 (-1.54, -0.32)	0.0034	-0.77 (-1.29, -0.25)	
		Stratification variable: Baseline ALP Level												0.6646
		< 350 U/L	93	1.99 (1.21)	93	-0.41 (0.10)	47	2.17 (1.20)	46	0.15 (0.15)	-0.56 (-0.91, -0.21)	0.0018	-0.55 (-0.91, -0.20)	
		>= 350 U/L	35	3.04 (1.48)	35	-0.95 (0.20)	18	2.36 (1.36)	18	-0.22 (0.29)	-0.73 (-1.45, -0.01)	0.0459	-0.60 (-1.18, -0.02)	
		Gamma-GT (GGT)												0.6676
		<= 3 x ULN	33	2.11 (1.29)	33	-0.07 (0.22)	14	1.99 (1.18)	13	0.65 (0.31)	-0.72 (-1.35, -0.09)	0.0273	-0.58 (-1.23, 0.08)	
		> 3 x ULN	95	2.33 (1.39)	95	-0.60 (0.11)	51	2.28 (1.26)	51	-0.03 (0.15)	-0.56 (-0.92, -0.20)	0.0025	-0.53 (-0.87, -0.18)	
		Total Bilirubin I												0.9075
		<= 1 x ULN	108	2.25 (1.32)	108	-0.57 (0.11)	60	2.23 (1.26)	59	0.03 (0.14)	-0.60 (-0.94, -0.26)	0.0006	-0.54 (-0.86, -0.21)	
		> 1 x ULN	20	2.41 (1.61)	20	-0.60 (0.18)	5	2.10 (1.08)	5	0.06 (0.49)	-0.66 (-1.73, 0.41)	0.2153	-0.74 (-1.74, 0.27)	
		Total Bilirubin II												0.0540
		< 0.6 x ULN	59	2.05 (1.18)	59	-0.34 (0.14)	32	2.20 (1.23)	31	-0.06 (0.20)	-0.28 (-0.75, 0.18)	0.2290	-0.25 (-0.69, 0.18)	
		>= 0.6 x ULN	69	2.47 (1.48)	69	-0.68 (0.12)	33	2.24 (1.27)	33	0.21 (0.18)	-0.89 (-1.32, -0.47)	<.0001	-0.86 (-1.30, -0.43)	

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p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

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Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
			Baseline		Change from BL		Baseline		Change from BL					
Score	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
ITCH5D-Modified Total Score	Month 6	Age at screening												0.5215
		< 65 years	99	8.52 (4.23)	99	-1.57 (0.27)	53	8.33 (4.15)	52	-0.22 (0.36)	-1.35 (-2.21, -0.49)	0.0024	-0.50 (-0.84, -0.16)	
		>= 65 years	29	7.47 (4.27)	29	-0.81 (0.43)	12	7.08 (2.92)	12	1.08 (0.66)	-1.89 (-3.38, -0.40)	0.0148	-0.80 (-1.50, -0.10)	
		Age at PBC diagnosis												0.8722
		< 50 years	61	8.75 (4.55)	61	-1.75 (0.36)	32	8.86 (4.35)	31	-0.35 (0.51)	-1.40 (-2.60, -0.19)	0.0236	-0.49 (-0.93, -0.05)	
		>= 50 years	67	7.86 (3.93)	67	-1.17 (0.29)	33	7.35 (3.45)	33	0.35 (0.38)	-1.52 (-2.42, -0.62)	0.0011	-0.66 (-1.08, -0.23)	
		Sex												NE
		female	123	8.36 (4.26)	123	-1.45 (0.23)	60	8.24 (4.00)	59	-0.06 (0.33)	-1.39 (-2.15, -0.63)	0.0004	-0.54 (-0.86, -0.23)	
		male	5	6.20 (3.62)	5	NE	5	6.40 (3.29)	5	NE	NE		NE	
		Race												
		white	114	8.33 (4.23)	114		56	8.10 (4.05)	55					
		black	2	11.17 (0.24)	2		2	5.75 (2.47)	2					
		asian	7	5.57 (2.32)	7		4	8.25 (3.30)	4					
		other	5	9.80 (6.09)	5		3	9.33 (4.86)	3					
		Region												0.5644
		North America	50	7.96 (3.63)	50	-1.19 (0.40)	13	7.82 (3.38)	13	-0.23 (0.71)	-0.96 (-2.47, 0.55)	0.2071	-0.34 (-0.96, 0.27)	
		Europe	39	8.38 (4.22)	39	-1.35 (0.38)	24	9.13 (4.32)	23	-0.06 (0.50)	-1.29 (-2.51, -0.08)	0.0379	-0.54 (-1.06, -0.01)	
		Rest-of-World	39	8.59 (5.01)	39	-1.71 (0.41)	28	7.34 (3.83)	28	0.22 (0.47)	-1.93 (-3.12, -0.74)	0.0019	-0.76 (-1.26, -0.26)	
		Cirrhosis												0.0474
		yes	18	9.72 (5.33)	18	-1.19 (0.71)	9	8.94 (3.20)	9	2.34 (0.97)	-3.53 (-6.06, -0.99)	0.0084	-1.14 (-2.01, -0.28)	
		no	110	8.04 (4.02)	110	-1.38 (0.23)	56	7.96 (4.08)	55	-0.40 (0.31)	-0.99 (-1.71, -0.26)	0.0082	-0.42 (-0.74, -0.09)	
		UDCA												NE
		UDCA Use	120	8.23 (4.27)	120	-1.32 (0.23)	62	8.19 (4.00)	61	0.06 (0.32)	-1.38 (-2.12, -0.64)	0.0003	-0.54 (-0.86, -0.23)	
		UDCA Intolerance	8	8.96 (3.95)	8	NE	3	6.22 (3.02)	3	NE	NE		NE	
		Prior Use of OCA and/or Fibrates												0.1414
		yes	20	9.53 (4.54)	20	-1.87 (0.57)	13	9.45 (4.11)	12	-1.63 (0.73)	-0.24 (-2.14, 1.65)	0.7944	-0.09 (-0.81, 0.62)	
		no	108	8.05 (4.17)	108	-1.32 (0.25)	52	7.76 (3.89)	52	0.41 (0.35)	-1.73 (-2.52, -0.93)	<.0001	-0.66 (-1.00, -0.32)	
		Therapy												NE
		Monotherapy (SEL)	8	8.96 (3.95)	8	NE	4	5.79 (2.62)	4	NE	NE		NE	
		Combinationtherapy (SEL + UDCA)	120	8.23 (4.27)	120	-1.34 (0.23)	61	8.25 (4.00)	60	0.04 (0.32)	-1.37 (-2.12, -0.62)	0.0004	-0.54 (-0.85, -0.22)	

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		Subgroup	Baseline		Change from BL		Baseline		Change from BL		Difference of			Interaction
Score	Timepoint	Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value
ITCH5D-Modified Total Score	Month 6	Stratification variable: Baseline Pruritus NRS												0.0085
		< 4	79	5.78 (2.36)	79	-0.36 (0.24)	42	5.74 (2.04)	42	0.28 (0.31)	-0.63 (-1.36, 0.10)	0.0890	-0.30 (-0.68, 0.07)	
		>= 4	49	12.31 (3.43)	49	-3.54 (0.43)	23	12.41 (2.80)	22	-0.65 (0.64)	-2.89 (-4.43, -1.34)	0.0004	-0.94 (-1.47, -0.42)	
		Stratification variable: Baseline ALP Level												0.1070
		< 350 U/L	93	7.40 (3.71)	93	-1.13 (0.25)	47	7.93 (4.01)	46	-0.17 (0.35)	-0.96 (-1.78, -0.14)	0.0219	-0.39 (-0.75, -0.04)	
		>= 350 U/L	35	10.62 (4.72)	35	-2.30 (0.48)	18	8.53 (3.92)	18	0.18 (0.70)	-2.48 (-4.18, -0.78)	0.0051	-0.85 (-1.44, -0.26)	
		Gamma-GT (GGT)												0.5144
		<= 3 x ULN	33	7.94 (4.10)	33	-0.85 (0.53)	14	6.87 (3.58)	13	0.14 (0.72)	-0.99 (-2.42, 0.43)	0.1666	-0.33 (-0.98, 0.31)	
		> 3 x ULN	95	8.40 (4.31)	95	-1.49 (0.27)	51	8.43 (4.03)	51	0.05 (0.36)	-1.54 (-2.40, -0.67)	0.0006	-0.59 (-0.94, -0.24)	
		Total Bilirubin I												0.9969
		<= 1 x ULN	108	8.04 (4.08)	108	-1.51 (0.25)	60	8.10 (4.01)	59	-0.07 (0.33)	-1.44 (-2.21, -0.67)	0.0003	-0.56 (-0.88, -0.23)	
		> 1 x ULN	20	9.57 (4.97)	20	-1.35 (0.60)	5	8.10 (3.75)	5	0.09 (1.44)	-1.44 (-4.63, 1.74)	0.3613	-0.50 (-1.49, 0.49)	
		Total Bilirubin II												0.0049
		< 0.6 x ULN	59	7.21 (3.39)	59	-0.80 (0.31)	32	8.09 (4.17)	31	-0.44 (0.41)	-0.36 (-1.31, 0.58)	0.4474	-0.15 (-0.59, 0.28)	
		>= 0.6 x ULN	69	9.19 (4.69)	69	-1.78 (0.32)	33	8.11 (3.81)	33	0.64 (0.46)	-2.42 (-3.51, -1.32)	<.0001	-0.90 (-1.33, -0.47)	

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			Baseline		Change from BL		Baseline		Change from BL					
Score	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
ITCH5D-Modified Total Score	Month 12	Age at screening												0.4500
		< 65 years	99	8.52 (4.23)	99	-1.77 (0.30)	53	8.33 (4.15)	52	-0.06 (0.41)	-1.71 (-2.70, -0.72)	0.0009	-0.56 (-0.91, -0.22)	
		>= 65 years	29	7.47 (4.27)	29	-0.94 (0.40)	12	7.08 (2.92)	12	1.38 (0.59)	-2.32 (-3.62, -1.02)	0.0009	-1.08 (-1.80, -0.36)	
		Age at PBC diagnosis												0.9020
		< 50 years	61	8.75 (4.55)	61	-1.82 (0.42)	32	8.86 (4.35)	31	0.07 (0.59)	-1.89 (-3.30, -0.48)	0.0092	-0.57 (-1.01, -0.13)	
		>= 50 years	67	7.86 (3.93)	67	-1.48 (0.28)	33	7.35 (3.45)	33	0.31 (0.39)	-1.79 (-2.70, -0.88)	0.0002	-0.77 (-1.20, -0.34)	
		Sex												NE
		female	123	8.36 (4.26)	123	-1.62 (0.26)	60	8.24 (4.00)	59	0.17 (0.37)	-1.79 (-2.66, -0.93)	<.0001	-0.62 (-0.94, -0.31)	
		male	5	6.20 (3.62)	5	NE	5	6.40 (3.29)	5	NE	NE		NE	
		Race												
		white	114	8.33 (4.23)	114		56	8.10 (4.05)	55					
		black	2	11.17 (0.24)	2		2	5.75 (2.47)	2					
		asian	7	5.57 (2.32)	7		4	8.25 (3.30)	4					
		other	5	9.80 (6.09)	5		3	9.33 (4.86)	3					
		Region												0.2835
		North America	50	7.96 (3.63)	50	-1.53 (0.54)	13	7.82 (3.38)	13	0.65 (1.10)	-2.18 (-4.56, 0.20)	0.0714	-0.56 (-1.18, 0.06)	
		Europe	39	8.38 (4.22)	39	-1.47 (0.36)	24	9.13 (4.32)	23	-0.34 (0.47)	-1.14 (-2.28, 0.01)	0.0515	-0.50 (-1.02, 0.02)	
		Rest-of-World	39	8.59 (5.01)	39	-1.90 (0.40)	28	7.34 (3.83)	28	0.51 (0.47)	-2.41 (-3.60, -1.22)	0.0001	-0.95 (-1.46, -0.44)	
		Cirrhosis												0.9406
		yes	18	9.72 (5.33)	18	-2.25 (0.68)	9	8.94 (3.20)	9	-0.57 (0.99)	-1.69 (-4.30, 0.93)	0.1925	-0.56 (-1.38, 0.25)	
		no	110	8.04 (4.02)	110	-1.44 (0.26)	56	7.96 (4.08)	55	0.15 (0.37)	-1.59 (-2.45, -0.72)	0.0004	-0.57 (-0.90, -0.24)	
		UDCA												NE
		UDCA Use	120	8.23 (4.27)	120	-1.64 (0.24)	62	8.19 (4.00)	61	0.23 (0.33)	-1.87 (-2.64, -1.11)	<.0001	-0.72 (-1.04, -0.40)	
		UDCA Intolerance	8	8.96 (3.95)	8	NE	3	6.22 (3.02)	3	NE	NE		NE	
		Prior Use of OCA and/or Fibrates												0.1796
		yes	20	9.53 (4.54)	20	-1.91 (0.55)	13	9.45 (4.11)	12	-1.18 (0.68)	-0.73 (-2.54, 1.07)	0.4069	-0.30 (-1.02, 0.42)	
		no	108	8.05 (4.17)	108	-1.49 (0.28)	52	7.76 (3.89)	52	0.57 (0.40)	-2.06 (-2.99, -1.13)	<.0001	-0.70 (-1.04, -0.36)	
		Therapy												NE
		Monotherapy (SEL)	8	8.96 (3.95)	8	NE	4	5.79 (2.62)	4	NE	NE		NE	
		Combinationtherapy (SEL + UDCA)	120	8.23 (4.27)	120	-1.65 (0.24)	61	8.25 (4.00)	60	0.23 (0.33)	-1.89 (-2.66, -1.12)	<.0001	-0.72 (-1.04, -0.40)	

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(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of change from baseline of 5-D Itch Scale at month 6 and 12 - Subgroup analysis
Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
		Subgroup	Baseline		Change from BL		Baseline		Change from BL		Difference of			Interaction
Score	Timepoint	Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value
ITCH5D-Modified Total Score	Month 12	Stratification variable: Baseline Pruritus NRS												0.0123
		< 4	79	5.78 (2.36)	79	-0.34 (0.29)	42	5.74 (2.04)	42	0.73 (0.39)	-1.06 (-1.99, -0.14)	0.0250	-0.41 (-0.79, -0.04)	
		>= 4	49	12.31 (3.43)	49	-4.24 (0.41)	23	12.41 (2.80)	22	-1.03 (0.60)	-3.21 (-4.65, -1.77)	<.0001	-1.12 (-1.66, -0.59)	
		Stratification variable: Baseline ALP Level												0.4534
		< 350 U/L	93	7.40 (3.71)	93	-1.29 (0.29)	47	7.93 (4.01)	46	0.24 (0.42)	-1.53 (-2.51, -0.55)	0.0025	-0.54 (-0.90, -0.18)	
		>= 350 U/L	35	10.62 (4.72)	35	-2.63 (0.46)	18	8.53 (3.92)	18	-0.38 (0.68)	-2.25 (-3.90, -0.59)	0.0090	-0.80 (-1.39, -0.21)	
		Gamma-GT (GGT)												0.7187
		<= 3 x ULN	33	7.94 (4.10)	33	-1.08 (0.55)	14	6.87 (3.58)	13	1.02 (0.76)	-2.10 (-3.61, -0.59)	0.0078	-0.67 (-1.33, -0.01)	
		> 3 x ULN	95	8.40 (4.31)	95	-1.70 (0.30)	51	8.43 (4.03)	51	0.07 (0.41)	-1.77 (-2.75, -0.79)	0.0005	-0.61 (-0.96, -0.26)	
		Total Bilirubin I												0.4230
		<= 1 x ULN	108	8.04 (4.08)	108	-1.53 (0.28)	60	8.10 (4.01)	59	0.11 (0.37)	-1.64 (-2.52, -0.75)	0.0004	-0.56 (-0.88, -0.23)	
		> 1 x ULN	20	9.57 (4.97)	20	-2.19 (0.47)	5	8.10 (3.75)	5	0.81 (1.57)	-3.00 (-6.32, 0.32)	0.0751	-1.20 (-2.25, -0.16)	
		Total Bilirubin II												0.0137
		< 0.6 x ULN	59	7.21 (3.39)	59	-0.65 (0.38)	32	8.09 (4.17)	31	0.06 (0.53)	-0.71 (-1.95, 0.53)	0.2594	-0.24 (-0.67, 0.20)	
		>= 0.6 x ULN	69	9.19 (4.69)	69	-2.33 (0.32)	33	8.11 (3.81)	33	0.41 (0.45)	-2.74 (-3.82, -1.67)	<.0001	-1.04 (-1.48, -0.60)	

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p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
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Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of change from baseline of 5-D Itch Scale at month 6 and 12 - Subgroup analysis
Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
		Subgroup	Baseline		Change from BL		Baseline		Change from BL		Difference of			Interaction
Score	Timepoint	Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value
ITCH5D-Total Score	Month 6	Age at screening												0.7628
		< 65 years	99	11.92 (4.77)	99	-2.23 (0.35)	53	11.48 (4.86)	52	-0.49 (0.47)	-1.74 (-2.86, -0.61)	0.0027	-0.50 (-0.84, -0.16)	
		>= 65 years	29	10.61 (5.10)	29	-1.30 (0.53)	12	10.08 (3.53)	12	0.75 (0.80)	-2.05 (-3.82, -0.28)	0.0247	-0.71 (-1.40, -0.01)	
		Age at PBC diagnosis												0.8951
		< 50 years	61	12.14 (5.18)	61	-2.37 (0.45)	32	12.01 (5.09)	31	-0.62 (0.63)	-1.75 (-3.25, -0.24)	0.0234	-0.49 (-0.93, -0.05)	
		>= 50 years	67	11.16 (4.53)	67	-1.84 (0.39)	33	10.47 (4.12)	33	0.03 (0.52)	-1.87 (-3.09, -0.66)	0.0029	-0.59 (-1.02, -0.17)	
		Sex												NE
		female	123	11.68 (4.90)	123	-2.10 (0.30)	60	11.40 (4.68)	59	-0.34 (0.43)	-1.77 (-2.76, -0.77)	0.0006	-0.53 (-0.84, -0.21)	
		male	5	10.20 (3.62)	5	NE	5	9.13 (4.09)	5	NE	NE		NE	
		Race												
		white	114	11.66 (4.85)	114		56	11.30 (4.70)	55					
		black	2	15.50 (0.71)	2		2	8.50 (2.83)	2					
		asian	7	8.64 (3.20)	7		4	10.88 (4.61)	4					
		other	5	13.50 (6.47)	5		3	12.17 (6.25)	3					
		Region												0.4791
		North America	50	11.40 (4.38)	50	-2.04 (0.53)	13	11.08 (4.01)	13	-1.09 (0.94)	-0.95 (-2.95, 1.05)	0.3470	-0.26 (-0.87, 0.36)	
		Europe	39	11.91 (4.45)	39	-1.95 (0.50)	24	12.59 (4.77)	23	-0.33 (0.66)	-1.61 (-3.22, -0.01)	0.0481	-0.51 (-1.04, 0.01)	
		Rest-of-World	39	11.64 (5.84)	39	-2.26 (0.54)	28	10.13 (4.67)	28	0.19 (0.62)	-2.45 (-4.03, -0.88)	0.0028	-0.73 (-1.23, -0.23)	
		Cirrhosis												0.0597
		yes	18	13.14 (6.23)	18	-1.99 (0.91)	9	12.33 (3.98)	9	2.33 (1.24)	-4.32 (-7.54, -1.10)	0.0106	-1.09 (-1.95, -0.23)	
		no	110	11.38 (4.58)	110	-1.98 (0.30)	56	11.05 (4.76)	55	-0.75 (0.41)	-1.24 (-2.20, -0.27)	0.0123	-0.39 (-0.72, -0.07)	
		UDCA												NE
		UDCA Use	120	11.59 (4.85)	120	-1.92 (0.30)	62	11.31 (4.67)	61	-0.19 (0.41)	-1.73 (-2.70, -0.77)	0.0005	-0.52 (-0.84, -0.21)	
		UDCA Intolerance	8	12.10 (5.24)	8	NE	3	9.44 (4.68)	3	NE	NE		NE	
		Prior Use of OCA and/or Fibrates												0.0250
		yes	20	12.75 (5.48)	20	-2.03 (0.76)	13	12.77 (5.03)	12	-2.68 (0.96)	0.66 (-1.84, 3.15)	0.5950	0.19 (-0.53, 0.91)	
		no	108	11.42 (4.73)	108	-2.02 (0.33)	52	10.84 (4.52)	52	0.29 (0.45)	-2.32 (-3.35, -1.29)	<.0001	-0.69 (-1.03, -0.35)	
		Therapy												NE
		Monotherapy (SEL)	8	12.10 (5.24)	8	NE	4	9.21 (3.85)	4	NE	NE		NE	
		Combinationtherapy (SEL + UDCA)	120	11.59 (4.85)	120	-1.93 (0.31)	61	11.36 (4.69)	60	-0.21 (0.42)	-1.72 (-2.69, -0.75)	0.0006	-0.52 (-0.83, -0.20)	

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Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
		Subgroup	Baseline		Change from BL		Baseline		Change from BL		Difference of			Interaction
Score	Timepoint	Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value
ITCH5D-Total Score	Month 6	Stratification variable: Baseline Pruritus NRS												0.0216
		< 4	79	8.76 (2.91)	79	-0.51 (0.34)	42	8.38 (2.47)	42	0.41 (0.45)	-0.92 (-1.96, 0.12)	0.0835	-0.31 (-0.68, 0.07)	
		>= 4	49	16.25 (3.64)	49	-4.73 (0.53)	23	16.41 (2.83)	22	-1.31 (0.79)	-3.42 (-5.32, -1.51)	0.0006	-0.91 (-1.43, -0.38)	
		Stratification variable: Baseline ALP Level												0.0947
		< 350 U/L	93	10.72 (4.33)	93	-1.76 (0.33)	47	11.07 (4.69)	46	-0.53 (0.46)	-1.23 (-2.29, -0.17)	0.0235	-0.39 (-0.74, -0.03)	
		>= 350 U/L	35	14.04 (5.39)	35	-2.92 (0.60)	18	11.64 (4.66)	18	0.31 (0.88)	-3.23 (-5.37, -1.08)	0.0039	-0.88 (-1.47, -0.28)	
		Gamma-GT (GGT)												0.6788
		<= 3 x ULN	33	11.25 (4.60)	33	-1.17 (0.71)	14	9.55 (3.99)	13	0.28 (0.98)	-1.45 (-3.47, 0.57)	0.1542	-0.36 (-1.01, 0.28)	
		> 3 x ULN	95	11.76 (4.96)	95	-2.19 (0.34)	51	11.69 (4.75)	51	-0.27 (0.46)	-1.93 (-3.04, -0.82)	0.0008	-0.58 (-0.93, -0.23)	
		Total Bilirubin I												0.9534
		<= 1 x ULN	108	11.33 (4.74)	108	-2.16 (0.33)	60	11.22 (4.70)	59	-0.34 (0.42)	-1.82 (-2.82, -0.83)	0.0004	-0.54 (-0.87, -0.22)	
		> 1 x ULN	20	13.22 (5.29)	20	-1.96 (0.81)	5	11.30 (4.55)	5	-0.01 (1.99)	-1.95 (-6.35, 2.45)	0.3716	-0.50 (-1.49, 0.49)	
		Total Bilirubin II												0.0099
		< 0.6 x ULN	59	10.36 (4.00)	59	-1.28 (0.42)	32	11.22 (4.83)	31	-0.73 (0.54)	-0.55 (-1.80, 0.70)	0.3839	-0.17 (-0.61, 0.26)	
		>= 0.6 x ULN	69	12.71 (5.27)	69	-2.50 (0.41)	33	11.23 (4.54)	33	0.50 (0.60)	-3.00 (-4.41, -1.59)	<.0001	-0.87 (-1.30, -0.44)	

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Mixed Effects Model (MMRM) analysis of change from baseline of 5-D Itch Scale at month 6 and 12 - Subgroup analysis
Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
			Baseline		Change from BL		Baseline		Change from BL					
Score	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
ITCH5D-Total Score	Month 12	Age at screening												0.7522
		< 65 years	99	11.92 (4.77)	99	-2.54 (0.40)	53	11.48 (4.86)	52	-0.25 (0.54)	-2.29 (-3.59, -1.00)	0.0006	-0.58 (-0.92, -0.24)	
		>= 65 years	29	10.61 (5.10)	29	-1.25 (0.56)	12	10.08 (3.53)	12	1.40 (0.84)	-2.65 (-4.51, -0.78)	0.0067	-0.86 (-1.57, -0.16)	
		Age at PBC diagnosis												0.9254
		< 50 years	61	12.14 (5.18)	61	-2.50 (0.53)	32	12.01 (5.09)	31	-0.09 (0.74)	-2.41 (-4.18, -0.65)	0.0081	-0.58 (-1.02, -0.14)	
		>= 50 years	67	11.16 (4.53)	67	-2.18 (0.41)	33	10.47 (4.12)	33	0.13 (0.56)	-2.31 (-3.62, -0.99)	0.0008	-0.69 (-1.12, -0.26)	
		Sex												NE
		female	123	11.68 (4.90)	123	-2.30 (0.34)	60	11.40 (4.68)	59	0.02 (0.49)	-2.32 (-3.47, -1.17)	0.0001	-0.61 (-0.93, -0.29)	
		male	5	10.20 (3.62)	5	NE	5	9.13 (4.09)	5	NE	NE		NE	
		Race												
		white	114	11.66 (4.85)	114		56	11.30 (4.70)	55					
		black	2	15.50 (0.71)	2		2	8.50 (2.83)	2					
		asian	7	8.64 (3.20)	7		4	10.88 (4.61)	4					
		other	5	13.50 (6.47)	5		3	12.17 (6.25)	3					
		Region												0.2053
		North America	50	11.40 (4.38)	50	-2.34 (0.68)	13	11.08 (4.01)	13	0.48 (1.40)	-2.82 (-5.85, 0.21)	0.0675	-0.57 (-1.19, 0.05)	
		Europe	39	11.91 (4.45)	39	-1.95 (0.50)	24	12.59 (4.77)	23	-0.64 (0.66)	-1.30 (-2.91, 0.30)	0.1095	-0.41 (-0.93, 0.11)	
		Rest-of-World	39	11.64 (5.84)	39	-2.63 (0.57)	28	10.13 (4.67)	28	0.71 (0.66)	-3.33 (-5.02, -1.65)	0.0002	-0.93 (-1.45, -0.42)	
		Cirrhosis												0.9249
		yes	18	13.14 (6.23)	18	-3.09 (0.84)	9	12.33 (3.98)	9	-1.11 (1.22)	-1.98 (-5.21, 1.25)	0.2167	-0.53 (-1.35, 0.28)	
		no	110	11.38 (4.58)	110	-2.08 (0.35)	56	11.05 (4.76)	55	0.05 (0.49)	-2.13 (-3.30, -0.97)	0.0004	-0.57 (-0.90, -0.24)	
		UDCA												NE
		UDCA Use	120	11.59 (4.85)	120	-2.30 (0.33)	62	11.31 (4.67)	61	0.14 (0.45)	-2.44 (-3.50, -1.39)	<.0001	-0.69 (-1.00, -0.37)	
		UDCA Intolerance	8	12.10 (5.24)	8	NE	3	9.44 (4.68)	3	NE	NE		NE	
		Prior Use of OCA and/or Fibrates												0.0546
		yes	20	12.75 (5.48)	20	-2.21 (0.84)	13	12.77 (5.03)	12	-2.20 (1.04)	-0.01 (-2.77, 2.75)	0.9957	-0.00 (-0.72, 0.71)	
		no	108	11.42 (4.73)	108	-2.21 (0.37)	52	10.84 (4.52)	52	0.63 (0.52)	-2.84 (-4.04, -1.63)	<.0001	-0.74 (-1.08, -0.40)	
		Therapy												NE
		Monotherapy (SEL)	8	12.10 (5.24)	8	NE	4	9.21 (3.85)	4	NE	NE		NE	
		Combinationtherapy (SEL + UDCA)	120	11.59 (4.85)	120	-2.31 (0.33)	61	11.36 (4.69)	60	0.14 (0.45)	-2.45 (-3.51, -1.39)	<.0001	-0.69 (-1.00, -0.37)	

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Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
			Baseline		Change from BL		Baseline		Change from BL					
Score	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
ITCH5D-Total Score	Month 12	Stratification variable: Baseline Pruritus NRS												0.0946
		< 4	79	8.76 (2.91)	79	-0.46 (0.39)	42	8.38 (2.47)	42	1.14 (0.54)	-1.60 (-2.86, -0.34)	0.0136	-0.45 (-0.83, -0.08)	
		>= 4	49	16.25 (3.64)	49	-5.52 (0.54)	23	16.41 (2.83)	22	-1.99 (0.80)	-3.53 (-5.47, -1.60)	0.0005	-0.92 (-1.45, -0.39)	
		Stratification variable: Baseline ALP Level												0.6282
		< 350 U/L	93	10.72 (4.33)	93	-2.06 (0.40)	47	11.07 (4.69)	46	0.06 (0.56)	-2.12 (-3.44, -0.80)	0.0018	-0.55 (-0.91, -0.19)	
		>= 350 U/L	35	14.04 (5.39)	35	-3.01 (0.57)	18	11.64 (4.66)	18	-0.30 (0.85)	-2.71 (-4.77, -0.65)	0.0113	-0.78 (-1.37, -0.19)	
		Gamma-GT (GGT)												0.3736
		<= 3 x ULN	33	11.25 (4.60)	33	-1.71 (0.74)	14	9.55 (3.99)	13	1.55 (1.04)	-3.26 (-5.38, -1.14)	0.0035	-0.78 (-1.44, -0.12)	
		> 3 x ULN	95	11.76 (4.96)	95	-2.38 (0.39)	51	11.69 (4.75)	51	-0.21 (0.53)	-2.16 (-3.44, -0.89)	0.0010	-0.57 (-0.92, -0.22)	
		Total Bilirubin I												0.2869
		<= 1 x ULN	108	11.33 (4.74)	108	-2.17 (0.38)	60	11.22 (4.70)	59	-0.03 (0.50)	-2.14 (-3.33, -0.96)	0.0005	-0.55 (-0.87, -0.23)	
		> 1 x ULN	20	13.22 (5.29)	20	-3.12 (0.59)	5	11.30 (4.55)	5	1.26 (1.91)	-4.38 (-8.44, -0.32)	0.0354	-1.41 (-2.48, -0.34)	
		Total Bilirubin II												0.0213
		< 0.6 x ULN	59	10.36 (4.00)	59	-1.10 (0.53)	32	11.22 (4.83)	31	-0.07 (0.72)	-1.02 (-2.71, 0.66)	0.2292	-0.25 (-0.69, 0.18)	
		>= 0.6 x ULN	69	12.71 (5.27)	69	-3.18 (0.41)	33	11.23 (4.54)	33	0.38 (0.59)	-3.56 (-4.97, -2.15)	<.0001	-1.04 (-1.48, -0.60)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Completion rates of PBC-40 Scores by visit
Intention-to-treat

Score	Timepoint	Seladelpar 10 mg (N=128) n/ N	Seladelpar 10 mg (N=128) Completion	Placebo (N=65) n/ N	Placebo (N=65) Completion
PBC40-Cognitive Domain Score	Baseline	128/ 128	100.0%	65/ 65	100.0%
	Month 1	118/ 128	92.19%	62/ 65	95.38%
	Month 3	121/ 128	94.53%	59/ 65	90.77%
	Month 6	113/ 128	88.28%	53/ 65	81.54%
	Month 9	112/ 128	87.50%	55/ 65	84.62%
	Month 12	94/ 128	73.44%	51/ 65	78.46%

n describes number of patients with non-missing value at the respective timepoint.
N defines number of patients still alive at beginning of respective visit window.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
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Intention-to-treat

Score	Timepoint	Seladelpar 10 mg (N=128) n/ N	Seladelpar 10 mg (N=128) Completion	Placebo (N=65) n/ N	Placebo (N=65) Completion
PBC40-Emotional Domain Score	Baseline	128/ 128	100.0%	65/ 65	100.0%
	Month 1	118/ 128	92.19%	62/ 65	95.38%
	Month 3	121/ 128	94.53%	59/ 65	90.77%
	Month 6	113/ 128	88.28%	53/ 65	81.54%
	Month 9	112/ 128	87.50%	55/ 65	84.62%
	Month 12	94/ 128	73.44%	51/ 65	78.46%

n describes number of patients with non-missing value at the respective timepoint.
N defines number of patients still alive at beginning of respective visit window.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Completion rates of PBC-40 Scores by visit
Intention-to-treat

Score	Timepoint	Seladelpar 10 mg (N=128) n/ N	Seladelpar 10 mg (N=128) Completion	Placebo (N=65) n/ N	Placebo (N=65) Completion
PBC40-Fatigue Domain Score	Baseline	128/ 128	100.0%	65/ 65	100.0%
	Month 1	118/ 128	92.19%	62/ 65	95.38%
	Month 3	121/ 128	94.53%	59/ 65	90.77%
	Month 6	113/ 128	88.28%	53/ 65	81.54%
	Month 9	112/ 128	87.50%	55/ 65	84.62%
	Month 12	94/ 128	73.44%	51/ 65	78.46%

n describes number of patients with non-missing value at the respective timepoint.
N defines number of patients still alive at beginning of respective visit window.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Completion rates of PBC-40 Scores by visit
Intention-to-treat

Score	Timepoint	Seladelpar 10 mg (N=128) n/ N	Seladelpar 10 mg (N=128) Completion	Placebo (N=65) n/ N	Placebo (N=65) Completion
PBC40-Itch Domain Score	Baseline	128/ 128	100.0%	65/ 65	100.0%
	Month 1	118/ 128	92.19%	62/ 65	95.38%
	Month 3	121/ 128	94.53%	59/ 65	90.77%
	Month 6	113/ 128	88.28%	53/ 65	81.54%
	Month 9	112/ 128	87.50%	55/ 65	84.62%
	Month 12	94/ 128	73.44%	51/ 65	78.46%

n describes number of patients with non-missing value at the respective timepoint.
N defines number of patients still alive at beginning of respective visit window.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Completion rates of PBC-40 Scores by visit
Intention-to-treat

Score	Timepoint	Seladelpar 10 mg (N=128) n/ N	Seladelpar 10 mg (N=128) Completion	Placebo (N=65) n/ N	Placebo (N=65) Completion
PBC40-Social Domain Score	Baseline	128/ 128	100.0%	65/ 65	100.0%
	Month 1	118/ 128	92.19%	62/ 65	95.38%
	Month 3	121/ 128	94.53%	59/ 65	90.77%
	Month 6	113/ 128	88.28%	53/ 65	81.54%
	Month 9	112/ 128	87.50%	55/ 65	84.62%
	Month 12	94/ 128	73.44%	51/ 65	78.46%

n describes number of patients with non-missing value at the respective timepoint.
N defines number of patients still alive at beginning of respective visit window.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Completion rates of PBC-40 Scores by visit
Intention-to-treat

Score	Timepoint	Seladelpar 10 mg (N=128) n/ N	Seladelpar 10 mg (N=128) Completion	Placebo (N=65) n/ N	Placebo (N=65) Completion
PBC40-Symptoms Domain Score	Baseline	128/ 128	100.0%	65/ 65	100.0%
	Month 1	118/ 128	92.19%	62/ 65	95.38%
	Month 3	121/ 128	94.53%	59/ 65	90.77%
	Month 6	113/ 128	88.28%	53/ 65	81.54%
	Month 9	112/ 128	87.50%	55/ 65	84.62%
	Month 12	94/ 128	73.44%	51/ 65	78.46%

n describes number of patients with non-missing value at the respective timepoint.
N defines number of patients still alive at beginning of respective visit window.

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Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Completion rates of PBC-40 Scores by visit
Intention-to-treat

Score	Timepoint	Seladelpar 10 mg (N=128) n/ N	Seladelpar 10 mg (N=128) Completion	Placebo (N=65) n/ N	Placebo (N=65) Completion
PBC40-Total Score	Baseline	128/ 128	100.0%	65/ 65	100.0%
	Month 1	118/ 128	92.19%	62/ 65	95.38%
	Month 3	121/ 128	94.53%	59/ 65	90.77%
	Month 6	113/ 128	88.28%	53/ 65	81.54%
	Month 9	112/ 128	87.50%	55/ 65	84.62%
	Month 12	94/ 128	73.44%	51/ 65	78.46%

n describes number of patients with non-missing value at the respective timepoint.
N defines number of patients still alive at beginning of respective visit window.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Summary of mean values and change from baseline of PBC-40 Scores by visit
Intention-to-treat

		Seladelpar 10 mg (N=128)				Placebo (N=65)			
		Value at Timepoint		Change from Baseline		Value at Timepoint		Change from Baseline	
Score	Timepoint	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
PBC40-Cognitive Domain Score	Baseline	128	13.22 (5.51)	128	0.00 (0.00)	65	12.84 (4.88)	65	0.00 (0.00)
	Month 1	118	12.44 (5.84)	118	-0.54 (2.54)	62	12.18 (5.38)	62	-0.57 (2.45)
	Month 3	121	12.69 (5.67)	121	-0.52 (2.76)	59	12.24 (5.41)	59	-0.67 (2.80)
	Month 6	113	12.68 (5.61)	113	-0.25 (2.80)	53	13.13 (5.93)	53	0.41 (3.27)
	Month 9	112	12.39 (5.69)	112	-0.42 (3.03)	55	12.45 (4.80)	55	-0.57 (3.23)
	Month 12	94	11.99 (5.61)	94	-0.55 (2.75)	51	12.39 (5.39)	51	-0.25 (3.82)

N describes number of patients with non-missing value at the respective timepoint.
N=Number of subjects included in the analysis, SD: Standard Deviation; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Summary of mean values and change from baseline of PBC-40 Scores by visit
Intention-to-treat

		Seladelpar 10 mg (N=128)				Placebo (N=65)			
		Value at Timepoint		Change from Baseline		Value at Timepoint		Change from Baseline	
Score	Timepoint	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
PBC40-Emotional Domain Score	Baseline	128	7.79 (2.89)	128	0.00 (0.00)	65	7.72 (3.15)	65	0.00 (0.00)
	Month 1	118	7.06 (2.97)	118	-0.59 (1.94)	62	6.76 (3.13)	62	-0.93 (1.83)
	Month 3	121	7.18 (2.94)	121	-0.64 (1.71)	59	6.97 (3.32)	59	-0.74 (2.14)
	Month 6	113	6.97 (2.94)	113	-0.65 (1.94)	53	6.94 (3.27)	53	-0.78 (1.86)
	Month 9	112	6.96 (2.75)	112	-0.77 (1.92)	55	6.82 (3.06)	55	-0.85 (2.11)
	Month 12	94	6.95 (3.02)	94	-0.76 (1.95)	51	6.73 (2.84)	51	-0.88 (2.34)

N describes number of patients with non-missing value at the respective timepoint.
N=Number of subjects included in the analysis, SD: Standard Deviation; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Summary of mean values and change from baseline of PBC-40 Scores by visit
Intention-to-treat

		Seladelpar 10 mg (N=128)				Placebo (N=65)			
		Value at Timepoint		Change from Baseline		Value at Timepoint		Change from Baseline	
Score	Timepoint	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
PBC40-Fatigue Domain Score	Baseline	128	27.57 (10.01)	128	0.00 (0.00)	65	27.41 (10.64)	65	0.00 (0.00)
	Month 1	118	25.93 (9.91)	118	-1.31 (5.66)	62	24.58 (10.36)	62	-2.33 (5.88)
	Month 3	121	25.75 (10.37)	121	-1.88 (4.98)	59	24.54 (10.22)	59	-2.28 (7.07)
	Month 6	113	24.97 (9.90)	113	-1.90 (5.53)	53	25.83 (10.12)	53	-0.42 (6.76)
	Month 9	112	24.51 (10.65)	112	-2.62 (6.46)	55	25.20 (10.15)	55	-1.50 (6.91)
	Month 12	94	23.78 (9.88)	94	-1.92 (6.09)	51	24.86 (9.81)	51	-1.17 (8.24)

N describes number of patients with non-missing value at the respective timepoint.
N=Number of subjects included in the analysis, SD: Standard Deviation; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Summary of mean values and change from baseline of PBC-40 Scores by visit
Intention-to-treat

		Seladelpar 10 mg (N=128)				Placebo (N=65)			
		Value at Timepoint		Change from Baseline		Value at Timepoint		Change from Baseline	
Score	Timepoint	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
PBC40-Itch Domain Score	Baseline	128	5.14 (3.85)	128	0.00 (0.00)	65	5.60 (3.97)	65	0.00 (0.00)
	Month 1	118	4.20 (3.07)	118	-0.72 (2.43)	62	5.05 (3.83)	62	-0.35 (2.60)
	Month 3	121	4.09 (3.14)	121	-0.95 (2.80)	59	5.31 (3.36)	59	-0.20 (2.80)
	Month 6	113	4.08 (3.15)	113	-0.88 (2.65)	53	5.23 (3.80)	53	-0.22 (3.06)
	Month 9	112	3.57 (2.77)	112	-1.24 (3.08)	55	4.87 (3.79)	55	-0.26 (2.59)
	Month 12	94	3.51 (3.33)	94	-1.38 (3.17)	51	4.31 (3.40)	51	-0.92 (2.82)

N describes number of patients with non-missing value at the respective timepoint.
N=Number of subjects included in the analysis, SD: Standard Deviation; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Summary of mean values and change from baseline of PBC-40 Scores by visit
Intention-to-treat

		Seladelpar 10 mg (N=128)				Placebo (N=65)			
		Value at Timepoint		Change from Baseline		Value at Timepoint		Change from Baseline	
Score	Timepoint	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
PBC40-Social Domain Score	Baseline	128	22.85 (8.44)	128	0.00 (0.00)	65	22.21 (8.32)	65	0.00 (0.00)
	Month 1	118	21.29 (7.96)	118	-0.92 (4.21)	62	20.56 (6.90)	62	-1.45 (5.16)
	Month 3	121	21.91 (8.27)	121	-0.99 (3.90)	59	20.37 (8.02)	59	-1.77 (4.93)
	Month 6	113	21.47 (7.96)	113	-0.59 (4.66)	53	20.64 (8.17)	53	-1.36 (5.21)
	Month 9	112	21.88 (8.62)	112	-0.67 (4.83)	55	20.35 (7.85)	55	-1.46 (5.13)
	Month 12	94	21.36 (8.53)	94	-0.73 (4.61)	51	19.80 (7.10)	51	-1.10 (5.10)

N describes number of patients with non-missing value at the respective timepoint.
N=Number of subjects included in the analysis, SD: Standard Deviation; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Summary of mean values and change from baseline of PBC-40 Scores by visit
Intention-to-treat

		Seladelpar 10 mg (N=128)				Placebo (N=65)			
		Value at Timepoint		Change from Baseline		Value at Timepoint		Change from Baseline	
Score	Timepoint	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
PBC40-Symptoms Domain Score	Baseline	128	15.06 (4.56)	128	0.00 (0.00)	65	15.67 (5.46)	65	0.00 (0.00)
	Month 1	118	14.55 (4.84)	118	-0.32 (2.78)	62	14.66 (5.29)	62	-0.68 (2.78)
	Month 3	121	14.80 (4.88)	121	-0.14 (2.52)	59	14.39 (5.24)	59	-0.90 (3.08)
	Month 6	113	14.33 (4.55)	113	-0.21 (2.54)	53	14.77 (5.08)	53	-0.58 (2.76)
	Month 9	112	14.54 (4.58)	112	-0.19 (2.89)	55	15.22 (5.02)	55	-0.31 (3.08)
	Month 12	94	14.43 (4.36)	94	-0.02 (2.65)	51	15.65 (5.57)	51	-0.27 (3.79)

N describes number of patients with non-missing value at the respective timepoint.
N=Number of subjects included in the analysis, SD: Standard Deviation; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Summary of mean values and change from baseline of PBC-40 Scores by visit
Intention-to-treat

		Seladelpar 10 mg (N=128)				Placebo (N=65)			
		Value at Timepoint		Change from Baseline		Value at Timepoint		Change from Baseline	
Score	Timepoint	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
PBC40-Total Score	Baseline	128	91.64 (29.32)	128	0.00 (0.00)	65	91.44 (29.45)	65	0.00 (0.00)
	Month 1	118	85.47 (28.34)	118	-4.40 (12.37)	62	83.79 (27.95)	62	-6.31 (13.48)
	Month 3	121	86.42 (29.59)	121	-5.12 (12.07)	59	83.81 (29.22)	59	-6.56 (15.34)
	Month 6	113	84.50 (27.31)	113	-4.48 (13.26)	53	86.55 (29.97)	53	-2.94 (15.78)
	Month 9	112	83.86 (29.49)	112	-5.91 (15.72)	55	84.91 (28.76)	55	-4.95 (15.86)
	Month 12	94	82.01 (28.84)	94	-5.36 (15.26)	51	83.75 (26.29)	51	-4.60 (19.03)

N describes number of patients with non-missing value at the respective timepoint.
N=Number of subjects included in the analysis, SD: Standard Deviation; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of change from baseline of PBC-40 Scores by visit
Intention-to-treat

		Seladelpar 10 mg (N=128)		Placebo (N=65)		Difference of		
Score	Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)
PBC40-Cognitive Domain Score	Month 1	126	-0.71 (0.24)	63	-0.74 (0.33)	0.03 (-0.73, 0.80)	0.9327	0.01 (-0.29, 0.31)
	Month 3	126	-0.60 (0.26)	63	-0.85 (0.37)	0.25 (-0.61, 1.12)	0.5601	0.09 (-0.22, 0.39)
	Month 6	126	-0.42 (0.29)	63	0.01 (0.41)	-0.43 (-1.38, 0.52)	0.3750	-0.13 (-0.44, 0.17)
	Month 9	126	-0.58 (0.29)	63	-0.65 (0.41)	0.08 (-0.89, 1.04)	0.8777	0.02 (-0.28, 0.33)
	Month 12	126	-0.55 (0.33)	63	-0.42 (0.44)	-0.13 (-1.20, 0.94)	0.8106	-0.04 (-0.34, 0.27)

(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
N=Number of subjects included in the analysis, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of change from baseline of PBC-40 Scores by visit
Intention-to-treat

		Seladelpar 10 mg (N=128)		Placebo (N=65)		Difference of		
Score	Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)
PBC40-Emotional Domain Score	Month 1	126	-0.66 (0.18)	63	-1.00 (0.24)	0.34 (-0.22, 0.90)	0.2376	0.17 (-0.13, 0.48)
	Month 3	126	-0.68 (0.17)	63	-0.85 (0.24)	0.17 (-0.40, 0.74)	0.5552	0.09 (-0.22, 0.39)
	Month 6	126	-0.68 (0.18)	63	-0.89 (0.26)	0.21 (-0.40, 0.81)	0.5013	0.10 (-0.20, 0.40)
	Month 9	126	-0.83 (0.18)	63	-0.88 (0.25)	0.05 (-0.54, 0.63)	0.8734	0.02 (-0.28, 0.33)
	Month 12	126	-0.70 (0.20)	63	-0.95 (0.27)	0.25 (-0.40, 0.90)	0.4488	0.11 (-0.19, 0.41)

(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
N=Number of subjects included in the analysis, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of change from baseline of PBC-40 Scores by visit
Intention-to-treat

		Seladelpar 10 mg (N=128)		Placebo (N=65)		Difference of		
Score	Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)
PBC40-Fatigue Domain Score	Month 1	126	-1.44 (0.54)	63	-2.42 (0.73)	0.98 (-0.73, 2.69)	0.2587	0.16 (-0.14, 0.47)
	Month 3	126	-1.88 (0.54)	63	-2.39 (0.75)	0.52 (-1.22, 2.26)	0.5573	0.09 (-0.22, 0.39)
	Month 6	126	-1.97 (0.57)	63	-0.78 (0.81)	-1.19 (-3.07, 0.69)	0.2131	-0.18 (-0.49, 0.12)
	Month 9	126	-2.69 (0.62)	63	-1.49 (0.86)	-1.20 (-3.21, 0.81)	0.2415	-0.17 (-0.48, 0.13)
	Month 12	126	-1.97 (0.67)	63	-1.50 (0.92)	-0.47 (-2.66, 1.71)	0.6692	-0.06 (-0.37, 0.24)

(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
N=Number of subjects included in the analysis, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
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Intention-to-treat

		Seladelpar 10 mg (N=128)		Placebo (N=65)		Difference of		
Score	Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)
PBC40-Itch Domain Score	Month 1	126	-0.62 (0.21)	63	-0.07 (0.29)	-0.56 (-1.22, 0.10)	0.0966	-0.24 (-0.54, 0.07)
	Month 3	126	-0.83 (0.22)	63	0.15 (0.31)	-0.98 (-1.70, -0.27)	0.0075	-0.39 (-0.69, -0.08)
	Month 6	126	-0.77 (0.23)	63	0.16 (0.33)	-0.93 (-1.68, -0.18)	0.0159	-0.35 (-0.66, -0.05)
	Month 9	126	-1.20 (0.24)	63	0.04 (0.33)	-1.24 (-1.99, -0.48)	0.0015	-0.47 (-0.77, -0.16)
	Month 12	126	-1.31 (0.26)	63	-0.48 (0.36)	-0.83 (-1.68, 0.02)	0.0544	-0.28 (-0.59, 0.02)

(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
N=Number of subjects included in the analysis, SE: Standard Error; CI=Confidence Interval

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Mixed Effects Model (MMRM) analysis of change from baseline of PBC-40 Scores by visit
Intention-to-treat

		Seladelpar 10 mg (N=128)		Placebo (N=65)		Difference of		
Score	Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)
PBC40-Social Domain Score	Month 1	126	-1.00 (0.41)	63	-1.53 (0.55)	0.53 (-0.77, 1.83)	0.4191	0.12 (-0.19, 0.42)
	Month 3	126	-0.94 (0.40)	63	-1.87 (0.56)	0.93 (-0.36, 2.23)	0.1575	0.21 (-0.10, 0.51)
	Month 6	126	-0.66 (0.46)	63	-1.61 (0.65)	0.95 (-0.58, 2.47)	0.2216	0.18 (-0.12, 0.49)
	Month 9	126	-0.74 (0.47)	63	-1.74 (0.65)	1.00 (-0.54, 2.54)	0.2025	0.19 (-0.11, 0.49)
	Month 12	126	-0.67 (0.47)	63	-1.72 (0.64)	1.05 (-0.47, 2.56)	0.1735	0.20 (-0.10, 0.50)

(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
N=Number of subjects included in the analysis, SE: Standard Error; CI=Confidence Interval

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Mixed Effects Model (MMRM) analysis of change from baseline of PBC-40 Scores by visit
Intention-to-treat

Score	Visit	Seladelpar 10 mg (N=128) N	Seladelpar 10 mg (N=128) LSMean (SE)	Placebo (N=65) N	Placebo (N=65) LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)
PBC40-Symptoms Domain Score	Month 1	126	-0.44 (0.26)	63	-0.68 (0.36)	0.24 (-0.60, 1.08)	0.5742	0.08 (-0.22, 0.38)
	Month 3	126	-0.19 (0.26)	63	-0.80 (0.36)	0.61 (-0.23, 1.44)	0.1524	0.21 (-0.09, 0.51)
	Month 6	126	-0.35 (0.24)	63	-0.52 (0.35)	0.17 (-0.64, 0.97)	0.6827	0.06 (-0.24, 0.36)
	Month 9	126	-0.28 (0.27)	63	-0.21 (0.38)	-0.07 (-0.96, 0.82)	0.8765	-0.02 (-0.33, 0.28)
	Month 12	126	-0.10 (0.30)	63	-0.19 (0.41)	0.09 (-0.87, 1.06)	0.8475	0.03 (-0.27, 0.33)

(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
N=Number of subjects included in the analysis, SE: Standard Error; CI=Confidence Interval

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RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of change from baseline of PBC-40 Scores by visit
Intention-to-treat

		Seladelpar 10 mg (N=128)		Placebo (N=65)		Difference of		
Score	Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)
PBC40-Total Score	Month 1	126	-5.62 (1.21)	63	-7.40 (1.62)	1.78 (-1.98, 5.55)	0.3512	0.13 (-0.17, 0.44)
	Month 3	126	-5.85 (1.25)	63	-7.60 (1.73)	1.75 (-2.26, 5.75)	0.3902	0.12 (-0.18, 0.43)
	Month 6	126	-5.57 (1.34)	63	-4.65 (1.88)	-0.92 (-5.30, 3.46)	0.6787	-0.06 (-0.36, 0.24)
	Month 9	126	-6.97 (1.47)	63	-5.64 (2.04)	-1.33 (-6.11, 3.45)	0.5839	-0.08 (-0.38, 0.22)
	Month 12	126	-5.85 (1.64)	63	-6.19 (2.23)	0.33 (-4.98, 5.64)	0.9019	0.02 (-0.28, 0.32)

(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
N=Number of subjects included in the analysis, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of change from baseline of PBC-40 Scores at month 6 and 12 - Subgroup analysis
Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
			Baseline		Change from BL		Baseline		Change from BL					
Score	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
PBC40-Cognitive Domain Score	Month 6	Age at screening												0.1621
		< 65 years	99	13.32 (5.47)	97	-0.48 (0.33)	53	12.77 (4.73)	51	0.27 (0.45)	-0.74 (-1.82, 0.33)	0.1735	-0.23 (-0.57, 0.11)	
		>= 65 years	29	12.86 (5.72)	29	-0.27 (0.58)	12	13.13 (5.73)	12	-1.22 (0.96)	0.95 (-1.24, 3.13)	0.3867	0.29 (-0.38, 0.97)	
		Age at PBC diagnosis												0.0906
		< 50 years	61	12.87 (5.41)	59	-0.44 (0.40)	32	12.81 (5.02)	30	0.82 (0.56)	-1.26 (-2.60, 0.08)	0.0651	-0.41 (-0.85, 0.03)	
		>= 50 years	67	13.54 (5.62)	67	-0.51 (0.42)	33	12.86 (4.82)	33	-0.89 (0.59)	0.37 (-1.00, 1.75)	0.5905	0.11 (-0.31, 0.53)	
		Sex												NE
		female	123	13.37 (5.46)	121	-0.47 (0.29)	60	12.97 (4.94)	58	-0.03 (0.42)	-0.44 (-1.42, 0.54)	0.3778	-0.14 (-0.45, 0.18)	
		male	5	9.60 (6.22)	5	NE	5	11.30 (4.35)	5	NE	NE		NE	
		Race												
		white	114	13.50 (5.63)	113		56	12.75 (4.92)	54					
		black	2	10.50 (3.54)	2		2	13.25 (4.60)	2					
		asian	7	10.29 (4.57)	7		4	13.25 (5.50)	4					
		other	5	12.00 (3.26)	4		3	13.67 (6.29)	3					
		Region												0.7791
		North America	50	14.37 (6.18)	49	-0.64 (0.49)	13	13.04 (5.05)	12	0.10 (0.99)	-0.75 (-2.88, 1.39)	0.4858	-0.21 (-0.85, 0.42)	
		Europe	39	12.94 (5.08)	39	-0.16 (0.58)	24	12.73 (4.17)	23	0.80 (0.79)	-0.95 (-2.90, 0.99)	0.3298	-0.25 (-0.77, 0.26)	
		Rest-of-World	39	12.03 (4.80)	38	-0.63 (0.44)	28	12.84 (5.51)	28	-0.45 (0.52)	-0.19 (-1.50, 1.13)	0.7793	-0.07 (-0.56, 0.42)	
		Cirrhosis												0.4003
		yes	18	13.83 (6.17)	18	-0.12 (0.85)	9	12.06 (5.51)	9	1.44 (1.32)	-1.56 (-4.88, 1.76)	0.3327	-0.41 (-1.22, 0.40)	
		no	110	13.12 (5.42)	108	-0.42 (0.31)	56	12.96 (4.82)	54	-0.24 (0.43)	-0.18 (-1.20, 0.84)	0.7300	-0.06 (-0.38, 0.27)	
		UDCA												NE
		UDCA Use	120	13.17 (5.41)	118	-0.36 (0.30)	62	12.98 (4.91)	60	0.03 (0.42)	-0.40 (-1.39, 0.60)	0.4321	-0.12 (-0.43, 0.19)	
		UDCA Intolerance	8	14.00 (7.20)	8	NE	3	10.00 (4.00)	3	NE	NE		NE	
		Prior Use of OCA and/or Fibrates												0.2241
		yes	20	13.50 (6.17)	18	-0.31 (0.72)	13	13.77 (4.17)	12	-1.24 (0.89)	0.93 (-1.44, 3.30)	0.4276	0.29 (-0.44, 1.03)	
		no	108	13.17 (5.41)	108	-0.48 (0.32)	52	12.61 (5.06)	51	0.13 (0.46)	-0.61 (-1.68, 0.45)	0.2542	-0.19 (-0.52, 0.15)	
		Therapy												0.0218
		Monotherapy (SEL)	8	14.00 (7.20)	8	-0.82 (0.70)	4	11.00 (3.83)	4	3.08 (1.23)	-3.91 (-7.85, 0.04)	0.0514	-1.69 (-3.15, -0.23)	
		Combinationtherapy (SEL + UDCA)	120	13.17 (5.41)	118	-0.36 (0.30)	61	12.96 (4.95)	59	-0.04 (0.42)	-0.32 (-1.32, 0.68)	0.5301	-0.10 (-0.41, 0.22)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

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Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
			Baseline		Change from BL		Baseline		Change from BL					
Score	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
PBC40-Cognitive Domain Score	Month 6	Stratification variable: Baseline Pruritus NRS												0.0207
		< 4	79	11.91 (5.32)	79	0.37 (0.38)	42	11.17 (4.56)	41	0.04 (0.50)	0.34 (-0.84, 1.51)	0.5710	0.10 (-0.28, 0.48)	
		>= 4	49	15.34 (5.18)	47	-1.37 (0.44)	23	15.89 (3.95)	22	0.61 (0.68)	-1.98 (-3.59, -0.36)	0.0172	-0.64 (-1.16, -0.12)	
		Stratification variable: Baseline ALP Level												0.9925
		< 350 U/L	93	13.18 (5.55)	92	-0.07 (0.34)	47	13.14 (4.87)	45	0.30 (0.49)	-0.37 (-1.52, 0.78)	0.5266	-0.11 (-0.47, 0.25)	
		>= 350 U/L	35	13.33 (5.48)	34	-0.85 (0.48)	18	12.06 (4.98)	18	-0.47 (0.70)	-0.38 (-2.09, 1.33)	0.6574	-0.13 (-0.70, 0.44)	
		Gamma-GT (GGT)												0.0314
		<= 3 x ULN	33	13.15 (5.55)	32	-0.02 (0.75)	14	12.79 (4.81)	13	-1.70 (1.07)	1.67 (-0.53, 3.87)	0.1325	0.39 (-0.26, 1.04)	
		> 3 x ULN	95	13.24 (5.52)	94	-0.47 (0.32)	51	12.85 (4.95)	50	0.47 (0.45)	-0.94 (-2.02, 0.14)	0.0863	-0.30 (-0.64, 0.05)	
		Total Bilirubin I												0.1242
		<= 1 x ULN	108	13.36 (5.62)	106	-0.72 (0.32)	60	12.90 (4.88)	59	-0.02 (0.41)	-0.70 (-1.68, 0.29)	0.1629	-0.22 (-0.53, 0.10)	
		> 1 x ULN	20	12.48 (4.96)	20	0.68 (0.75)	5	12.10 (5.50)	4	-2.20 (2.14)	2.87 (-1.82, 7.57)	0.2182	0.79 (-0.31, 1.89)	
		Total Bilirubin II												0.1441
		< 0.6 x ULN	59	13.38 (5.05)	58	-0.77 (0.49)	32	13.34 (4.73)	31	0.36 (0.62)	-1.13 (-2.58, 0.32)	0.1239	-0.31 (-0.75, 0.13)	
		>= 0.6 x ULN	69	13.08 (5.90)	68	-0.11 (0.35)	33	12.35 (5.05)	32	-0.39 (0.54)	0.28 (-0.98, 1.54)	0.6611	0.09 (-0.33, 0.51)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
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p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

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			Seladelpar 10 mg (N=128)				Placebo (N=65)							
			Baseline		Change from BL		Baseline		Change from BL					
Score	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
PBC40-Cognitive Domain Score	Month 12	Age at screening												0.3271
		< 65 years	99	13.32 (5.47)	97	-0.47 (0.40)	53	12.77 (4.73)	51	-0.59 (0.54)	0.12 (-1.17, 1.41)	0.8547	0.03 (-0.31, 0.37)	
		>= 65 years	29	12.86 (5.72)	29	-1.00 (0.54)	12	13.13 (5.73)	12	-0.08 (0.70)	-0.92 (-2.62, 0.79)	0.2806	-0.32 (-1.00, 0.35)	
		Age at PBC diagnosis												0.2770
		< 50 years	61	12.87 (5.41)	59	-0.98 (0.49)	32	12.81 (5.02)	30	-0.21 (0.67)	-0.77 (-2.40, 0.87)	0.3528	-0.20 (-0.64, 0.24)	
		>= 50 years	67	13.54 (5.62)	67	-0.25 (0.45)	33	12.86 (4.82)	33	-0.67 (0.60)	0.42 (-1.02, 1.86)	0.5617	0.12 (-0.30, 0.53)	
		Sex												NE
		female	123	13.37 (5.46)	121	-0.52 (0.34)	60	12.97 (4.94)	58	-0.52 (0.47)	0.00 (-1.12, 1.13)	0.9952	0.00 (-0.31, 0.31)	
		male	5	9.60 (6.22)	5	NE	5	11.30 (4.35)	5	NE	NE		NE	
		Race												
		white	114	13.50 (5.63)	113		56	12.75 (4.92)	54					
		black	2	10.50 (3.54)	2		2	13.25 (4.60)	2					
		asian	7	10.29 (4.57)	7		4	13.25 (5.50)	4					
		other	5	12.00 (3.26)	4		3	13.67 (6.29)	3					
		Region												0.0357
		North America	50	14.37 (6.18)	49	-0.57 (0.47)	13	13.04 (5.05)	12	-1.94 (0.90)	1.37 (-0.55, 3.30)	0.1583	0.42 (-0.22, 1.05)	
		Europe	39	12.94 (5.08)	39	-0.68 (0.56)	24	12.73 (4.17)	23	1.20 (0.72)	-1.88 (-3.67, -0.09)	0.0403	-0.53 (-1.06, -0.01)	
		Rest-of-World	39	12.03 (4.80)	38	-0.67 (0.66)	28	12.84 (5.51)	28	-1.11 (0.74)	0.44 (-1.52, 2.40)	0.6525	0.11 (-0.38, 0.60)	
		Cirrhosis												0.6993
		yes	18	13.83 (6.17)	18	-0.72 (0.55)	9	12.06 (5.51)	9	-1.10 (1.02)	0.37 (-2.01, 2.75)	0.7437	0.14 (-0.66, 0.94)	
		no	110	13.12 (5.42)	108	-0.50 (0.37)	56	12.96 (4.82)	54	-0.38 (0.48)	-0.12 (-1.29, 1.06)	0.8439	-0.03 (-0.36, 0.30)	
		UDCA												NE
		UDCA Use	120	13.17 (5.41)	118	-0.52 (0.35)	62	12.98 (4.91)	60	-0.37 (0.47)	-0.15 (-1.28, 0.98)	0.7915	-0.04 (-0.35, 0.27)	
		UDCA Intolerance	8	14.00 (7.20)	8	NE	3	10.00 (4.00)	3	NE	NE		NE	
		Prior Use of OCA and/or Fibrates												0.7198
		yes	20	13.50 (6.17)	18	0.09 (0.99)	13	13.77 (4.17)	12	-0.41 (1.16)	0.50 (-2.70, 3.70)	0.7489	0.12 (-0.61, 0.85)	
		no	108	13.17 (5.41)	108	-0.59 (0.36)	52	12.61 (5.06)	51	-0.49 (0.51)	-0.09 (-1.29, 1.10)	0.8767	-0.03 (-0.36, 0.31)	
		Therapy												0.3447
		Monotherapy (SEL)	8	14.00 (7.20)	8	-0.69 (0.53)	4	11.00 (3.83)	4	-2.12 (1.41)	1.42 (-4.44, 7.29)	0.4457	0.66 (-0.58, 1.90)	
		Combinationtherapy (SEL + UDCA)	120	13.17 (5.41)	118	-0.51 (0.35)	61	12.96 (4.95)	59	-0.37 (0.47)	-0.15 (-1.28, 0.98)	0.7976	-0.04 (-0.35, 0.27)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of change from baseline of PBC-40 Scores at month 6 and 12 - Subgroup analysis
Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
			Baseline		Change from BL		Baseline		Change from BL					
Score	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
PBC40-Cognitive Domain Score	Month 12	Stratification variable: Baseline Pruritus NRS												0.4555
		< 4	79	11.91 (5.32)	79	0.12 (0.43)	42	11.17 (4.56)	41	-0.00 (0.55)	0.12 (-1.20, 1.44)	0.8566	0.03 (-0.35, 0.41)	
		>= 4	49	15.34 (5.18)	47	-1.35 (0.52)	23	15.89 (3.95)	22	-0.62 (0.78)	-0.74 (-2.62, 1.14)	0.4351	-0.20 (-0.71, 0.31)	
		Stratification variable: Baseline ALP Level												0.7549
		< 350 U/L	93	13.18 (5.55)	92	-0.54 (0.41)	47	13.14 (4.87)	45	-0.34 (0.57)	-0.20 (-1.56, 1.16)	0.7743	-0.05 (-0.41, 0.31)	
		>= 350 U/L	35	13.33 (5.48)	34	-0.28 (0.45)	18	12.06 (4.98)	18	-0.40 (0.61)	0.12 (-1.40, 1.64)	0.8732	0.05 (-0.53, 0.62)	
		Gamma-GT (GGT)												0.2382
		<= 3 x ULN	33	13.15 (5.55)	32	0.32 (0.98)	14	12.79 (4.81)	13	-1.20 (1.49)	1.53 (-1.76, 4.81)	0.3516	0.27 (-0.37, 0.92)	
		> 3 x ULN	95	13.24 (5.52)	94	-0.76 (0.34)	51	12.85 (4.95)	50	-0.28 (0.43)	-0.48 (-1.55, 0.59)	0.3731	-0.15 (-0.49, 0.19)	
		Total Bilirubin I												0.9653
		<= 1 x ULN	108	13.36 (5.62)	106	-0.72 (0.37)	60	12.90 (4.88)	59	-0.54 (0.47)	-0.18 (-1.32, 0.96)	0.7565	-0.05 (-0.37, 0.27)	
		> 1 x ULN	20	12.48 (4.96)	20	-0.25 (0.70)	5	12.10 (5.50)	4	-0.16 (1.88)	-0.09 (-4.25, 4.07)	0.9653	-0.03 (-1.10, 1.05)	
		Total Bilirubin II												0.7874
		< 0.6 x ULN	59	13.38 (5.05)	58	-0.40 (0.56)	32	13.34 (4.73)	31	-0.44 (0.72)	0.04 (-1.68, 1.76)	0.9617	0.01 (-0.43, 0.45)	
		>= 0.6 x ULN	69	13.08 (5.90)	68	-0.64 (0.42)	33	12.35 (5.05)	32	-0.38 (0.58)	-0.26 (-1.67, 1.15)	0.7151	-0.08 (-0.50, 0.34)	

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p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of change from baseline of PBC-40 Scores at month 6 and 12 - Subgroup analysis
Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
			Baseline		Change from BL		Baseline		Change from BL					
Score	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
PBC40-Emotional Domain Score	Month 6	Age at screening												0.4581
		< 65 years	99	8.01 (2.91)	97	-0.76 (0.21)	53	7.73 (3.11)	51	-0.80 (0.29)	0.04 (-0.65, 0.72)	0.9173	0.02 (-0.32, 0.36)	
		>= 65 years	29	7.05 (2.73)	29	-0.44 (0.36)	12	7.67 (3.45)	12	-1.03 (0.61)	0.59 (-0.76, 1.95)	0.3800	0.29 (-0.38, 0.97)	
		Age at PBC diagnosis												0.9401
		< 50 years	61	8.09 (2.91)	59	-0.60 (0.25)	32	7.84 (2.96)	30	-0.84 (0.35)	0.23 (-0.60, 1.07)	0.5815	0.12 (-0.32, 0.56)	
		>= 50 years	67	7.52 (2.87)	67	-0.67 (0.28)	33	7.59 (3.36)	33	-0.85 (0.39)	0.19 (-0.70, 1.08)	0.6778	0.08 (-0.33, 0.50)	
		Sex												0.0622
		female	123	7.88 (2.86)	121	-0.70 (0.19)	60	7.87 (3.08)	58	-1.02 (0.28)	0.32 (-0.32, 0.96)	0.3237	0.15 (-0.16, 0.47)	
		male	5	5.60 (3.03)	5	0.79 (1.15)	5	5.90 (3.80)	5	2.26 (1.45)	-1.47 (-3.79, 0.85)	0.1643	-0.46 (-1.72, 0.81)	
		Race												
		white	114	7.85 (2.91)	113		56	7.46 (3.06)	54					
		black	2	8.00 (0.00)	2		2	9.25 (1.77)	2					
		asian	7	6.71 (2.72)	7		4	9.88 (3.71)	4					
		other	5	8.00 (3.61)	4		3	8.67 (4.75)	3					
		Region												0.1122
		North America	50	7.51 (2.72)	49	-0.59 (0.29)	13	7.85 (4.06)	12	-1.78 (0.56)	1.19 (-0.01, 2.38)	0.0510	0.59 (-0.05, 1.23)	
		Europe	39	7.94 (3.08)	39	-0.40 (0.37)	24	6.94 (2.28)	23	-0.79 (0.50)	0.39 (-0.85, 1.63)	0.5311	0.16 (-0.35, 0.68)	
		Rest-of-World	39	8.01 (2.95)	38	-0.86 (0.32)	28	8.32 (3.29)	28	-0.45 (0.39)	-0.41 (-1.38, 0.57)	0.4096	-0.20 (-0.69, 0.29)	
		Cirrhosis												0.8244
		yes	18	8.36 (3.09)	18	-0.94 (0.36)	9	8.72 (4.79)	9	-1.01 (0.57)	0.07 (-1.30, 1.43)	0.9206	0.04 (-0.76, 0.84)	
		no	110	7.70 (2.86)	108	-0.66 (0.21)	56	7.55 (2.83)	54	-0.89 (0.29)	0.23 (-0.44, 0.90)	0.5013	0.11 (-0.22, 0.43)	
		UDCA												NE
		UDCA Use	120	7.79 (2.94)	118	-0.65 (0.19)	62	7.77 (3.05)	60	-0.87 (0.27)	0.22 (-0.41, 0.85)	0.4850	0.11 (-0.20, 0.42)	
		UDCA Intolerance	8	7.81 (2.15)	8	NE	3	6.50 (5.63)	3	NE	NE		NE	
		Prior Use of OCA and/or Fibrates												0.3315
		yes	20	8.13 (3.27)	18	-0.20 (0.58)	13	7.77 (2.96)	12	-1.15 (0.70)	0.96 (-0.92, 2.83)	0.3027	0.38 (-0.36, 1.12)	
		no	108	7.73 (2.83)	108	-0.76 (0.20)	52	7.70 (3.22)	51	-0.78 (0.29)	0.02 (-0.64, 0.67)	0.9554	0.01 (-0.32, 0.34)	
		Therapy												NE
		Monotherapy (SEL)	8	7.81 (2.15)	8	NE	4	7.25 (4.84)	4	NE	NE		NE	
		Combinationtherapy (SEL + UDCA)	120	7.79 (2.94)	118	-0.64 (0.19)	61	7.75 (3.06)	59	-0.95 (0.27)	0.31 (-0.32, 0.93)	0.3313	0.15 (-0.16, 0.46)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
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p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of change from baseline of PBC-40 Scores at month 6 and 12 - Subgroup analysis
Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
			Baseline		Change from BL		Baseline		Change from BL					
Score	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
PBC40-Emotional Domain Score	Month 6	Stratification variable: Baseline Pruritus NRS												0.3608
		< 4	79	6.92 (2.66)	79	-0.48 (0.22)	42	6.61 (2.83)	41	-0.86 (0.29)	0.38 (-0.29, 1.05)	0.2664	0.20 (-0.18, 0.58)	
		>= 4	49	9.20 (2.70)	47	-1.07 (0.33)	23	9.74 (2.70)	22	-0.81 (0.51)	-0.26 (-1.47, 0.96)	0.6738	-0.11 (-0.62, 0.40)	
		Stratification variable: Baseline ALP Level												0.5180
		< 350 U/L	93	7.51 (2.92)	92	-0.42 (0.21)	47	7.76 (3.25)	45	-0.53 (0.29)	0.11 (-0.58, 0.80)	0.7542	0.05 (-0.30, 0.41)	
		>= 350 U/L	35	8.54 (2.70)	34	-0.87 (0.36)	18	7.61 (2.94)	18	-1.45 (0.53)	0.58 (-0.71, 1.88)	0.3705	0.27 (-0.31, 0.84)	
		Gamma-GT (GGT)												0.4233
		<= 3 x ULN	33	7.65 (2.73)	32	-0.76 (0.47)	14	7.14 (2.69)	13	-1.39 (0.65)	0.63 (-0.69, 1.94)	0.3393	0.24 (-0.41, 0.89)	
		> 3 x ULN	95	7.84 (2.96)	94	-0.75 (0.21)	51	7.87 (3.27)	50	-0.79 (0.29)	0.04 (-0.66, 0.73)	0.9168	0.02 (-0.33, 0.36)	
		Total Bilirubin I												0.6469
		<= 1 x ULN	108	7.69 (2.84)	106	-0.78 (0.21)	60	7.66 (3.04)	59	-0.90 (0.27)	0.12 (-0.52, 0.76)	0.7042	0.06 (-0.26, 0.38)	
		> 1 x ULN	20	8.33 (3.17)	20	-0.46 (0.36)	5	8.40 (4.63)	4	-1.13 (1.10)	0.67 (-1.74, 3.08)	0.5668	0.38 (-0.70, 1.46)	
		Total Bilirubin II												0.3701
		< 0.6 x ULN	59	7.76 (2.80)	58	-0.96 (0.33)	32	7.84 (2.88)	31	-0.82 (0.41)	-0.14 (-1.09, 0.80)	0.7662	-0.06 (-0.49, 0.38)	
		>= 0.6 x ULN	69	7.82 (2.99)	68	-0.55 (0.21)	33	7.59 (3.43)	32	-0.96 (0.33)	0.41 (-0.37, 1.18)	0.2970	0.23 (-0.19, 0.65)	

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Mixed Effects Model (MMRM) analysis of change from baseline of PBC-40 Scores at month 6 and 12 - Subgroup analysis
Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
			Baseline		Change from BL		Baseline		Change from BL					
Score	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
PBC40-Emotional Domain Score	Month 12	Age at screening												0.5237
		< 65 years	99	8.01 (2.91)	97	-0.80 (0.23)	53	7.73 (3.11)	51	-0.91 (0.31)	0.11 (-0.65, 0.86)	0.7822	0.05 (-0.29, 0.39)	
		>= 65 years	29	7.05 (2.73)	29	-0.38 (0.40)	12	7.67 (3.45)	12	-0.96 (0.56)	0.58 (-0.73, 1.90)	0.3731	0.28 (-0.40, 0.95)	
		Age at PBC diagnosis												0.4713
		< 50 years	61	8.09 (2.91)	59	-0.94 (0.29)	32	7.84 (2.96)	30	-0.94 (0.41)	-0.01 (-1.00, 0.98)	0.9855	-0.00 (-0.44, 0.44)	
		>= 50 years	67	7.52 (2.87)	67	-0.41 (0.29)	33	7.59 (3.36)	33	-0.88 (0.38)	0.47 (-0.43, 1.37)	0.2980	0.20 (-0.21, 0.62)	
		Sex												0.6343
		female	123	7.88 (2.86)	121	-0.72 (0.21)	60	7.87 (3.08)	58	-1.03 (0.29)	0.31 (-0.37, 1.00)	0.3666	0.14 (-0.18, 0.45)	
		male	5	5.60 (3.03)	5	0.99 (1.36)	5	5.90 (3.80)	5	-0.00 (1.63)	0.99 (-2.28, 4.26)	0.4966	0.27 (-0.98, 1.52)	
		Race												
		white	114	7.85 (2.91)	113		56	7.46 (3.06)	54					
		black	2	8.00 (0.00)	2		2	9.25 (1.77)	2					
		asian	7	6.71 (2.72)	7		4	9.88 (3.71)	4					
		other	5	8.00 (3.61)	4		3	8.67 (4.75)	3					
		Region												0.4135
		North America	50	7.51 (2.72)	49	-0.52 (0.34)	13	7.85 (4.06)	12	-1.43 (0.67)	0.91 (-0.53, 2.35)	0.2115	0.38 (-0.26, 1.01)	
		Europe	39	7.94 (3.08)	39	-0.57 (0.31)	24	6.94 (2.28)	23	-0.31 (0.40)	-0.25 (-1.26, 0.75)	0.6165	-0.13 (-0.64, 0.39)	
		Rest-of-World	39	8.01 (2.95)	38	-0.87 (0.38)	28	8.32 (3.29)	28	-0.94 (0.42)	0.07 (-1.04, 1.18)	0.8948	0.03 (-0.46, 0.52)	
		Cirrhosis												0.4082
		yes	18	8.36 (3.09)	18	-0.79 (0.62)	9	8.72 (4.79)	9	-2.01 (1.00)	1.21 (-1.22, 3.65)	0.3130	0.43 (-0.38, 1.24)	
		no	110	7.70 (2.86)	108	-0.65 (0.21)	56	7.55 (2.83)	54	-0.85 (0.28)	0.20 (-0.48, 0.88)	0.5589	0.09 (-0.24, 0.42)	
		UDCA												NE
		UDCA Use	120	7.79 (2.94)	118	-0.69 (0.21)	62	7.77 (3.05)	60	-0.95 (0.28)	0.26 (-0.41, 0.93)	0.4463	0.11 (-0.20, 0.43)	
		UDCA Intolerance	8	7.81 (2.15)	8	NE	3	6.50 (5.63)	3	NE	NE		NE	
		Prior Use of OCA and/or Fibrates												0.5887
		yes	20	8.13 (3.27)	18	-0.77 (0.47)	13	7.77 (2.96)	12	-1.36 (0.54)	0.59 (-0.92, 2.10)	0.4192	0.30 (-0.44, 1.03)	
		no	108	7.73 (2.83)	108	-0.68 (0.23)	52	7.70 (3.22)	51	-0.84 (0.31)	0.16 (-0.58, 0.89)	0.6747	0.07 (-0.27, 0.40)	
		Therapy												NE
		Monotherapy (SEL)	8	7.81 (2.15)	8	NE	4	7.25 (4.84)	4	NE	NE		NE	
		Combinationtherapy (SEL + UDCA)	120	7.79 (2.94)	118	-0.69 (0.21)	61	7.75 (3.06)	59	-0.96 (0.28)	0.27 (-0.40, 0.95)	0.4219	0.12 (-0.19, 0.43)	

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Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
			Baseline		Change from BL		Baseline		Change from BL					
Score	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
PBC40-Emotional Domain Score	Month 12	Stratification variable: Baseline Pruritus NRS												0.6678
		< 4	79	6.92 (2.66)	79	-0.63 (0.26)	42	6.61 (2.83)	41	-0.98 (0.33)	0.34 (-0.45, 1.14)	0.3929	0.15 (-0.22, 0.53)	
		>= 4	49	9.20 (2.70)	47	-0.87 (0.33)	23	9.74 (2.70)	22	-0.91 (0.49)	0.04 (-1.15, 1.22)	0.9485	0.02 (-0.49, 0.52)	
		Stratification variable: Baseline ALP Level												0.5293
		< 350 U/L	93	7.51 (2.92)	92	-0.45 (0.23)	47	7.76 (3.25)	45	-0.86 (0.31)	0.41 (-0.34, 1.16)	0.2807	0.19 (-0.17, 0.55)	
		>= 350 U/L	35	8.54 (2.70)	34	-0.88 (0.41)	18	7.61 (2.94)	18	-0.79 (0.55)	-0.09 (-1.49, 1.32)	0.9010	-0.04 (-0.61, 0.54)	
		Gamma-GT (GGT)												0.1984
		<= 3 x ULN	33	7.65 (2.73)	32	-0.82 (0.50)	14	7.14 (2.69)	13	-1.89 (0.71)	1.07 (-0.40, 2.53)	0.1489	0.38 (-0.27, 1.03)	
		> 3 x ULN	95	7.84 (2.96)	94	-0.78 (0.23)	51	7.87 (3.27)	50	-0.80 (0.30)	0.02 (-0.72, 0.76)	0.9587	0.01 (-0.33, 0.35)	
		Total Bilirubin I												0.3995
		<= 1 x ULN	108	7.69 (2.84)	106	-0.67 (0.22)	60	7.66 (3.04)	59	-0.94 (0.27)	0.28 (-0.39, 0.94)	0.4110	0.13 (-0.19, 0.44)	
		> 1 x ULN	20	8.33 (3.17)	20	-0.90 (0.59)	5	8.40 (4.63)	4	-2.66 (1.63)	1.76 (-1.86, 5.39)	0.3218	0.62 (-0.47, 1.71)	
		Total Bilirubin II												0.1962
		< 0.6 x ULN	59	7.76 (2.80)	58	-0.78 (0.32)	32	7.84 (2.88)	31	-1.40 (0.40)	0.62 (-0.31, 1.54)	0.1862	0.26 (-0.18, 0.70)	
		>= 0.6 x ULN	69	7.82 (2.99)	68	-0.73 (0.28)	33	7.59 (3.43)	32	-0.49 (0.38)	-0.23 (-1.16, 0.70)	0.6206	-0.10 (-0.52, 0.32)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of change from baseline of PBC-40 Scores at month 6 and 12 - Subgroup analysis
Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
		Subgroup	Baseline		Change from BL		Baseline		Change from BL		Difference of			Interaction
Score	Timepoint	Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value
PBC40-Fatigue Domain Score	Month 6	Age at screening												0.7108
		< 65 years	99	27.80 (10.06)	97	-2.40 (0.67)	53	27.02 (10.45)	51	-1.28 (0.90)	-1.12 (-3.27, 1.03)	0.3041	-0.17 (-0.51, 0.17)	
		>= 65 years	29	26.79 (9.97)	29	-0.73 (1.11)	12	29.13 (11.77)	12	1.23 (1.85)	-1.96 (-6.04, 2.12)	0.3335	-0.32 (-0.99, 0.36)	
		Age at PBC diagnosis												0.2022
		< 50 years	61	27.78 (10.45)	59	-2.70 (0.90)	32	27.83 (11.40)	30	-0.24 (1.26)	-2.46 (-5.47, 0.55)	0.1076	-0.35 (-0.80, 0.09)	
		>= 50 years	67	27.39 (9.67)	67	-1.38 (0.73)	33	27.00 (10.01)	33	-1.37 (1.02)	-0.01 (-2.37, 2.34)	0.9919	-0.00 (-0.42, 0.41)	
		Sex												NE
		female	123	27.98 (9.99)	121	-1.91 (0.58)	60	27.73 (10.33)	58	-0.98 (0.84)	-0.93 (-2.88, 1.03)	0.3496	-0.14 (-0.46, 0.17)	
		male	5	17.70 (3.56)	5	NE	5	23.50 (14.76)	5	NE	NE		NE	
		Race												
		white	114	28.25 (10.10)	113		56	27.10 (10.69)	54					
		black	2	25.50 (8.49)	2		2	31.50 (7.07)	2					
		asian	7	20.93 (7.17)	7		4	31.38 (10.31)	4					
		other	5	22.40 (8.96)	4		3	25.17 (15.49)	3					
		Region												0.3829
		North America	50	28.12 (9.82)	49	-0.78 (1.04)	13	29.46 (11.80)	12	-1.52 (1.99)	0.74 (-3.52, 5.00)	0.7272	0.10 (-0.53, 0.73)	
		Europe	39	28.26 (9.97)	39	-2.20 (1.14)	24	26.08 (10.32)	23	0.94 (1.54)	-3.15 (-6.92, 0.63)	0.1003	-0.43 (-0.95, 0.09)	
		Rest-of-World	39	26.19 (10.41)	38	-2.82 (0.92)	28	27.59 (10.59)	28	-1.74 (1.10)	-1.08 (-3.83, 1.68)	0.4375	-0.19 (-0.67, 0.30)	
		Cirrhosis												0.6212
		yes	18	29.83 (11.08)	18	-1.71 (1.36)	9	30.28 (13.42)	9	0.53 (2.09)	-2.24 (-7.30, 2.83)	0.3682	-0.36 (-1.17, 0.44)	
		no	110	27.20 (9.83)	108	-1.96 (0.63)	56	26.95 (10.20)	54	-1.03 (0.88)	-0.93 (-2.98, 1.12)	0.3716	-0.14 (-0.47, 0.19)	
		UDCA												NE
		UDCA Use	120	27.58 (10.11)	118	-1.96 (0.61)	62	27.79 (10.58)	60	-0.80 (0.83)	-1.16 (-3.12, 0.80)	0.2431	-0.18 (-0.49, 0.14)	
		UDCA Intolerance	8	27.56 (8.85)	8	NE	3	19.50 (10.58)	3	NE	NE		NE	
		Prior Use of OCA and/or Fibrates												0.4743
		yes	20	27.33 (11.52)	18	-2.25 (1.38)	13	29.62 (10.67)	12	0.40 (1.73)	-2.65 (-7.23, 1.94)	0.2445	-0.43 (-1.17, 0.31)	
		no	108	27.62 (9.76)	108	-2.01 (0.64)	52	26.86 (10.67)	51	-1.13 (0.92)	-0.89 (-3.00, 1.23)	0.4077	-0.13 (-0.47, 0.20)	
		Therapy												NE
		Monotherapy (SEL)	8	27.56 (8.85)	8	NE	4	24.00 (12.48)	4	NE	NE		NE	
		Combinationtherapy (SEL + UDCA)	120	27.58 (10.11)	118	-1.94 (0.61)	61	27.63 (10.59)	59	-0.91 (0.84)	-1.03 (-3.00, 0.94)	0.3038	-0.16 (-0.47, 0.16)	

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p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of change from baseline of PBC-40 Scores at month 6 and 12 - Subgroup analysis
Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
			Baseline		Change from BL		Baseline		Change from BL					
Score	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
PBC40-Fatigue Domain Score	Month 6	Stratification variable: Baseline Pruritus NRS												0.6669
		< 4	79	24.87 (10.09)	79	-0.98 (0.78)	42	23.43 (9.34)	41	-0.06 (1.02)	-0.92 (-3.31, 1.48)	0.4484	-0.13 (-0.51, 0.24)	
		>= 4	49	31.94 (8.26)	47	-3.64 (0.90)	23	34.67 (9.02)	22	-1.84 (1.38)	-1.80 (-5.08, 1.49)	0.2786	-0.28 (-0.79, 0.22)	
		Stratification variable: Baseline ALP Level												0.4884
		< 350 U/L	93	26.84 (10.58)	92	-1.87 (0.65)	47	28.34 (10.78)	45	-0.20 (0.92)	-1.67 (-3.82, 0.48)	0.1262	-0.27 (-0.63, 0.09)	
		>= 350 U/L	35	29.51 (8.12)	34	-1.99 (1.12)	18	24.97 (10.15)	18	-1.88 (1.62)	-0.10 (-4.10, 3.89)	0.9585	-0.02 (-0.59, 0.56)	
		Gamma-GT (GGT)												0.6176
		<= 3 x ULN	33	25.53 (10.08)	32	-1.26 (1.87)	14	26.14 (10.20)	13	-1.02 (2.58)	-0.24 (-5.22, 4.75)	0.9233	-0.02 (-0.67, 0.62)	
		> 3 x ULN	95	28.28 (9.94)	94	-2.26 (0.63)	51	27.75 (10.83)	50	-0.69 (0.87)	-1.57 (-3.64, 0.51)	0.1389	-0.26 (-0.60, 0.09)	
		Total Bilirubin I												0.3336
		<= 1 x ULN	108	27.40 (9.91)	106	-2.52 (0.62)	60	27.10 (10.26)	59	-0.87 (0.80)	-1.65 (-3.54, 0.24)	0.0868	-0.26 (-0.58, 0.06)	
		> 1 x ULN	20	28.53 (10.76)	20	-0.08 (1.56)	5	31.10 (15.48)	4	-3.26 (4.65)	3.18 (-6.99, 13.35)	0.5234	0.42 (-0.66, 1.50)	
		Total Bilirubin II												0.9534
		< 0.6 x ULN	59	27.36 (9.97)	58	-1.67 (0.97)	32	27.41 (10.27)	31	-0.24 (1.19)	-1.43 (-4.14, 1.27)	0.2943	-0.20 (-0.64, 0.24)	
		>= 0.6 x ULN	69	27.75 (10.11)	68	-2.04 (0.77)	33	27.41 (11.15)	32	-0.72 (1.19)	-1.32 (-4.10, 1.46)	0.3482	-0.20 (-0.62, 0.22)	

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Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
			Baseline		Change from BL		Baseline		Change from BL					
Score	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
PBC40-Fatigue Domain Score	Month 12	Age at screening												0.7528
		< 65 years	99	27.80 (10.06)	97	-2.23 (0.78)	53	27.02 (10.45)	51	-1.89 (1.05)	-0.34 (-2.85, 2.18)	0.7919	-0.04 (-0.38, 0.30)	
		>= 65 years	29	26.79 (9.97)	29	-1.21 (1.40)	12	29.13 (11.77)	12	-0.03 (2.04)	-1.18 (-5.96, 3.61)	0.6196	-0.16 (-0.83, 0.52)	
		Age at PBC diagnosis												0.9926
		< 50 years	61	27.78 (10.45)	59	-2.26 (1.00)	32	27.83 (11.40)	30	-1.81 (1.38)	-0.45 (-3.77, 2.87)	0.7881	-0.06 (-0.50, 0.38)	
		>= 50 years	67	27.39 (9.67)	67	-1.74 (0.94)	33	27.00 (10.01)	33	-1.31 (1.26)	-0.43 (-3.44, 2.58)	0.7777	-0.06 (-0.47, 0.36)	
		Sex												NE
		female	123	27.98 (9.99)	121	-1.98 (0.70)	60	27.73 (10.33)	58	-1.55 (0.97)	-0.43 (-2.74, 1.87)	0.7103	-0.06 (-0.37, 0.26)	
		male	5	17.70 (3.56)	5	NE	5	23.50 (14.76)	5	NE	NE		NE	
		Race												
		white	114	28.25 (10.10)	113		56	27.10 (10.69)	54					
		black	2	25.50 (8.49)	2		2	31.50 (7.07)	2					
		asian	7	20.93 (7.17)	7		4	31.38 (10.31)	4					
		other	5	22.40 (8.96)	4		3	25.17 (15.49)	3					
		Region												0.0307
		North America	50	28.12 (9.82)	49	-0.49 (1.01)	13	29.46 (11.80)	12	-0.59 (1.88)	0.10 (-3.93, 4.13)	0.9589	0.01 (-0.62, 0.65)	
		Europe	39	28.26 (9.97)	39	-3.00 (1.17)	24	26.08 (10.32)	23	2.06 (1.52)	-5.06 (-8.85, -1.28)	0.0097	-0.68 (-1.21, -0.15)	
		Rest-of-World	39	26.19 (10.41)	38	-2.43 (1.29)	28	27.59 (10.59)	28	-4.15 (1.46)	1.72 (-2.08, 5.53)	0.3690	0.22 (-0.27, 0.71)	
		Cirrhosis												0.6884
		yes	18	29.83 (11.08)	18	-2.49 (2.32)	9	30.28 (13.42)	9	-4.01 (4.26)	1.52 (-8.71, 11.75)	0.7558	0.14 (-0.67, 0.94)	
		no	110	27.20 (9.83)	108	-1.80 (0.70)	56	26.95 (10.20)	54	-1.34 (0.94)	-0.46 (-2.69, 1.77)	0.6852	-0.06 (-0.39, 0.26)	
		UDCA												NE
		UDCA Use	120	27.58 (10.11)	118	-2.01 (0.71)	62	27.79 (10.58)	60	-1.70 (0.94)	-0.31 (-2.57, 1.95)	0.7889	-0.04 (-0.35, 0.27)	
		UDCA Intolerance	8	27.56 (8.85)	8	NE	3	19.50 (10.58)	3	NE	NE		NE	
		Prior Use of OCA and/or Fibrates												0.8361
		yes	20	27.33 (11.52)	18	-0.75 (1.87)	13	29.62 (10.67)	12	0.10 (2.18)	-0.85 (-6.77, 5.08)	0.7710	-0.11 (-0.84, 0.63)	
		no	108	27.62 (9.76)	108	-2.23 (0.74)	52	26.86 (10.67)	51	-2.03 (1.03)	-0.20 (-2.62, 2.22)	0.8704	-0.03 (-0.36, 0.31)	
		Therapy												NE
		Monotherapy (SEL)	8	27.56 (8.85)	8	NE	4	24.00 (12.48)	4	NE	NE		NE	
		Combinationtherapy (SEL + UDCA)	120	27.58 (10.11)	118	-1.99 (0.71)	61	27.63 (10.59)	59	-1.67 (0.95)	-0.32 (-2.59, 1.95)	0.7789	-0.04 (-0.35, 0.27)	

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Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
			Baseline		Change from BL		Baseline		Change from BL					
Score	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
PBC40-Fatigue Domain Score	Month 12	Stratification variable: Baseline Pruritus NRS												0.4063
		< 4	79	24.87 (10.09)	79	-0.93 (0.91)	42	23.43 (9.34)	41	-1.16 (1.16)	0.23 (-2.56, 3.01)	0.8718	0.03 (-0.35, 0.41)	
		>= 4	49	31.94 (8.26)	47	-3.60 (1.03)	23	34.67 (9.02)	22	-1.90 (1.54)	-1.70 (-5.40, 2.00)	0.3615	-0.24 (-0.74, 0.27)	
		Stratification variable: Baseline ALP Level												0.6281
		< 350 U/L	93	26.84 (10.58)	92	-2.05 (0.78)	47	28.34 (10.78)	45	-1.89 (1.08)	-0.16 (-2.72, 2.41)	0.9046	-0.02 (-0.38, 0.34)	
		>= 350 U/L	35	29.51 (8.12)	34	-1.47 (1.24)	18	24.97 (10.15)	18	-0.11 (1.70)	-1.36 (-5.62, 2.90)	0.5244	-0.18 (-0.76, 0.39)	
		Gamma-GT (GGT)												0.8024
		<= 3 x ULN	33	25.53 (10.08)	32	-2.15 (1.97)	14	26.14 (10.20)	13	-2.15 (2.77)	0.01 (-5.50, 5.52)	0.9982	0.00 (-0.64, 0.65)	
		> 3 x ULN	95	28.28 (9.94)	94	-1.98 (0.76)	51	27.75 (10.83)	50	-1.24 (0.99)	-0.74 (-3.18, 1.70)	0.5494	-0.10 (-0.44, 0.24)	
		Total Bilirubin I												0.5426
		<= 1 x ULN	108	27.40 (9.91)	106	-1.98 (0.74)	60	27.10 (10.26)	59	-1.66 (0.93)	-0.32 (-2.59, 1.95)	0.7813	-0.04 (-0.36, 0.28)	
		> 1 x ULN	20	28.53 (10.76)	20	-2.92 (1.61)	5	31.10 (15.48)	4	0.35 (4.42)	-3.27 (-13.02, 6.48)	0.4945	-0.42 (-1.51, 0.66)	
		Total Bilirubin II												0.1739
		< 0.6 x ULN	59	27.36 (9.97)	58	-0.97 (1.11)	32	27.41 (10.27)	31	-1.90 (1.40)	0.92 (-2.35, 4.20)	0.5757	0.11 (-0.33, 0.55)	
		>= 0.6 x ULN	69	27.75 (10.11)	68	-2.66 (0.87)	33	27.41 (11.15)	32	-0.57 (1.23)	-2.09 (-5.05, 0.87)	0.1637	-0.29 (-0.71, 0.13)	

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			Seladelpar 10 mg (N=128)				Placebo (N=65)							
		Subgroup	Baseline		Change from BL		Baseline		Change from BL		Difference of			Interaction
Score	Timepoint	Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value
PBC40-Itch Domain Score	Month 6	Age at screening												0.3337
		< 65 years	99	5.32 (3.85)	97	-0.80 (0.27)	53	5.67 (4.08)	51	-0.06 (0.37)	-0.74 (-1.60, 0.12)	0.0898	-0.28 (-0.62, 0.06)	
		>= 65 years	29	4.53 (3.87)	29	-0.77 (0.47)	12	5.29 (3.56)	12	0.88 (0.78)	-1.65 (-3.34, 0.04)	0.0557	-0.62 (-1.31, 0.06)	
		Age at PBC diagnosis												0.2198
		< 50 years	61	5.57 (4.10)	59	-0.84 (0.36)	32	5.98 (4.12)	30	0.57 (0.51)	-1.41 (-2.59, -0.23)	0.0197	-0.51 (-0.96, -0.06)	
		>= 50 years	67	4.76 (3.60)	67	-0.67 (0.31)	33	5.23 (3.84)	33	-0.21 (0.44)	-0.46 (-1.45, 0.52)	0.3505	-0.18 (-0.60, 0.24)	
		Sex												NE
		female	123	5.23 (3.85)	121	-0.84 (0.24)	60	5.72 (4.02)	58	0.02 (0.35)	-0.85 (-1.64, -0.06)	0.0343	-0.32 (-0.64, -0.01)	
		male	5	3.10 (3.73)	5	NE	5	4.20 (3.31)	5	NE	NE		NE	
		Race												
		white	114	5.09 (3.84)	113		56	5.57 (4.05)	54					
		black	2	7.50 (0.71)	2		2	4.75 (2.47)	2					
		asian	7	3.71 (2.21)	7		4	5.63 (4.33)	4					
		other	5	7.40 (5.89)	4		3	6.67 (4.25)	3					
		Region												0.9207
		North America	50	4.60 (3.40)	49	-0.89 (0.36)	13	5.92 (3.63)	12	-0.06 (0.71)	-0.83 (-2.35, 0.68)	0.2766	-0.33 (-0.96, 0.30)	
		Europe	39	5.65 (3.69)	39	-1.10 (0.41)	24	6.54 (4.06)	23	-0.29 (0.57)	-0.81 (-2.16, 0.54)	0.2364	-0.30 (-0.82, 0.21)	
		Rest-of-World	39	5.33 (4.51)	38	-0.61 (0.42)	28	4.64 (3.95)	28	0.53 (0.49)	-1.14 (-2.36, 0.08)	0.0664	-0.43 (-0.93, 0.06)	
		Cirrhosis												0.0681
		yes	18	6.31 (3.92)	18	-1.14 (0.69)	9	5.78 (2.72)	9	1.80 (1.02)	-2.95 (-5.46, -0.43)	0.0239	-0.96 (-1.81, -0.11)	
		no	110	4.95 (3.83)	108	-0.71 (0.25)	56	5.57 (4.15)	54	-0.11 (0.35)	-0.61 (-1.40, 0.19)	0.1340	-0.24 (-0.56, 0.09)	
		UDCA												NE
		UDCA Use	120	5.13 (3.86)	118	-0.70 (0.24)	62	5.68 (3.93)	60	0.27 (0.33)	-0.97 (-1.74, -0.20)	0.0137	-0.37 (-0.68, -0.06)	
		UDCA Intolerance	8	5.38 (3.95)	8	NE	3	4.00 (5.29)	3	NE	NE		NE	
		Prior Use of OCA and/or Fibrates												0.9641
		yes	20	6.40 (4.35)	18	-1.20 (0.60)	13	6.81 (3.50)	12	-0.32 (0.75)	-0.87 (-2.85, 1.11)	0.3727	-0.33 (-1.07, 0.40)	
		no	108	4.91 (3.73)	108	-0.67 (0.26)	52	5.30 (4.05)	51	0.25 (0.37)	-0.92 (-1.76, -0.08)	0.0319	-0.34 (-0.68, -0.01)	
		Therapy												NE
		Monotherapy (SEL)	8	5.38 (3.95)	8	NE	4	3.38 (4.50)	4	NE	NE		NE	
		Combinationtherapy (SEL + UDCA)	120	5.13 (3.86)	118	-0.72 (0.24)	61	5.75 (3.93)	59	0.14 (0.33)	-0.85 (-1.61, -0.09)	0.0277	-0.33 (-0.65, -0.02)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of change from baseline of PBC-40 Scores at month 6 and 12 - Subgroup analysis
Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
			Baseline		Change from BL		Baseline		Change from BL					
Score	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
PBC40-Itch Domain Score	Month 6	Stratification variable: Baseline Pruritus NRS												0.1401
		< 4	79	2.94 (2.61)	79	-0.21 (0.29)	42	3.43 (2.69)	41	0.36 (0.38)	-0.57 (-1.46, 0.32)	0.2093	-0.22 (-0.60, 0.15)	
		>= 4	49	8.70 (2.68)	47	-2.20 (0.38)	23	9.57 (2.62)	22	-0.40 (0.60)	-1.80 (-3.22, -0.39)	0.0131	-0.67 (-1.18, -0.15)	
		Stratification variable: Baseline ALP Level												0.8311
		< 350 U/L	93	4.32 (3.37)	92	-0.51 (0.26)	47	5.40 (3.97)	45	0.35 (0.39)	-0.87 (-1.74, 0.01)	0.0522	-0.34 (-0.70, 0.02)	
		>= 350 U/L	35	7.33 (4.24)	34	-1.50 (0.45)	18	6.11 (4.02)	18	-0.45 (0.65)	-1.06 (-2.66, 0.54)	0.1883	-0.39 (-0.97, 0.19)	
		Gamma-GT (GGT)												0.0924
		<= 3 x ULN	33	4.65 (3.82)	32	-0.18 (0.53)	14	4.14 (3.16)	13	-0.35 (0.74)	0.17 (-1.30, 1.64)	0.8144	0.06 (-0.59, 0.70)	
		> 3 x ULN	95	5.32 (3.87)	94	-0.88 (0.27)	51	6.00 (4.10)	50	0.38 (0.37)	-1.26 (-2.13, -0.38)	0.0051	-0.48 (-0.83, -0.13)	
		Total Bilirubin I												0.1247
		<= 1 x ULN	108	4.95 (3.75)	106	-0.80 (0.27)	60	5.55 (3.95)	59	0.22 (0.35)	-1.01 (-1.83, -0.20)	0.0151	-0.37 (-0.69, -0.05)	
		> 1 x ULN	20	6.18 (4.32)	20	-1.08 (0.40)	5	6.20 (4.62)	4	-2.15 (1.23)	1.07 (-1.61, 3.75)	0.4168	0.54 (-0.54, 1.63)	
		Total Bilirubin II												0.3114
		< 0.6 x ULN	59	4.24 (3.32)	58	-0.12 (0.36)	32	5.28 (3.88)	31	0.41 (0.46)	-0.53 (-1.56, 0.50)	0.3085	-0.20 (-0.63, 0.24)	
		>= 0.6 x ULN	69	5.92 (4.12)	68	-1.23 (0.32)	33	5.91 (4.09)	32	0.08 (0.49)	-1.31 (-2.44, -0.18)	0.0239	-0.49 (-0.91, -0.06)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
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p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of change from baseline of PBC-40 Scores at month 6 and 12 - Subgroup analysis
Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
		Subgroup	Baseline		Change from BL		Baseline		Change from BL		Difference of			Interaction
Score	Timepoint	Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value
PBC40-Itch Domain Score	Month 12	Age at screening												0.6501
		< 65 years	99	5.32 (3.85)	97	-1.51 (0.32)	53	5.67 (4.08)	51	-0.53 (0.43)	-0.98 (-2.00, 0.04)	0.0583	-0.32 (-0.66, 0.03)	
		>= 65 years	29	4.53 (3.87)	29	-0.85 (0.47)	12	5.29 (3.56)	12	-0.30 (0.71)	-0.56 (-2.13, 1.02)	0.4761	-0.22 (-0.89, 0.46)	
		Age at PBC diagnosis												0.7403
		< 50 years	61	5.57 (4.10)	59	-1.63 (0.36)	32	5.98 (4.12)	30	-0.67 (0.50)	-0.96 (-2.14, 0.21)	0.1061	-0.35 (-0.79, 0.09)	
		>= 50 years	67	4.76 (3.60)	67	-0.95 (0.39)	33	5.23 (3.84)	33	-0.27 (0.52)	-0.68 (-1.91, 0.55)	0.2740	-0.22 (-0.63, 0.20)	
		Sex												NE
		female	123	5.23 (3.85)	121	-1.37 (0.27)	60	5.72 (4.02)	58	-0.64 (0.38)	-0.73 (-1.62, 0.15)	0.1041	-0.25 (-0.56, 0.07)	
		male	5	3.10 (3.73)	5	NE	5	4.20 (3.31)	5	NE	NE		NE	
		Race												
		white	114	5.09 (3.84)	113		56	5.57 (4.05)	54					
		black	2	7.50 (0.71)	2		2	4.75 (2.47)	2					
		asian	7	3.71 (2.21)	7		4	5.63 (4.33)	4					
		other	5	7.40 (5.89)	4		3	6.67 (4.25)	3					
		Region												0.2400
		North America	50	4.60 (3.40)	49	-0.74 (0.43)	13	5.92 (3.63)	12	-0.91 (0.86)	0.17 (-1.70, 2.04)	0.8580	0.05 (-0.58, 0.69)	
		Europe	39	5.65 (3.69)	39	-2.20 (0.40)	24	6.54 (4.06)	23	-0.48 (0.52)	-1.73 (-2.98, -0.47)	0.0080	-0.69 (-1.22, -0.16)	
		Rest-of-World	39	5.33 (4.51)	38	-1.44 (0.51)	28	4.64 (3.95)	28	-0.32 (0.56)	-1.12 (-2.56, 0.33)	0.1263	-0.36 (-0.85, 0.13)	
		Cirrhosis												0.6406
		yes	18	6.31 (3.92)	18	-2.07 (0.67)	9	5.78 (2.72)	9	-1.98 (1.13)	-0.09 (-2.79, 2.61)	0.9450	-0.03 (-0.83, 0.77)	
		no	110	4.95 (3.83)	108	-1.19 (0.29)	56	5.57 (4.15)	54	-0.46 (0.39)	-0.73 (-1.64, 0.18)	0.1155	-0.25 (-0.57, 0.08)	
		UDCA												NE
		UDCA Use	120	5.13 (3.86)	118	-1.39 (0.27)	62	5.68 (3.93)	60	-0.40 (0.36)	-1.00 (-1.85, -0.15)	0.0219	-0.34 (-0.66, -0.03)	
		UDCA Intolerance	8	5.38 (3.95)	8	NE	3	4.00 (5.29)	3	NE	NE		NE	
		Prior Use of OCA and/or Fibrates												0.1133
		yes	20	6.40 (4.35)	18	-1.16 (0.60)	13	6.81 (3.50)	12	-1.72 (0.71)	0.56 (-1.37, 2.49)	0.5576	0.22 (-0.52, 0.95)	
		no	108	4.91 (3.73)	108	-1.30 (0.30)	52	5.30 (4.05)	51	-0.19 (0.42)	-1.11 (-2.07, -0.15)	0.0234	-0.36 (-0.70, -0.03)	
		Therapy												NE
		Monotherapy (SEL)	8	5.38 (3.95)	8	NE	4	3.38 (4.50)	4	NE	NE		NE	
		Combinationtherapy (SEL + UDCA)	120	5.13 (3.86)	118	-1.41 (0.27)	61	5.75 (3.93)	59	-0.45 (0.36)	-0.96 (-1.81, -0.11)	0.0272	-0.33 (-0.65, -0.02)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
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p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
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Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of change from baseline of PBC-40 Scores at month 6 and 12 - Subgroup analysis
Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
			Baseline		Change from BL		Baseline		Change from BL					
Score	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
PBC40-Itch Domain Score	Month 12	Stratification variable: Baseline Pruritus NRS												0.3420
		< 4	79	2.94 (2.61)	79	-0.65 (0.31)	42	3.43 (2.69)	41	-0.08 (0.40)	-0.58 (-1.53, 0.37)	0.2319	-0.21 (-0.59, 0.17)	
		>= 4	49	8.70 (2.68)	47	-2.92 (0.48)	23	9.57 (2.62)	22	-1.41 (0.72)	-1.51 (-3.25, 0.22)	0.0851	-0.45 (-0.96, 0.06)	
		Stratification variable: Baseline ALP Level												0.0704
		< 350 U/L	93	4.32 (3.37)	92	-0.96 (0.29)	47	5.40 (3.97)	45	-0.63 (0.41)	-0.33 (-1.27, 0.61)	0.4836	-0.12 (-0.48, 0.24)	
		>= 350 U/L	35	7.33 (4.24)	34	-2.25 (0.56)	18	6.11 (4.02)	18	-0.01 (0.76)	-2.25 (-4.15, -0.34)	0.0220	-0.68 (-1.27, -0.09)	
		Gamma-GT (GGT)												0.3565
		<= 3 x ULN	33	4.65 (3.82)	32	0.00 (0.59)	14	4.14 (3.16)	13	0.25 (0.85)	-0.25 (-2.02, 1.52)	0.7771	-0.08 (-0.72, 0.57)	
		> 3 x ULN	95	5.32 (3.87)	94	-1.71 (0.30)	51	6.00 (4.10)	50	-0.54 (0.40)	-1.17 (-2.14, -0.20)	0.0186	-0.40 (-0.75, -0.05)	
		Total Bilirubin I												0.4216
		<= 1 x ULN	108	4.95 (3.75)	106	-1.14 (0.29)	60	5.55 (3.95)	59	-0.49 (0.38)	-0.66 (-1.55, 0.23)	0.1450	-0.22 (-0.54, 0.10)	
		> 1 x ULN	20	6.18 (4.32)	20	-2.35 (0.71)	5	6.20 (4.62)	4	0.07 (2.02)	-2.41 (-6.90, 2.07)	0.2734	-0.71 (-1.80, 0.39)	
		Total Bilirubin II												0.1545
		< 0.6 x ULN	59	4.24 (3.32)	58	-0.79 (0.42)	32	5.28 (3.88)	31	-0.60 (0.54)	-0.19 (-1.43, 1.06)	0.7667	-0.06 (-0.50, 0.38)	
		>= 0.6 x ULN	69	5.92 (4.12)	68	-1.68 (0.35)	33	5.91 (4.09)	32	-0.26 (0.49)	-1.41 (-2.60, -0.23)	0.0198	-0.49 (-0.92, -0.06)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
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N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
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Mixed Effects Model (MMRM) analysis of change from baseline of PBC-40 Scores at month 6 and 12 - Subgroup analysis
Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
			Baseline		Change from BL		Baseline		Change from BL					
Score	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
PBC40-Social Domain Score	Month 6	Age at screening												0.5382
		< 65 years	99	23.46 (8.55)	97	-0.70 (0.54)	53	22.48 (8.43)	51	-1.87 (0.74)	1.17 (-0.59, 2.94)	0.1899	0.22 (-0.12, 0.56)	
		>= 65 years	29	20.76 (7.82)	29	-0.75 (0.88)	12	21.00 (8.03)	12	-0.78 (1.48)	0.04 (-3.26, 3.33)	0.9828	0.01 (-0.67, 0.68)	
		Age at PBC diagnosis												0.5298
		< 50 years	61	23.28 (8.40)	59	-0.62 (0.63)	32	22.61 (9.29)	30	-1.05 (0.89)	0.43 (-1.70, 2.56)	0.6891	0.09 (-0.35, 0.53)	
		>= 50 years	67	22.46 (8.51)	67	-0.64 (0.68)	33	21.82 (7.37)	33	-2.04 (0.96)	1.40 (-0.81, 3.61)	0.2109	0.25 (-0.17, 0.67)	
		Sex												NE
		female	123	22.98 (8.48)	121	-0.54 (0.46)	60	22.08 (8.05)	58	-1.54 (0.68)	0.99 (-0.57, 2.56)	0.2122	0.19 (-0.12, 0.51)	
		male	5	19.80 (7.32)	5	NE	5	23.70 (12.14)	5	NE	NE		NE	
		Race												
		white	114	23.08 (8.51)	113		56	21.93 (8.32)	54					
		black	2	19.75 (3.89)	2		2	24.25 (6.01)	2					
		asian	7	20.86 (5.77)	7		4	23.25 (9.13)	4					
		other	5	21.70 (12.09)	4		3	24.67 (12.29)	3					
		Region												0.9996
		North America	50	23.04 (8.15)	49	-1.34 (0.77)	13	21.81 (9.83)	12	-2.50 (1.49)	1.15 (-2.03, 4.34)	0.4708	0.21 (-0.42, 0.85)	
		Europe	39	21.96 (9.00)	39	-0.49 (0.90)	24	22.38 (7.84)	23	-1.67 (1.23)	1.18 (-1.83, 4.19)	0.4359	0.20 (-0.31, 0.72)	
		Rest-of-World	39	23.50 (8.36)	38	-0.13 (0.81)	28	22.25 (8.28)	28	-1.26 (0.95)	1.12 (-1.27, 3.51)	0.3522	0.22 (-0.27, 0.71)	
		Cirrhosis												0.8074
		yes	18	24.75 (8.87)	18	-1.95 (1.40)	9	25.72 (10.51)	9	-2.34 (2.08)	0.38 (-4.82, 5.59)	0.8776	0.06 (-0.74, 0.86)	
		no	110	22.54 (8.36)	108	-0.48 (0.50)	56	21.64 (7.88)	54	-1.49 (0.70)	1.01 (-0.63, 2.66)	0.2259	0.19 (-0.13, 0.52)	
		UDCA												NE
		UDCA Use	120	22.86 (8.49)	118	-0.49 (0.49)	62	22.46 (8.36)	60	-1.59 (0.67)	1.09 (-0.49, 2.67)	0.1737	0.21 (-0.10, 0.52)	
		UDCA Intolerance	8	22.69 (8.15)	8	NE	3	17.00 (6.24)	3	NE	NE		NE	
		Prior Use of OCA and/or Fibrates												0.9723
		yes	20	23.08 (8.58)	18	-0.90 (1.45)	13	21.65 (9.36)	12	-1.79 (1.77)	0.90 (-3.84, 5.63)	0.6978	0.14 (-0.59, 0.87)	
		no	108	22.81 (8.45)	108	-0.73 (0.50)	52	22.35 (8.13)	51	-1.54 (0.72)	0.81 (-0.83, 2.46)	0.3304	0.16 (-0.18, 0.49)	
		Therapy												NE
		Monotherapy (SEL)	8	22.69 (8.15)	8	NE	4	19.88 (7.69)	4	NE	NE		NE	
		Combinationtherapy (SEL + UDCA)	120	22.86 (8.49)	118	-0.50 (0.49)	61	22.36 (8.39)	59	-1.72 (0.67)	1.22 (-0.36, 2.80)	0.1283	0.23 (-0.08, 0.55)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of change from baseline of PBC-40 Scores at month 6 and 12 - Subgroup analysis
Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
			Baseline		Change from BL		Baseline		Change from BL					
Score	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
PBC40-Social Domain Score	Month 6	Stratification variable: Baseline Pruritus NRS												0.0288
		< 4	79	20.29 (8.18)	79	0.20 (0.56)	42	18.98 (6.40)	41	-2.05 (0.75)	2.26 (0.50, 4.01)	0.0122	0.46 (0.08, 0.84)	
		>= 4	49	26.98 (7.16)	47	-2.11 (0.76)	23	28.11 (8.29)	22	-0.75 (1.18)	-1.36 (-4.16, 1.44)	0.3343	-0.25 (-0.76, 0.26)	
		Stratification variable: Baseline ALP Level												0.4135
		< 350 U/L	93	22.14 (8.62)	92	-0.28 (0.54)	47	22.45 (8.54)	45	-0.74 (0.76)	0.46 (-1.33, 2.25)	0.6127	0.09 (-0.27, 0.45)	
		>= 350 U/L	35	24.74 (7.71)	34	-0.86 (0.85)	18	21.58 (7.91)	18	-2.75 (1.24)	1.89 (-1.15, 4.93)	0.2150	0.37 (-0.21, 0.95)	
		Gamma-GT (GGT)												0.1354
		<= 3 x ULN	33	23.23 (8.84)	32	-0.29 (1.19)	14	22.14 (8.83)	13	-3.61 (1.72)	3.32 (-0.27, 6.90)	0.0689	0.50 (-0.16, 1.15)	
		> 3 x ULN	95	22.72 (8.33)	94	-0.92 (0.51)	51	22.23 (8.27)	50	-1.29 (0.71)	0.37 (-1.32, 2.07)	0.6636	0.07 (-0.27, 0.42)	
		Total Bilirubin I												0.3816
		<= 1 x ULN	108	22.43 (8.40)	106	-0.69 (0.51)	60	21.86 (8.37)	59	-1.50 (0.67)	0.82 (-0.76, 2.39)	0.3074	0.16 (-0.16, 0.48)	
		> 1 x ULN	20	25.15 (8.47)	20	-0.92 (1.12)	5	26.40 (7.14)	4	-4.82 (3.25)	3.90 (-3.21, 11.01)	0.2680	0.72 (-0.38, 1.81)	
		Total Bilirubin II												0.8955
		< 0.6 x ULN	59	22.40 (8.48)	58	0.39 (0.75)	32	22.25 (8.94)	31	-0.83 (0.94)	1.21 (-0.96, 3.38)	0.2697	0.22 (-0.22, 0.65)	
		>= 0.6 x ULN	69	23.24 (8.44)	68	-1.19 (0.61)	33	22.17 (7.81)	32	-2.20 (0.94)	1.01 (-1.19, 3.21)	0.3655	0.20 (-0.23, 0.62)	

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p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
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Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of change from baseline of PBC-40 Scores at month 6 and 12 - Subgroup analysis
Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
			Baseline		Change from BL		Baseline		Change from BL					
Score	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
PBC40-Social Domain Score	Month 12	Age at screening												0.4350
		< 65 years	99	23.46 (8.55)	97	-0.98 (0.57)	53	22.48 (8.43)	51	-1.72 (0.76)	0.75 (-1.08, 2.57)	0.4194	0.13 (-0.20, 0.47)	
		>= 65 years	29	20.76 (7.82)	29	0.01 (0.83)	12	21.00 (8.03)	12	-1.98 (1.15)	1.99 (-0.67, 4.66)	0.1369	0.45 (-0.23, 1.13)	
		Age at PBC diagnosis												0.7138
		< 50 years	61	23.28 (8.40)	59	-0.86 (0.68)	32	22.61 (9.29)	30	-1.54 (0.93)	0.68 (-1.57, 2.94)	0.5481	0.13 (-0.31, 0.57)	
		>= 50 years	67	22.46 (8.51)	67	-0.48 (0.68)	33	21.82 (7.37)	33	-1.73 (0.90)	1.25 (-0.87, 3.37)	0.2430	0.23 (-0.19, 0.65)	
		Sex												NE
		female	123	22.98 (8.48)	121	-0.74 (0.49)	60	22.08 (8.05)	58	-1.79 (0.67)	1.04 (-0.55, 2.64)	0.1989	0.20 (-0.12, 0.51)	
		male	5	19.80 (7.32)	5	NE	5	23.70 (12.14)	5	NE	NE		NE	
		Race												
		white	114	23.08 (8.51)	113		56	21.93 (8.32)	54					
		black	2	19.75 (3.89)	2		2	24.25 (6.01)	2					
		asian	7	20.86 (5.77)	7		4	23.25 (9.13)	4					
		other	5	21.70 (12.09)	4		3	24.67 (12.29)	3					
		Region												0.3695
		North America	50	23.04 (8.15)	49	-0.74 (0.77)	13	21.81 (9.83)	12	-2.38 (1.46)	1.64 (-1.49, 4.76)	0.2974	0.30 (-0.33, 0.94)	
		Europe	39	21.96 (9.00)	39	-1.49 (0.72)	24	22.38 (7.84)	23	-1.11 (0.93)	-0.37 (-2.65, 1.91)	0.7450	-0.08 (-0.60, 0.43)	
		Rest-of-World	39	23.50 (8.36)	38	-0.15 (0.96)	28	22.25 (8.28)	28	-2.07 (1.08)	1.92 (-0.89, 4.73)	0.1772	0.32 (-0.17, 0.82)	
		Cirrhosis												0.8796
		yes	18	24.75 (8.87)	18	-1.69 (1.25)	9	25.72 (10.51)	9	-3.16 (1.89)	1.46 (-3.21, 6.13)	0.5166	0.26 (-0.54, 1.07)	
		no	110	22.54 (8.36)	108	-0.48 (0.52)	56	21.64 (7.88)	54	-1.59 (0.68)	1.11 (-0.53, 2.74)	0.1823	0.21 (-0.12, 0.54)	
		UDCA												NE
		UDCA Use	120	22.86 (8.49)	118	-0.62 (0.49)	62	22.46 (8.36)	60	-1.64 (0.65)	1.03 (-0.53, 2.58)	0.1947	0.19 (-0.12, 0.51)	
		UDCA Intolerance	8	22.69 (8.15)	8	NE	3	17.00 (6.24)	3	NE	NE		NE	
		Prior Use of OCA and/or Fibrates												0.3420
		yes	20	23.08 (8.58)	18	0.29 (1.05)	13	21.65 (9.36)	12	-2.25 (1.23)	2.54 (-0.83, 5.90)	0.1314	0.56 (-0.18, 1.31)	
		no	108	22.81 (8.45)	108	-0.91 (0.53)	52	22.35 (8.13)	51	-1.70 (0.74)	0.79 (-0.93, 2.52)	0.3626	0.15 (-0.19, 0.48)	
		Therapy												NE
		Monotherapy (SEL)	8	22.69 (8.15)	8	NE	4	19.88 (7.69)	4	NE	NE		NE	
		Combinationtherapy (SEL + UDCA)	120	22.86 (8.49)	118	-0.62 (0.50)	61	22.36 (8.39)	59	-1.63 (0.65)	1.00 (-0.56, 2.57)	0.2057	0.19 (-0.12, 0.50)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
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Gilead Sciences, Inc.
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RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of change from baseline of PBC-40 Scores at month 6 and 12 - Subgroup analysis
Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
			Baseline		Change from BL		Baseline		Change from BL					
Score	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
PBC40-Social Domain Score	Month 12	Stratification variable: Baseline Pruritus NRS												0.1669
		< 4	79	20.29 (8.18)	79	0.08 (0.57)	42	18.98 (6.40)	41	-1.93 (0.72)	2.01 (0.30, 3.72)	0.0217	0.41 (0.03, 0.79)	
		>= 4	49	26.98 (7.16)	47	-1.82 (0.82)	23	28.11 (8.29)	22	-1.49 (1.22)	-0.33 (-3.26, 2.59)	0.8201	-0.06 (-0.56, 0.45)	
		Stratification variable: Baseline ALP Level												0.3973
		< 350 U/L	93	22.14 (8.62)	92	-0.25 (0.52)	47	22.45 (8.54)	45	-1.75 (0.72)	1.50 (-0.20, 3.20)	0.0833	0.30 (-0.06, 0.66)	
		>= 350 U/L	35	24.74 (7.71)	34	-0.89 (0.98)	18	21.58 (7.91)	18	-0.81 (1.35)	-0.08 (-3.46, 3.29)	0.9598	-0.01 (-0.59, 0.56)	
		Gamma-GT (GGT)												0.1518
		<= 3 x ULN	33	23.23 (8.84)	32	-1.06 (1.15)	14	22.14 (8.83)	13	-4.25 (1.61)	3.19 (-0.13, 6.51)	0.0593	0.50 (-0.16, 1.15)	
		> 3 x ULN	95	22.72 (8.33)	94	-0.68 (0.53)	51	22.23 (8.27)	50	-1.21 (0.69)	0.53 (-1.16, 2.23)	0.5342	0.10 (-0.24, 0.45)	
		Total Bilirubin I												0.5157
		<= 1 x ULN	108	22.43 (8.40)	106	-0.66 (0.51)	60	21.86 (8.37)	59	-1.83 (0.63)	1.17 (-0.35, 2.69)	0.1303	0.23 (-0.09, 0.55)	
		> 1 x ULN	20	25.15 (8.47)	20	-1.35 (1.37)	5	26.40 (7.14)	4	0.23 (3.93)	-1.58 (-10.18, 7.02)	0.7076	-0.24 (-1.32, 0.84)	
		Total Bilirubin II												0.1574
		< 0.6 x ULN	59	22.40 (8.48)	58	0.15 (0.77)	32	22.25 (8.94)	31	-2.03 (0.96)	2.18 (-0.06, 4.43)	0.0566	0.38 (-0.06, 0.82)	
		>= 0.6 x ULN	69	23.24 (8.44)	68	-0.96 (0.63)	33	22.17 (7.81)	32	-0.95 (0.87)	-0.01 (-2.13, 2.11)	0.9920	-0.00 (-0.42, 0.42)	

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Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
			Baseline		Change from BL		Baseline		Change from BL					
Score	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
PBC40-Symptoms Domain Score	Month 6	Age at screening												0.0505
		< 65 years	99	15.11 (4.58)	97	-0.14 (0.28)	53	15.41 (5.43)	51	-0.70 (0.39)	0.56 (-0.36, 1.48)	0.2291	0.20 (-0.14, 0.54)	
		>= 65 years	29	14.88 (4.54)	29	-1.08 (0.49)	12	16.83 (5.69)	12	0.30 (0.84)	-1.39 (-3.17, 0.40)	0.1241	-0.50 (-1.18, 0.18)	
		Age at PBC diagnosis												0.5333
		< 50 years	61	14.44 (4.39)	59	0.26 (0.34)	32	15.58 (5.26)	30	-0.21 (0.49)	0.47 (-0.70, 1.63)	0.4276	0.17 (-0.27, 0.61)	
		>= 50 years	67	15.62 (4.66)	67	-0.93 (0.34)	33	15.76 (5.73)	33	-0.89 (0.49)	-0.04 (-1.14, 1.07)	0.9474	-0.01 (-0.43, 0.40)	
		Sex												NE
		female	123	15.25 (4.50)	121	-0.29 (0.25)	60	15.88 (5.49)	58	-0.66 (0.36)	0.36 (-0.47, 1.20)	0.3912	0.13 (-0.18, 0.45)	
		male	5	10.40 (3.52)	5	NE	5	13.10 (4.83)	5	NE	NE		NE	
		Race												
		white	114	15.22 (4.59)	113		56	15.74 (5.25)	54					
		black	2	12.75 (2.47)	2		2	13.50 (0.71)	2					
		asian	7	12.00 (3.30)	7		4	12.88 (6.94)	4					
		other	5	16.50 (4.78)	4		3	19.50 (9.10)	3					
		Region												0.5261
		North America	50	15.14 (4.86)	49	-0.50 (0.46)	13	15.35 (5.10)	12	-0.29 (0.92)	-0.21 (-2.19, 1.77)	0.8322	-0.06 (-0.70, 0.57)	
		Europe	39	15.14 (3.94)	39	-0.63 (0.40)	24	15.56 (5.08)	23	-0.53 (0.56)	-0.10 (-1.42, 1.22)	0.8793	-0.04 (-0.55, 0.48)	
		Rest-of-World	39	14.87 (4.83)	38	0.17 (0.44)	28	15.91 (6.09)	28	-0.67 (0.54)	0.84 (-0.49, 2.16)	0.2113	0.30 (-0.19, 0.79)	
		Cirrhosis												0.4236
		yes	18	15.92 (4.12)	18	-0.36 (0.68)	9	18.00 (6.38)	9	0.30 (1.06)	-0.67 (-3.25, 1.92)	0.5968	-0.22 (-1.02, 0.59)	
		no	110	14.92 (4.63)	108	-0.34 (0.26)	56	15.29 (5.27)	54	-0.73 (0.37)	0.39 (-0.47, 1.24)	0.3767	0.14 (-0.19, 0.47)	
		UDCA												NE
		UDCA Use	120	15.05 (4.63)	118	-0.33 (0.26)	62	15.73 (5.57)	60	-0.49 (0.36)	0.16 (-0.67, 0.99)	0.6969	0.06 (-0.25, 0.37)	
		UDCA Intolerance	8	15.19 (3.51)	8	NE	3	14.50 (2.65)	3	NE	NE		NE	
		Prior Use of OCA and/or Fibrates												0.3100
		yes	20	15.70 (5.22)	18	0.05 (0.71)	13	15.27 (5.70)	12	-1.11 (0.86)	1.16 (-1.11, 3.44)	0.3034	0.38 (-0.36, 1.12)	
		no	108	14.94 (4.44)	108	-0.46 (0.26)	52	15.77 (5.46)	51	-0.41 (0.38)	-0.05 (-0.92, 0.83)	0.9153	-0.02 (-0.35, 0.32)	
		Therapy												NE
		Monotherapy (SEL)	8	15.19 (3.51)	8	NE	4	14.63 (2.17)	4	NE	NE		NE	
		Combinationtherapy (SEL + UDCA)	120	15.05 (4.63)	118	-0.32 (0.26)	61	15.74 (5.61)	59	-0.54 (0.36)	0.22 (-0.62, 1.05)	0.6066	0.08 (-0.23, 0.39)	

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			Seladelpar 10 mg (N=128)				Placebo (N=65)						
			Baseline		Change from BL		Baseline		Change from BL				
Score	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
PBC40-Symptoms Domain Score	Month 6	Stratification variable: Baseline Pruritus NRS												0.1916
		< 4	79	13.47 (4.23)	79	-0.17 (0.34)	42	13.58 (4.47)	41	0.03 (0.44)	-0.20 (-1.23, 0.82)	0.6972	-0.07 (-0.45, 0.31)	
		>= 4	49	17.61 (3.88)	47	-0.82 (0.36)	23	19.48 (5.11)	22	-1.72 (0.56)	0.90 (-0.43, 2.23)	0.1815	0.36 (-0.15, 0.87)	
		Stratification variable: Baseline ALP Level												0.6073
		< 350 U/L	93	14.61 (4.57)	92	-0.01 (0.29)	47	15.23 (5.00)	45	-0.04 (0.41)	0.03 (-0.92, 0.98)	0.9563	0.01 (-0.35, 0.37)	
		>= 350 U/L	35	16.26 (4.37)	34	-0.88 (0.44)	18	16.81 (6.55)	18	-1.38 (0.64)	0.50 (-1.07, 2.07)	0.5270	0.19 (-0.39, 0.76)	
		Gamma-GT (GGT)												0.6401
		<= 3 x ULN	33	14.86 (5.15)	32	-0.07 (0.54)	14	13.32 (4.11)	13	-0.53 (0.76)	0.46 (-1.03, 1.95)	0.5332	0.15 (-0.49, 0.80)	
		> 3 x ULN	95	15.13 (4.36)	94	-0.48 (0.29)	51	16.31 (5.64)	50	-0.53 (0.40)	0.05 (-0.91, 1.01)	0.9179	0.02 (-0.33, 0.36)	
		Total Bilirubin I												0.7422
		<= 1 x ULN	108	14.95 (4.63)	106	-0.24 (0.28)	60	15.43 (5.29)	59	-0.53 (0.37)	0.29 (-0.56, 1.15)	0.5014	0.10 (-0.22, 0.42)	
		> 1 x ULN	20	15.63 (4.23)	20	-0.97 (0.47)	5	18.60 (7.26)	4	-0.73 (1.49)	-0.24 (-3.49, 3.00)	0.8785	-0.10 (-1.18, 0.97)	
		Total Bilirubin II												0.0527
		< 0.6 x ULN	59	14.72 (4.47)	58	-0.18 (0.42)	32	15.95 (4.96)	31	-1.09 (0.53)	0.91 (-0.28, 2.11)	0.1331	0.29 (-0.15, 0.73)	
		>= 0.6 x ULN	69	15.35 (4.64)	68	-0.51 (0.30)	33	15.39 (5.98)	32	0.15 (0.47)	-0.67 (-1.76, 0.43)	0.2290	-0.26 (-0.68, 0.16)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of change from baseline of PBC-40 Scores at month 6 and 12 - Subgroup analysis
Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
			Baseline		Change from BL		Baseline		Change from BL					Interaction
Score	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value
PBC40-Symptoms Domain Score	Month 12	Age at screening												0.6797
		< 65 years	99	15.11 (4.58)	97	-0.08 (0.34)	53	15.41 (5.43)	51	-0.30 (0.46)	0.22 (-0.89, 1.34)	0.6901	0.07 (-0.27, 0.41)	
		>= 65 years	29	14.88 (4.54)	29	-0.08 (0.61)	12	16.83 (5.69)	12	0.19 (0.93)	-0.26 (-2.36, 1.84)	0.8015	-0.08 (-0.75, 0.59)	
		Age at PBC diagnosis												0.5965
		< 50 years	61	14.44 (4.39)	59	0.20 (0.44)	32	15.58 (5.26)	30	-0.26 (0.62)	0.46 (-1.03, 1.96)	0.5403	0.13 (-0.31, 0.57)	
		>= 50 years	67	15.62 (4.66)	67	-0.33 (0.41)	33	15.76 (5.73)	33	-0.27 (0.54)	-0.06 (-1.35, 1.22)	0.9229	-0.02 (-0.44, 0.40)	
		Sex												NE
		female	123	15.25 (4.50)	121	-0.09 (0.30)	60	15.88 (5.49)	58	-0.08 (0.42)	-0.01 (-1.01, 0.98)	0.9786	-0.00 (-0.32, 0.31)	
		male	5	10.40 (3.52)	5	NE	5	13.10 (4.83)	5	NE	NE		NE	
		Race												
		white	114	15.22 (4.59)	113		56	15.74 (5.25)	54					
		black	2	12.75 (2.47)	2		2	13.50 (0.71)	2					
		asian	7	12.00 (3.30)	7		4	12.88 (6.94)	4					
		other	5	16.50 (4.78)	4		3	19.50 (9.10)	3					
		Region												0.0830
		North America	50	15.14 (4.86)	49	0.04 (0.45)	13	15.35 (5.10)	12	0.97 (0.86)	-0.93 (-2.79, 0.92)	0.3173	-0.30 (-0.93, 0.34)	
		Europe	39	15.14 (3.94)	39	-0.72 (0.51)	24	15.56 (5.08)	23	0.31 (0.66)	-1.03 (-2.66, 0.60)	0.2101	-0.32 (-0.84, 0.20)	
		Rest-of-World	39	14.87 (4.83)	38	0.30 (0.60)	28	15.91 (6.09)	28	-1.11 (0.69)	1.42 (-0.37, 3.20)	0.1172	0.38 (-0.11, 0.87)	
		Cirrhosis												0.6964
		yes	18	15.92 (4.12)	18	-0.16 (0.77)	9	18.00 (6.38)	9	-0.74 (1.18)	0.58 (-2.30, 3.46)	0.6801	0.17 (-0.63, 0.97)	
		no	110	14.92 (4.63)	108	-0.10 (0.32)	56	15.29 (5.27)	54	-0.10 (0.42)	0.00 (-1.01, 1.02)	0.9963	0.00 (-0.33, 0.33)	
		UDCA												NE
		UDCA Use	120	15.05 (4.63)	118	-0.05 (0.31)	62	15.73 (5.57)	60	-0.21 (0.42)	0.16 (-0.84, 1.16)	0.7502	0.05 (-0.26, 0.36)	
		UDCA Intolerance	8	15.19 (3.51)	8	NE	3	14.50 (2.65)	3	NE	NE		NE	
		Prior Use of OCA and/or Fibrates												0.5081
		yes	20	15.70 (5.22)	18	0.03 (0.62)	13	15.27 (5.70)	12	-0.68 (0.73)	0.72 (-1.26, 2.69)	0.4628	0.27 (-0.47, 1.00)	
		no	108	14.94 (4.44)	108	-0.14 (0.34)	52	15.77 (5.46)	51	-0.12 (0.47)	-0.02 (-1.13, 1.09)	0.9716	-0.01 (-0.34, 0.33)	
		Therapy												NE
		Monotherapy (SEL)	8	15.19 (3.51)	8	NE	4	14.63 (2.17)	4	NE	NE		NE	
		Combinationtherapy (SEL + UDCA)	120	15.05 (4.63)	118	-0.04 (0.31)	61	15.74 (5.61)	59	-0.17 (0.42)	0.13 (-0.87, 1.14)	0.7921	0.04 (-0.27, 0.35)	

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p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of change from baseline of PBC-40 Scores at month 6 and 12 - Subgroup analysis
Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
		Subgroup	Baseline		Change from BL		Baseline		Change from BL		Difference of			Interaction
Score	Timepoint	Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value
PBC40-Symptoms Domain Score	Month 12	Stratification variable: Baseline Pruritus NRS												0.5238
		< 4	79	13.47 (4.23)	79	0.09 (0.42)	42	13.58 (4.47)	41	-0.23 (0.54)	0.31 (-0.98, 1.61)	0.6324	0.08 (-0.29, 0.46)	
		>= 4	49	17.61 (3.88)	47	-0.53 (0.40)	23	19.48 (5.11)	22	-0.21 (0.61)	-0.31 (-1.79, 1.16)	0.6711	-0.11 (-0.62, 0.40)	
		Stratification variable: Baseline ALP Level												0.3835
		< 350 U/L	93	14.61 (4.57)	92	0.25 (0.35)	47	15.23 (5.00)	45	0.44 (0.49)	-0.19 (-1.36, 0.98)	0.7504	-0.06 (-0.41, 0.30)	
		>= 350 U/L	35	16.26 (4.37)	34	-0.63 (0.51)	18	16.81 (6.55)	18	-1.35 (0.69)	0.72 (-1.01, 2.45)	0.4065	0.24 (-0.33, 0.81)	
		Gamma-GT (GGT)												0.8404
		<= 3 x ULN	33	14.86 (5.15)	32	-0.30 (0.62)	14	13.32 (4.11)	13	-0.46 (0.88)	0.16 (-1.68, 2.00)	0.8603	0.05 (-0.60, 0.69)	
		> 3 x ULN	95	15.13 (4.36)	94	-0.17 (0.36)	51	16.31 (5.64)	50	-0.11 (0.47)	-0.06 (-1.20, 1.09)	0.9232	-0.02 (-0.36, 0.33)	
		Total Bilirubin I												0.2100
		<= 1 x ULN	108	14.95 (4.63)	106	-0.03 (0.33)	60	15.43 (5.29)	59	-0.29 (0.42)	0.26 (-0.76, 1.28)	0.6180	0.08 (-0.24, 0.39)	
		> 1 x ULN	20	15.63 (4.23)	20	-0.50 (0.67)	5	18.60 (7.26)	4	1.72 (1.78)	-2.22 (-6.16, 1.73)	0.2568	-0.69 (-1.79, 0.40)	
		Total Bilirubin II												0.0768
		< 0.6 x ULN	59	14.72 (4.47)	58	0.25 (0.47)	32	15.95 (4.96)	31	-0.70 (0.60)	0.94 (-0.45, 2.33)	0.1799	0.27 (-0.17, 0.70)	
		>= 0.6 x ULN	69	15.35 (4.64)	68	-0.57 (0.40)	33	15.39 (5.98)	32	0.22 (0.56)	-0.79 (-2.16, 0.58)	0.2545	-0.24 (-0.66, 0.18)	

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Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
			Baseline		Change from BL		Baseline		Change from BL					
Score	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
PBC40-Total Score	Month 6	Age at screening												0.7299
		< 65 years	99	93.04 (28.98)	97	-6.00 (1.61)	53	91.08 (29.78)	51	-5.25 (2.16)	-0.75 (-5.90, 4.40)	0.7740	-0.05 (-0.39, 0.29)	
		>= 65 years	29	86.88 (30.46)	29	-4.39 (2.38)	12	93.04 (29.16)	12	-1.91 (3.97)	-2.48 (-11.23, 6.26)	0.5672	-0.19 (-0.86, 0.49)	
		Age at PBC diagnosis												0.1978
		< 50 years	61	92.02 (29.27)	59	-5.36 (2.07)	32	92.66 (30.88)	30	-1.49 (2.91)	-3.88 (-10.80, 3.05)	0.2684	-0.24 (-0.68, 0.20)	
		>= 50 years	67	91.29 (29.58)	67	-5.78 (1.75)	33	90.26 (28.43)	33	-7.67 (2.44)	1.89 (-3.71, 7.48)	0.5049	0.13 (-0.29, 0.55)	
		Sex												NE
		female	123	92.67 (29.07)	121	-5.41 (1.37)	60	92.25 (28.68)	58	-5.10 (1.98)	-0.31 (-4.88, 4.26)	0.8921	-0.02 (-0.33, 0.29)	
		male	5	66.20 (25.78)	5	NE	5	81.70 (40.17)	5	NE	NE		NE	
		Race												
		white	114	92.99 (29.44)	113		56	90.54 (29.19)	54					
		black	2	84.00 (17.68)	2		2	96.50 (7.07)	2					
		asian	7	74.50 (23.42)	7		4	96.25 (32.02)	4					
		other	5	88.00 (36.01)	4		3	98.33 (50.90)	3					
		Region												0.5280
		North America	50	92.78 (30.06)	49	-4.38 (2.50)	13	93.42 (32.95)	12	-8.24 (4.80)	3.85 (-6.46, 14.17)	0.4553	0.22 (-0.41, 0.85)	
		Europe	39	91.88 (28.96)	39	-5.21 (2.72)	24	90.23 (25.87)	23	-1.39 (3.65)	-3.81 (-12.76, 5.13)	0.3965	-0.22 (-0.74, 0.30)	
		Rest-of-World	39	89.94 (29.38)	38	-6.24 (2.16)	28	91.55 (31.62)	28	-5.94 (2.60)	-0.30 (-6.72, 6.13)	0.9269	-0.02 (-0.51, 0.47)	
		Cirrhosis												0.1535
		yes	18	99.00 (30.53)	18	-6.93 (3.56)	9	100.56 (39.01)	9	2.38 (5.43)	-9.31 (-22.50, 3.88)	0.1551	-0.58 (-1.40, 0.24)	
		no	110	90.44 (29.08)	108	-5.33 (1.45)	56	89.97 (27.79)	54	-5.58 (2.01)	0.25 (-4.43, 4.94)	0.9156	0.02 (-0.31, 0.34)	
		UDCA												NE
		UDCA Use	120	91.58 (29.42)	118	-5.28 (1.43)	62	92.40 (29.31)	60	-4.56 (1.95)	-0.71 (-5.28, 3.86)	0.7581	-0.05 (-0.36, 0.26)	
		UDCA Intolerance	8	92.63 (29.67)	8	NE	3	71.50 (30.43)	3	NE	NE		NE	
		Prior Use of OCA and/or Fibrates												0.7448
		yes	20	94.13 (34.59)	18	-4.64 (3.66)	13	94.88 (29.33)	12	-5.34 (4.50)	0.70 (-11.24, 12.63)	0.9052	0.04 (-0.69, 0.77)	
		no	108	91.18 (28.39)	108	-6.00 (1.48)	52	90.58 (29.70)	51	-4.65 (2.11)	-1.35 (-6.18, 3.49)	0.5824	-0.09 (-0.42, 0.25)	
		Therapy												NE
		Monotherapy (SEL)	8	92.63 (29.67)	8	NE	4	80.13 (30.24)	4	NE	NE		NE	
		Combinationtherapy (SEL + UDCA)	120	91.58 (29.42)	118	-5.24 (1.42)	61	92.18 (29.50)	59	-5.13 (1.96)	-0.11 (-4.67, 4.44)	0.9611	-0.01 (-0.32, 0.31)	

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Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
			Baseline		Change from BL		Baseline		Change from BL					
Score	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
PBC40-Total Score	Month 6	Stratification variable: Baseline Pruritus NRS												0.1569
		< 4	79	80.39 (27.39)	79	-1.62 (1.78)	42	77.19 (21.72)	41	-2.63 (2.33)	1.01 (-4.46, 6.47)	0.7152	0.06 (-0.31, 0.44)	
		>= 4	49	109.78 (22.60)	47	-11.08 (2.13)	23	117.46 (23.43)	22	-5.31 (3.28)	-5.77 (-13.58, 2.05)	0.1455	-0.38 (-0.89, 0.13)	
		Stratification variable: Baseline ALP Level												0.7074
		< 350 U/L	93	88.60 (29.80)	92	-4.01 (1.54)	47	92.32 (30.46)	45	-2.55 (2.17)	-1.45 (-6.49, 3.58)	0.5686	-0.10 (-0.46, 0.26)	
		>= 350 U/L	35	99.71 (26.75)	34	-7.26 (2.63)	18	89.14 (27.33)	18	-7.79 (3.80)	0.53 (-8.81, 9.87)	0.9092	0.03 (-0.54, 0.60)	
		Gamma-GT (GGT)												0.1796
		<= 3 x ULN	33	89.08 (31.17)	32	-4.52 (4.00)	14	85.68 (28.17)	13	-9.41 (5.54)	4.89 (-6.02, 15.79)	0.3682	0.22 (-0.43, 0.87)	
		> 3 x ULN	95	92.53 (28.76)	94	-6.32 (1.50)	51	93.02 (29.87)	50	-3.28 (2.07)	-3.04 (-7.99, 1.91)	0.2261	-0.21 (-0.55, 0.14)	
		Total Bilirubin I												0.1945
		<= 1 x ULN	108	90.78 (29.28)	106	-6.65 (1.47)	60	90.49 (28.84)	59	-5.01 (1.90)	-1.63 (-6.10, 2.84)	0.4716	-0.11 (-0.43, 0.21)	
		> 1 x ULN	20	96.28 (29.81)	20	-2.96 (3.42)	5	102.80 (37.87)	4	-14.89 (9.63)	11.93 (-9.18, 33.04)	0.2543	0.72 (-0.37, 1.82)	
		Total Bilirubin II												0.9646
		< 0.6 x ULN	59	89.86 (27.55)	58	-4.69 (2.33)	32	92.08 (29.09)	31	-3.76 (2.86)	-0.93 (-7.40, 5.53)	0.7749	-0.05 (-0.49, 0.38)	
		>= 0.6 x ULN	69	93.16 (30.86)	68	-6.00 (1.72)	33	90.82 (30.23)	32	-4.87 (2.65)	-1.13 (-7.32, 5.06)	0.7177	-0.08 (-0.50, 0.34)	

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			Seladelpar 10 mg (N=128)				Placebo (N=65)							
			Baseline		Change from BL		Baseline		Change from BL					
Score	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
PBC40-Total Score	Month 12	Age at screening												0.7471
		< 65 years	99	93.04 (28.98)	97	-6.75 (1.97)	53	91.08 (29.78)	51	-6.61 (2.64)	-0.14 (-6.50, 6.23)	0.9663	-0.01 (-0.35, 0.33)	
		>= 65 years	29	86.88 (30.46)	29	-2.86 (2.91)	12	93.04 (29.16)	12	-4.60 (4.22)	1.74 (-8.15, 11.63)	0.7222	0.11 (-0.56, 0.78)	
		Age at PBC diagnosis												0.5756
		< 50 years	61	92.02 (29.27)	59	-7.00 (2.36)	32	92.66 (30.88)	30	-5.55 (3.27)	-1.46 (-9.33, 6.42)	0.7135	-0.08 (-0.52, 0.36)	
		>= 50 years	67	91.29 (29.58)	67	-4.95 (2.32)	33	90.26 (28.43)	33	-6.54 (3.09)	1.58 (-5.83, 9.00)	0.6719	0.08 (-0.33, 0.50)	
		Sex												NE
		female	123	92.67 (29.07)	121	-5.92 (1.72)	60	92.25 (28.68)	58	-6.36 (2.37)	0.44 (-5.21, 6.08)	0.8785	0.02 (-0.29, 0.34)	
		male	5	66.20 (25.78)	5	NE	5	81.70 (40.17)	5	NE	NE		NE	
		Race												
		white	114	92.99 (29.44)	113		56	90.54 (29.19)	54					
		black	2	84.00 (17.68)	2		2	96.50 (7.07)	2					
		asian	7	74.50 (23.42)	7		4	96.25 (32.02)	4					
		other	5	88.00 (36.01)	4		3	98.33 (50.90)	3					
		Region												0.0233
		North America	50	92.78 (30.06)	49	-2.43 (2.46)	13	93.42 (32.95)	12	-6.10 (4.63)	3.68 (-6.28, 13.64)	0.4611	0.21 (-0.42, 0.85)	
		Europe	39	91.88 (28.96)	39	-8.64 (2.46)	24	90.23 (25.87)	23	1.27 (3.18)	-9.91 (-17.76, -2.06)	0.0143	-0.64 (-1.17, -0.11)	
		Rest-of-World	39	89.94 (29.38)	38	-6.34 (3.39)	28	91.55 (31.62)	28	-11.62 (3.85)	5.28 (-4.75, 15.31)	0.2964	0.25 (-0.24, 0.74)	
		Cirrhosis												0.4446
		yes	18	99.00 (30.53)	18	-9.07 (4.30)	9	100.56 (39.01)	9	-16.40 (7.42)	7.34 (-10.42, 25.09)	0.3948	0.36 (-0.44, 1.17)	
		no	110	90.44 (29.08)	108	-5.36 (1.77)	56	89.97 (27.79)	54	-5.92 (2.36)	0.56 (-5.10, 6.21)	0.8463	0.03 (-0.30, 0.36)	
		UDCA												NE
		UDCA Use	120	91.58 (29.42)	118	-5.85 (1.73)	62	92.40 (29.31)	60	-6.34 (2.31)	0.49 (-5.04, 6.01)	0.8624	0.03 (-0.28, 0.34)	
		UDCA Intolerance	8	92.63 (29.67)	8	NE	3	71.50 (30.43)	3	NE	NE		NE	
		Prior Use of OCA and/or Fibrates												0.4703
		yes	20	94.13 (34.59)	18	-2.34 (3.66)	13	94.88 (29.33)	12	-6.76 (4.27)	4.42 (-7.22, 16.06)	0.4407	0.28 (-0.45, 1.02)	
		no	108	91.18 (28.39)	108	-6.71 (1.86)	52	90.58 (29.70)	51	-6.49 (2.59)	-0.22 (-6.31, 5.88)	0.9439	-0.01 (-0.34, 0.32)	
		Therapy												NE
		Monotherapy (SEL)	8	92.63 (29.67)	8	NE	4	80.13 (30.24)	4	NE	NE		NE	
		Combinationtherapy (SEL + UDCA)	120	91.58 (29.42)	118	-5.83 (1.74)	61	92.18 (29.50)	59	-6.29 (2.32)	0.46 (-5.09, 6.02)	0.8691	0.02 (-0.29, 0.34)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of change from baseline of PBC-40 Scores at month 6 and 12 - Subgroup analysis
Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
			Baseline		Change from BL		Baseline		Change from BL					
Score	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
PBC40-Total Score	Month 12	Stratification variable: Baseline Pruritus NRS												0.3131
		< 4	79	80.39 (27.39)	79	-2.21 (2.18)	42	77.19 (21.72)	41	-4.57 (2.80)	2.36 (-4.40, 9.11)	0.4905	0.12 (-0.25, 0.50)	
		>= 4	49	109.78 (22.60)	47	-10.58 (2.56)	23	117.46 (23.43)	22	-7.15 (3.84)	-3.43 (-12.66, 5.80)	0.4602	-0.19 (-0.70, 0.32)	
		Stratification variable: Baseline ALP Level												0.3669
		< 350 U/L	93	88.60 (29.80)	92	-4.70 (1.93)	47	92.32 (30.46)	45	-6.57 (2.66)	1.88 (-4.45, 8.20)	0.5580	0.10 (-0.25, 0.46)	
		>= 350 U/L	35	99.71 (26.75)	34	-5.94 (2.97)	18	89.14 (27.33)	18	-2.41 (4.09)	-3.53 (-13.74, 6.69)	0.4899	-0.20 (-0.77, 0.37)	
		Gamma-GT (GGT)												0.2796
		<= 3 x ULN	33	89.08 (31.17)	32	-6.11 (4.80)	14	85.68 (28.17)	13	-13.05 (7.05)	6.94 (-8.14, 22.02)	0.3548	0.26 (-0.39, 0.90)	
		> 3 x ULN	95	92.53 (28.76)	94	-6.45 (1.76)	51	93.02 (29.87)	50	-4.83 (2.30)	-1.62 (-7.26, 4.03)	0.5721	-0.10 (-0.44, 0.25)	
		Total Bilirubin I												0.2909
		<= 1 x ULN	108	90.78 (29.28)	106	-5.86 (1.83)	60	90.49 (28.84)	59	-7.05 (2.31)	1.19 (-4.41, 6.79)	0.6746	0.06 (-0.25, 0.38)	
		> 1 x ULN	20	96.28 (29.81)	20	-9.06 (3.75)	5	102.80 (37.87)	4	1.77 (10.36)	-10.83 (-33.62, 11.95)	0.3360	-0.60 (-1.69, 0.49)	
		Total Bilirubin II												0.0730
		< 0.6 x ULN	59	89.86 (27.55)	58	-3.93 (2.83)	32	92.08 (29.09)	31	-9.18 (3.59)	5.25 (-3.19, 13.69)	0.2192	0.25 (-0.19, 0.69)	
		>= 0.6 x ULN	69	93.16 (30.86)	68	-7.55 (2.01)	33	90.82 (30.23)	32	-3.03 (2.82)	-4.51 (-11.32, 2.29)	0.1908	-0.27 (-0.70, 0.15)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Completion rates of PGI by visit
Intention-to-treat

Score	Timepoint	Seladelpar 10 mg (N=128) n/ N	Seladelpar 10 mg (N=128) Completion	Placebo (N=65) n/ N	Placebo (N=65) Completion
PGI01-Severity	Baseline	128/ 128	100.0%	64/ 65	98.46%
	Month 1	116/ 128	90.63%	61/ 65	93.85%
	Month 3	116/ 128	90.63%	57/ 65	87.69%
	Month 6	110/ 128	85.94%	53/ 65	81.54%
	Month 9	111/ 128	86.72%	53/ 65	81.54%
	Month 12	94/ 128	73.44%	51/ 65	78.46%

n describes number of patients with non-missing value at the respective timepoint.
N defines number of patients still alive at beginning of respective visit window.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Completion rates of PGI by visit
Intention-to-treat

Score	Timepoint	Seladelpar 10 mg (N=128) n/ N	Seladelpar 10 mg (N=128) Completion	Placebo (N=65) n/ N	Placebo (N=65) Completion
PGI01-Change	Month 1	116/ 128	90.63%	61/ 65	93.85%
	Month 3	115/ 128	89.84%	57/ 65	87.69%
	Month 6	105/ 128	82.03%	52/ 65	80.00%
	Month 9	111/ 128	86.72%	53/ 65	81.54%
	Month 12	94/ 128	73.44%	51/ 65	78.46%

n describes number of patients with non-missing value at the respective timepoint.
N defines number of patients still alive at beginning of respective visit window.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Summary of mean values and change from baseline of PGI by visit
Intention-to-treat

		Seladelpar 10 mg (N=128)				Placebo (N=65)			
		Value at Timepoint		Change from Baseline		Value at Timepoint		Change from Baseline	
Score	Timepoint	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
PGI01-Severity	Baseline	128	2.13 (0.98)	128	0.00 (0.00)	64	2.16 (0.95)	64	0.00 (0.00)
	Month 1	116	1.89 (0.81)	116	-0.21 (0.73)	61	2.13 (0.96)	60	-0.02 (0.68)
	Month 3	116	1.79 (0.72)	116	-0.32 (0.81)	57	2.25 (0.95)	56	0.04 (0.76)
	Month 6	110	1.67 (0.67)	110	-0.39 (0.79)	53	2.17 (0.91)	52	0.02 (0.73)
	Month 9	111	1.62 (0.74)	111	-0.44 (0.84)	53	1.94 (0.95)	53	-0.13 (0.62)
	Month 12	94	1.70 (0.80)	94	-0.37 (0.84)	51	1.82 (0.93)	50	-0.30 (0.71)

N describes number of patients with non-missing value at the respective timepoint.
N=Number of subjects included in the analysis, SD: Standard Deviation; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Summary of mean values and change from baseline of PGI by visit
Intention-to-treat

		Seladelpar 10 mg (N=128)				Placebo (N=65)			
		Value at Timepoint		Change from Baseline		Value at Timepoint		Change from Baseline	
Score	Timepoint	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
PGI01-Change	Month 1	116	3.38 (1.08)	116	3.38 (1.08)	61	3.44 (1.27)	61	3.44 (1.27)
	Month 3	115	2.82 (1.29)	115	2.82 (1.29)	57	3.09 (1.33)	57	3.09 (1.33)
	Month 6	105	2.74 (1.27)	105	2.74 (1.27)	52	3.08 (1.38)	52	3.08 (1.38)
	Month 9	111	2.34 (1.40)	111	2.34 (1.40)	53	2.92 (1.38)	53	2.92 (1.38)
	Month 12	94	2.64 (1.42)	94	2.64 (1.42)	51	3.12 (1.18)	51	3.12 (1.18)

N describes number of patients with non-missing value at the respective timepoint.
N=Number of subjects included in the analysis, SD: Standard Deviation; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of change from baseline of PGI by visit
Intention-to-treat

Score	Visit	Seladelpar 10 mg (N=128) N	Seladelpar 10 mg (N=128) LSMean (SE)	Placebo (N=65) N	Placebo (N=65) LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)
PGI01-Severity	Month 1	125	-0.18 (0.06)	62	0.01 (0.08)	-0.20 (-0.39, -0.01)	0.0386	-0.30 (-0.60, 0.01)
	Month 3	125	-0.30 (0.06)	62	0.08 (0.09)	-0.38 (-0.58, -0.18)	0.0002	-0.55 (-0.86, -0.24)
	Month 6	125	-0.37 (0.06)	62	0.04 (0.08)	-0.42 (-0.61, -0.23)	<.0001	-0.64 (-0.95, -0.32)
	Month 9	125	-0.44 (0.06)	62	-0.10 (0.09)	-0.34 (-0.53, -0.14)	0.0009	-0.49 (-0.80, -0.18)
	Month 12	125	-0.36 (0.07)	62	-0.26 (0.09)	-0.10 (-0.32, 0.11)	0.3453	-0.14 (-0.44, 0.17)

(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
N=Number of subjects included in the analysis, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of change from baseline of PGI by visit
Intention-to-treat

		Seladelpar 10 mg (N=128)		Placebo (N=65)				
Score	Visit	N	LSMean (SE)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)
PGI01-Change	Month 1	124	3.28 (0.11)	63	3.32 (0.15)	-0.04 (-0.39, 0.30)	0.8080	-0.04 (-0.34, 0.27)
	Month 3	124	2.71 (0.12)	63	2.99 (0.17)	-0.28 (-0.68, 0.13)	0.1788	-0.20 (-0.50, 0.10)
	Month 6	124	2.61 (0.13)	63	3.07 (0.18)	-0.45 (-0.88, -0.02)	0.0391	-0.31 (-0.61, -0.01)
	Month 9	124	2.24 (0.13)	63	2.85 (0.19)	-0.61 (-1.04, -0.17)	0.0064	-0.41 (-0.72, -0.11)
	Month 12	124	2.60 (0.14)	63	3.01 (0.18)	-0.41 (-0.85, 0.03)	0.0673	-0.27 (-0.58, 0.03)

(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
N=Number of subjects included in the analysis, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of change from baseline of PGI at month 6 and 12 - Subgroup analysis
Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
			Baseline		Change from BL		Baseline		Change from BL					
Score	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
PGI01-Severity	Month 6	Age at screening												0.4356
		< 65 years	99	2.18 (0.94)	96	-0.40 (0.07)	52	2.17 (0.98)	50	-0.02 (0.09)	-0.38 (-0.59, -0.17)	0.0006	-0.58 (-0.93, -0.23)	
		>= 65 years	29	1.97 (1.09)	29	-0.28 (0.13)	12	2.08 (0.79)	12	0.29 (0.22)	-0.58 (-1.05, -0.11)	0.0175	-0.78 (-1.48, -0.09)	
		Age at PBC diagnosis												0.4156
		< 50 years	61	2.18 (0.97)	59	-0.38 (0.08)	32	2.19 (1.00)	30	0.10 (0.12)	-0.48 (-0.75, -0.21)	0.0006	-0.76 (-1.21, -0.31)	
		>= 50 years	67	2.09 (0.98)	66	-0.34 (0.09)	32	2.13 (0.91)	32	-0.01 (0.12)	-0.33 (-0.60, -0.05)	0.0221	-0.45 (-0.88, -0.03)	
		Sex												NE
		female	123	2.15 (0.96)	120	-0.39 (0.06)	59	2.19 (0.96)	57	0.05 (0.09)	-0.43 (-0.63, -0.24)	<.0001	-0.66 (-0.98, -0.33)	
		male	5	1.80 (1.30)	5	NE	5	1.80 (0.84)	5	NE	NE		NE	
		Race												
		white	114	2.13 (0.98)	112		55	2.16 (0.96)	53					
		black	2	3.00 (0.00)	2		2	2.00 (0.00)	2					
		asian	7	1.71 (0.76)	7		4	2.00 (1.41)	4					
		other	5	2.40 (1.14)	4		3	2.33 (0.58)	3					
		Region												0.6462
		North America	50	2.04 (0.90)	48	-0.30 (0.11)	13	2.15 (0.99)	12	0.04 (0.21)	-0.34 (-0.76, 0.08)	0.1117	-0.46 (-1.10, 0.18)	
		Europe	39	2.15 (0.93)	39	-0.43 (0.11)	23	2.39 (0.89)	22	-0.07 (0.16)	-0.36 (-0.73, 0.01)	0.0565	-0.51 (-1.04, 0.02)	
		Rest-of-World	39	2.23 (1.11)	38	-0.40 (0.10)	28	1.96 (0.96)	28	0.14 (0.11)	-0.54 (-0.82, -0.25)	0.0004	-0.87 (-1.38, -0.36)	
		Cirrhosis												0.4008
		yes	18	2.44 (0.92)	18	-0.52 (0.15)	9	2.44 (1.13)	9	0.08 (0.21)	-0.60 (-1.12, -0.07)	0.0274	-0.91 (-1.76, -0.07)	
		no	110	2.08 (0.98)	107	-0.34 (0.06)	55	2.11 (0.92)	53	0.02 (0.09)	-0.37 (-0.57, -0.17)	0.0005	-0.56 (-0.90, -0.23)	
		UDCA												NE
		UDCA Use	120	2.13 (0.97)	117	-0.37 (0.06)	61	2.18 (0.94)	59	0.08 (0.08)	-0.45 (-0.64, -0.25)	<.0001	-0.68 (-1.00, -0.36)	
		UDCA Intolerance	8	2.25 (1.16)	8	NE	3	1.67 (1.15)	3	NE	NE		NE	
		Prior Use of OCA and/or Fibrates												0.1951
		yes	20	2.45 (1.10)	18	-0.62 (0.17)	13	2.46 (0.78)	12	0.11 (0.21)	-0.73 (-1.29, -0.17)	0.0126	-0.98 (-1.76, -0.20)	
		no	108	2.07 (0.94)	107	-0.32 (0.06)	51	2.08 (0.98)	50	0.03 (0.09)	-0.35 (-0.56, -0.15)	0.0008	-0.54 (-0.88, -0.19)	
		Therapy												NE
		Monotherapy (SEL)	8	2.25 (1.16)	8	NE	4	1.75 (0.96)	4	NE	NE		NE	
		Combinationtherapy (SEL + UDCA)	120	2.13 (0.97)	117	-0.37 (0.06)	60	2.18 (0.95)	58	0.06 (0.08)	-0.43 (-0.62, -0.24)	<.0001	-0.65 (-0.97, -0.33)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
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N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of change from baseline of PGI at month 6 and 12 - Subgroup analysis
Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
			Baseline		Change from BL		Baseline		Change from BL					
Score	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
PGI01-Severity	Month 6	Stratification variable: Baseline Pruritus NRS												0.2079
		< 4	79	1.58 (0.71)	79	-0.15 (0.07)	41	1.61 (0.63)	40	0.18 (0.10)	-0.33 (-0.56, -0.11)	0.0045	-0.51 (-0.90, -0.13)	
		>= 4	49	3.02 (0.63)	46	-0.88 (0.09)	23	3.13 (0.55)	22	-0.29 (0.14)	-0.59 (-0.93, -0.25)	0.0010	-0.91 (-1.44, -0.38)	
		Stratification variable: Baseline ALP Level												0.6613
		< 350 U/L	93	1.96 (0.90)	91	-0.26 (0.07)	46	2.07 (0.95)	44	0.12 (0.10)	-0.39 (-0.61, -0.17)	0.0007	-0.59 (-0.96, -0.23)	
		>= 350 U/L	35	2.60 (1.03)	34	-0.60 (0.11)	18	2.39 (0.92)	18	-0.12 (0.16)	-0.48 (-0.87, -0.10)	0.0157	-0.73 (-1.32, -0.14)	
		Gamma-GT (GGT)												0.6215
		<= 3 x ULN	33	2.03 (0.88)	31	-0.16 (0.16)	13	1.77 (0.73)	12	0.17 (0.23)	-0.34 (-0.77, 0.10)	0.1255	-0.37 (-1.04, 0.30)	
		> 3 x ULN	95	2.17 (1.01)	94	-0.41 (0.07)	51	2.25 (0.98)	50	0.04 (0.09)	-0.46 (-0.67, -0.24)	<.0001	-0.70 (-1.05, -0.34)	
		Total Bilirubin I												0.5820
		<= 1 x ULN	108	2.10 (0.98)	105	-0.40 (0.07)	59	2.17 (0.95)	58	0.05 (0.09)	-0.45 (-0.65, -0.25)	<.0001	-0.67 (-0.99, -0.34)	
		> 1 x ULN	20	2.30 (0.98)	20	-0.35 (0.13)	5	2.00 (1.00)	4	-0.13 (0.38)	-0.22 (-1.06, 0.63)	0.5962	-0.34 (-1.42, 0.74)	
		Total Bilirubin II												0.1917
		< 0.6 x ULN	59	1.90 (0.84)	58	-0.15 (0.10)	32	2.16 (0.92)	31	0.13 (0.12)	-0.28 (-0.55, -0.01)	0.0396	-0.39 (-0.83, 0.05)	
		>= 0.6 x ULN	69	2.33 (1.04)	67	-0.53 (0.08)	32	2.16 (0.99)	31	0.00 (0.12)	-0.54 (-0.82, -0.25)	0.0003	-0.80 (-1.24, -0.36)	

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(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of change from baseline of PGI at month 6 and 12 - Subgroup analysis
Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
			Baseline		Change from BL		Baseline		Change from BL					
Score	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
PGI01-Severity	Month 12	Age at screening												0.2783
		< 65 years	99	2.18 (0.94)	96	-0.44 (0.08)	52	2.17 (0.98)	50	-0.26 (0.10)	-0.18 (-0.42, 0.06)	0.1433	-0.24 (-0.59, 0.10)	
		>= 65 years	29	1.97 (1.09)	29	-0.09 (0.16)	12	2.08 (0.79)	12	-0.22 (0.22)	0.12 (-0.39, 0.63)	0.6302	0.14 (-0.53, 0.82)	
		Age at PBC diagnosis												0.3464
		< 50 years	61	2.18 (0.97)	59	-0.44 (0.08)	32	2.19 (1.00)	30	-0.23 (0.11)	-0.21 (-0.48, 0.06)	0.1327	-0.32 (-0.76, 0.12)	
		>= 50 years	67	2.09 (0.98)	66	-0.28 (0.11)	32	2.13 (0.91)	32	-0.28 (0.15)	-0.00 (-0.34, 0.34)	0.9987	-0.00 (-0.42, 0.42)	
		Sex												NE
		female	123	2.15 (0.96)	120	-0.37 (0.07)	59	2.19 (0.96)	57	-0.28 (0.10)	-0.09 (-0.32, 0.13)	0.4133	-0.12 (-0.44, 0.19)	
		male	5	1.80 (1.30)	5	NE	5	1.80 (0.84)	5	NE	NE		NE	
		Race												
		white	114	2.13 (0.98)	112		55	2.16 (0.96)	53					
		black	2	3.00 (0.00)	2		2	2.00 (0.00)	2					
		asian	7	1.71 (0.76)	7		4	2.00 (1.41)	4					
		other	5	2.40 (1.14)	4		3	2.33 (0.58)	3					
		Region												0.4396
		North America	50	2.04 (0.90)	48	-0.14 (0.12)	13	2.15 (0.99)	12	-0.26 (0.22)	0.12 (-0.34, 0.58)	0.6075	0.14 (-0.49, 0.78)	
		Europe	39	2.15 (0.93)	39	-0.62 (0.11)	23	2.39 (0.89)	22	-0.41 (0.15)	-0.21 (-0.56, 0.14)	0.2380	-0.31 (-0.83, 0.22)	
		Rest-of-World	39	2.23 (1.11)	38	-0.37 (0.14)	28	1.96 (0.96)	28	-0.15 (0.15)	-0.23 (-0.62, 0.16)	0.2456	-0.28 (-0.77, 0.21)	
		Cirrhosis												0.0463
		yes	18	2.44 (0.92)	18	-0.46 (0.19)	9	2.44 (1.13)	9	-1.13 (0.35)	0.68 (-0.14, 1.50)	0.0988	0.73 (-0.10, 1.56)	
		no	110	2.08 (0.98)	107	-0.35 (0.07)	55	2.11 (0.92)	53	-0.22 (0.10)	-0.13 (-0.36, 0.10)	0.2611	-0.18 (-0.51, 0.15)	
		UDCA												NE
		UDCA Use	120	2.13 (0.97)	117	-0.38 (0.07)	61	2.18 (0.94)	59	-0.24 (0.09)	-0.15 (-0.37, 0.08)	0.1947	-0.19 (-0.51, 0.12)	
		UDCA Intolerance	8	2.25 (1.16)	8	NE	3	1.67 (1.15)	3	NE	NE		NE	
		Prior Use of OCA and/or Fibrates												0.6024
		yes	20	2.45 (1.10)	18	-0.58 (0.15)	13	2.46 (0.78)	12	-0.58 (0.18)	0.01 (-0.50, 0.51)	0.9832	0.01 (-0.72, 0.74)	
		no	108	2.07 (0.94)	107	-0.31 (0.08)	51	2.08 (0.98)	50	-0.17 (0.11)	-0.14 (-0.39, 0.11)	0.2753	-0.17 (-0.51, 0.16)	
		Therapy												NE
		Monotherapy (SEL)	8	2.25 (1.16)	8	NE	4	1.75 (0.96)	4	NE	NE		NE	
		Combinationtherapy (SEL + UDCA)	120	2.13 (0.97)	117	-0.39 (0.07)	60	2.18 (0.95)	58	-0.25 (0.09)	-0.14 (-0.36, 0.08)	0.2160	-0.19 (-0.50, 0.13)	

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N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of change from baseline of PGI at month 6 and 12 - Subgroup analysis
Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
			Baseline		Change from BL		Baseline		Change from BL					
Score	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
PGI01-Severity	Month 12	Stratification variable: Baseline Pruritus NRS												0.2120
		< 4	79	1.58 (0.71)	79	-0.16 (0.08)	41	1.61 (0.63)	40	-0.15 (0.10)	-0.01 (-0.25, 0.23)	0.9245	-0.02 (-0.40, 0.36)	
		>= 4	49	3.02 (0.63)	46	-0.81 (0.13)	23	3.13 (0.55)	22	-0.46 (0.20)	-0.34 (-0.82, 0.13)	0.1533	-0.38 (-0.89, 0.14)	
		Stratification variable: Baseline ALP Level												0.0221
		< 350 U/L	93	1.96 (0.90)	91	-0.23 (0.07)	46	2.07 (0.95)	44	-0.30 (0.10)	0.07 (-0.17, 0.31)	0.5728	0.10 (-0.26, 0.46)	
		>= 350 U/L	35	2.60 (1.03)	34	-0.65 (0.14)	18	2.39 (0.92)	18	-0.12 (0.19)	-0.53 (-1.01, -0.06)	0.0271	-0.66 (-1.24, -0.07)	
		Gamma-GT (GGT)												0.3465
		<= 3 x ULN	33	2.03 (0.88)	31	-0.07 (0.18)	13	1.77 (0.73)	12	-0.16 (0.26)	0.09 (-0.43, 0.60)	0.7282	0.09 (-0.58, 0.76)	
		> 3 x ULN	95	2.17 (1.01)	94	-0.43 (0.08)	51	2.25 (0.98)	50	-0.25 (0.10)	-0.18 (-0.43, 0.07)	0.1621	-0.24 (-0.58, 0.11)	
		Total Bilirubin I												0.0257
		<= 1 x ULN	108	2.10 (0.98)	105	-0.34 (0.08)	59	2.17 (0.95)	58	-0.28 (0.10)	-0.06 (-0.29, 0.17)	0.6141	-0.08 (-0.40, 0.24)	
		> 1 x ULN	20	2.30 (0.98)	20	-0.45 (0.16)	5	2.00 (1.00)	4	0.75 (0.47)	-1.21 (-2.26, -0.16)	0.0261	-1.52 (-2.70, -0.35)	
		Total Bilirubin II												0.0033
		< 0.6 x ULN	59	1.90 (0.84)	58	-0.08 (0.10)	32	2.16 (0.92)	31	-0.30 (0.13)	0.22 (-0.08, 0.52)	0.1520	0.28 (-0.16, 0.72)	
		>= 0.6 x ULN	69	2.33 (1.04)	67	-0.58 (0.09)	32	2.16 (0.99)	31	-0.16 (0.13)	-0.42 (-0.73, -0.11)	0.0085	-0.57 (-1.00, -0.13)	

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Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
			Baseline		Change from BL		Baseline		Change from BL					
Score	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
PGI01-Change	Month 6	Age at screening												0.2890
		< 65 years	0	-	95	2.52 (0.15)	0	-	51	2.92 (0.20)	-0.39 (-0.88, 0.09)	0.1066	-0.27 (-0.61, 0.07)	
		>= 65 years	0	-	29	3.06 (0.27)	0	-	12	4.00 (0.42)	-0.95 (-1.88, -0.01)	0.0470	-0.64 (-1.33, 0.05)	
		Age at PBC diagnosis												0.8797
		< 50 years	0	-	59	2.68 (0.19)	0	-	30	3.16 (0.26)	-0.48 (-1.10, 0.15)	0.1325	-0.33 (-0.77, 0.11)	
		>= 50 years	0	-	65	2.56 (0.19)	0	-	33	2.97 (0.26)	-0.41 (-1.01, 0.18)	0.1719	-0.27 (-0.70, 0.15)	
		Sex												NE
		female	0	-	119	2.61 (0.13)	0	-	58	3.15 (0.19)	-0.53 (-0.98, -0.08)	0.0213	-0.36 (-0.68, -0.04)	
		male	0	-	5	NE	0	-	5	NE	NE		NE	
		Race												
		white	0	-	111		0	-	54					
		black	0	-	2		0	-	2					
		asian	0	-	7		0	-	4					
		other	0	-	4		0	-	3					
		Region												0.1043
		North America	0	-	48	2.76 (0.23)	0	-	12	2.49 (0.44)	0.26 (-0.69, 1.22)	0.5799	0.16 (-0.47, 0.80)	
		Europe	0	-	38	2.56 (0.22)	0	-	23	2.93 (0.30)	-0.37 (-1.10, 0.35)	0.3078	-0.26 (-0.78, 0.26)	
		Rest-of-World	0	-	38	2.44 (0.24)	0	-	28	3.42 (0.28)	-0.98 (-1.69, -0.27)	0.0078	-0.66 (-1.16, -0.16)	
		Cirrhosis												0.8697
		yes	0	-	18	2.64 (0.40)	0	-	9	2.95 (0.59)	-0.31 (-1.76, 1.14)	0.6603	-0.17 (-0.98, 0.63)	
		no	0	-	106	2.63 (0.14)	0	-	54	3.06 (0.19)	-0.43 (-0.88, 0.01)	0.0572	-0.31 (-0.64, 0.02)	
		UDCA												NE
		UDCA Use	0	-	116	2.60 (0.14)	0	-	60	3.10 (0.19)	-0.50 (-0.94, -0.05)	0.0282	-0.34 (-0.65, -0.02)	
		UDCA Intolerance	0	-	8	NE	0	-	3	NE	NE		NE	
		Prior Use of OCA and/or Fibrates												0.4761
		yes	0	-	18	2.68 (0.35)	0	-	12	2.79 (0.43)	-0.11 (-1.25, 1.03)	0.8453	-0.07 (-0.80, 0.66)	
		no	0	-	106	2.60 (0.14)	0	-	51	3.14 (0.20)	-0.54 (-1.01, -0.07)	0.0258	-0.37 (-0.70, -0.03)	
		Therapy												NE
		Monotherapy (SEL)	0	-	8	NE	0	-	4	NE	NE		NE	
		Combinationtherapy (SEL + UDCA)	0	-	116	2.60 (0.14)	0	-	59	3.04 (0.19)	-0.44 (-0.88, -0.00)	0.0487	-0.30 (-0.62, 0.01)	

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			Seladelpar 10 mg (N=128)				Placebo (N=65)							
			Baseline		Change from BL		Baseline		Change from BL					
Score	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
PGI01-Change	Month 6	Stratification variable: Baseline Pruritus NRS												0.3952
		< 4	0	-	78	2.86 (0.17)	0	-	41	3.16 (0.23)	-0.30 (-0.84, 0.23)	0.2607	-0.20 (-0.58, 0.18)	
		>= 4	0	-	46	2.36 (0.21)	0	-	22	3.06 (0.31)	-0.70 (-1.45, 0.06)	0.0690	-0.48 (-0.99, 0.04)	
		Stratification variable: Baseline ALP Level												0.9442
		< 350 U/L	0	-	90	2.63 (0.15)	0	-	45	3.09 (0.21)	-0.46 (-0.96, 0.03)	0.0650	-0.33 (-0.69, 0.03)	
		>= 350 U/L	0	-	34	2.66 (0.25)	0	-	18	3.09 (0.36)	-0.43 (-1.30, 0.44)	0.3275	-0.29 (-0.86, 0.29)	
		Gamma-GT (GGT)												0.8029
		<= 3 x ULN	0	-	31	2.67 (0.33)	0	-	13	3.23 (0.47)	-0.56 (-1.51, 0.39)	0.2424	-0.30 (-0.95, 0.35)	
		> 3 x ULN	0	-	93	2.63 (0.15)	0	-	50	3.06 (0.20)	-0.42 (-0.92, 0.07)	0.0913	-0.29 (-0.64, 0.05)	
		Total Bilirubin I												0.3096
		<= 1 x ULN	0	-	104	2.58 (0.14)	0	-	59	3.09 (0.18)	-0.52 (-0.95, -0.08)	0.0214	-0.36 (-0.68, -0.04)	
		> 1 x ULN	0	-	20	2.92 (0.35)	0	-	4	2.26 (1.09)	0.66 (-1.74, 3.06)	0.5683	0.39 (-0.69, 1.47)	
		Total Bilirubin II												0.7433
		< 0.6 x ULN	0	-	57	2.58 (0.22)	0	-	31	2.98 (0.27)	-0.39 (-1.03, 0.24)	0.2210	-0.24 (-0.68, 0.19)	
		>= 0.6 x ULN	0	-	67	2.63 (0.17)	0	-	32	3.17 (0.25)	-0.54 (-1.14, 0.06)	0.0798	-0.38 (-0.80, 0.05)	

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			Seladelpar 10 mg (N=128)				Placebo (N=65)							
			Baseline		Change from BL		Baseline		Change from BL					
Score	Timepoint	Subgroup Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	Interaction p-Value
PGI01-Change	Month 12	Age at screening												0.6261
		< 65 years	0	-	95	2.42 (0.16)	0	-	51	2.95 (0.21)	-0.52 (-1.03, -0.02)	0.0433	-0.34 (-0.69, -0.00)	
		>= 65 years	0	-	29	3.25 (0.27)	0	-	12	3.53 (0.39)	-0.28 (-1.15, 0.59)	0.5161	-0.20 (-0.87, 0.48)	
		Age at PBC diagnosis												0.3719
		< 50 years	0	-	59	2.58 (0.18)	0	-	30	2.79 (0.25)	-0.21 (-0.81, 0.39)	0.4939	-0.15 (-0.59, 0.29)	
		>= 50 years	0	-	65	2.61 (0.20)	0	-	33	3.21 (0.27)	-0.60 (-1.24, 0.04)	0.0657	-0.37 (-0.79, 0.05)	
		Sex												NE
		female	0	-	119	2.62 (0.14)	0	-	58	2.98 (0.19)	-0.36 (-0.82, 0.10)	0.1203	-0.24 (-0.55, 0.08)	
		male	0	-	5	NE	0	-	5	NE	NE		NE	
		Race												
		white	0	-	111		0	-	54					
		black	0	-	2		0	-	2					
		asian	0	-	7		0	-	4					
		other	0	-	4		0	-	3					
		Region												0.6642
		North America	0	-	48	2.75 (0.23)	0	-	12	2.85 (0.45)	-0.10 (-1.06, 0.86)	0.8331	-0.06 (-0.70, 0.57)	
		Europe	0	-	38	2.18 (0.22)	0	-	23	2.64 (0.29)	-0.46 (-1.18, 0.26)	0.2031	-0.33 (-0.85, 0.19)	
		Rest-of-World	0	-	38	2.76 (0.25)	0	-	28	3.40 (0.27)	-0.64 (-1.37, 0.08)	0.0798	-0.43 (-0.92, 0.07)	
		Cirrhosis												0.8378
		yes	0	-	18	2.52 (0.40)	0	-	9	3.09 (0.66)	-0.57 (-2.12, 0.99)	0.4564	-0.31 (-1.11, 0.50)	
		no	0	-	106	2.59 (0.15)	0	-	54	2.99 (0.19)	-0.41 (-0.87, 0.06)	0.0842	-0.28 (-0.60, 0.05)	
		UDCA												NE
		UDCA Use	0	-	116	2.56 (0.14)	0	-	60	3.01 (0.19)	-0.45 (-0.91, 0.01)	0.0527	-0.30 (-0.61, 0.02)	
		UDCA Intolerance	0	-	8	NE	0	-	3	NE	NE		NE	
		Prior Use of OCA and/or Fibrates												0.8325
		yes	0	-	18	2.44 (0.45)	0	-	12	2.98 (0.53)	-0.54 (-1.98, 0.90)	0.4444	-0.28 (-1.01, 0.46)	
		no	0	-	106	2.63 (0.14)	0	-	51	3.01 (0.19)	-0.39 (-0.84, 0.07)	0.0938	-0.27 (-0.61, 0.06)	
		Therapy												NE
		Monotherapy (SEL)	0	-	8	NE	0	-	4	NE	NE		NE	
		Combinationtherapy (SEL + UDCA)	0	-	116	2.56 (0.14)	0	-	59	2.99 (0.19)	-0.43 (-0.89, 0.03)	0.0655	-0.28 (-0.60, 0.03)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Mixed Effects Model (MMRM) analysis of change from baseline of PGI at month 6 and 12 - Subgroup analysis
Intention-to-treat

			Seladelpar 10 mg (N=128)				Placebo (N=65)							
		Subgroup	Baseline		Change from BL		Baseline		Change from BL		Difference of			Interaction
Score	Timepoint	Level	N	Mean (SD)	N	LSMean (SE)	N	Mean (SD)	N	LSMean (SE)	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value
PGI01-Change	Month 12	Stratification variable: Baseline Pruritus NRS												0.5512
		< 4	0	-	78	2.85 (0.17)	0	-	41	3.14 (0.22)	-0.29 (-0.81, 0.23)	0.2685	-0.20 (-0.57, 0.18)	
		>= 4	0	-	46	2.32 (0.23)	0	-	22	2.91 (0.35)	-0.58 (-1.42, 0.25)	0.1646	-0.36 (-0.88, 0.15)	
		Stratification variable: Baseline ALP Level												0.1545
		< 350 U/L	0	-	90	2.65 (0.15)	0	-	45	2.89 (0.21)	-0.24 (-0.74, 0.26)	0.3374	-0.17 (-0.53, 0.19)	
		>= 350 U/L	0	-	34	2.45 (0.28)	0	-	18	3.45 (0.38)	-1.01 (-1.96, -0.05)	0.0399	-0.61 (-1.19, -0.02)	
		Gamma-GT (GGT)												0.8172
		<= 3 x ULN	0	-	31	2.61 (0.33)	0	-	13	2.91 (0.46)	-0.29 (-1.21, 0.62)	0.5224	-0.16 (-0.81, 0.49)	
		> 3 x ULN	0	-	93	2.62 (0.16)	0	-	50	3.03 (0.21)	-0.41 (-0.94, 0.11)	0.1213	-0.26 (-0.61, 0.08)	
		Total Bilirubin I												0.9885
		<= 1 x ULN	0	-	104	2.55 (0.15)	0	-	59	2.99 (0.19)	-0.44 (-0.90, 0.03)	0.0652	-0.28 (-0.61, 0.04)	
		> 1 x ULN	0	-	20	2.83 (0.34)	0	-	4	3.25 (0.94)	-0.42 (-2.49, 1.65)	0.6765	-0.26 (-1.34, 0.82)	
		Total Bilirubin II												0.8089
		< 0.6 x ULN	0	-	57	2.53 (0.21)	0	-	31	2.91 (0.26)	-0.38 (-1.00, 0.23)	0.2209	-0.24 (-0.68, 0.19)	
		>= 0.6 x ULN	0	-	67	2.61 (0.20)	0	-	32	3.10 (0.28)	-0.49 (-1.16, 0.18)	0.1463	-0.31 (-0.73, 0.12)	

Effect measures are calculated if each subgroup level comprises at least 10 patients.
(Percent) Change from baseline is estimated by Mixed-Effect Model Repeated Measure (MMRM) model including terms for baseline value, stratification variables (baseline ALP level, baseline pruritus NRS), treatment group, week, and treatment-by-week interaction. Unstructured structure is applied for the repeated measure and Kenward-Roger correction is applied for the denominator degrees of freedom. Treatment by baseline value interaction was explored and added as a term if effect is significant effect (p-value < .05).
N describes number of patients included in the MMRM, e.g. all patients with non-missing values at baseline and at least one post-baseline visit up to Month 12.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
BL: Baseline, N: Number of subjects included in the analysis, SD: Standard Deviation; LSMean: Least Square Mean, SE: Standard Error; CI=Confidence Interval

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with Adverse Events
Safety

	Seladelpar 10 mg	Placebo
Number of subjects with event, n/N (%)	111/128 (86.7)	55/ 65 (84.6)
Analysis Seladelpar 10 mg vs. Placebo		
Relative Risk (95% CI)	1.02 (0.91, 1.16)	
p-value	0.6976	
Odds Ratio (95% CI)	1.19 (0.51, 2.76)	
p-value	0.6908	
Peto Odds Ratio (95% CI)	1.19 (0.50, 2.81)	
p-value	0.6913	
Risk Difference (95% CI)	0.02 (-0.08, 0.13)	
p-value	0.6962	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
RR, OR and RD estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with Adverse Events - Subgroup analysis
Safety

Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	OR (95% CI); p-Value	RD (95% CI); p-Value	Interaction p-Value
Age at screening						0.0987
< 65 years	86/ 99 (86.9)	48/ 53 (90.6)	0.96 (0.85, 1.08); p=0.4806	0.69 (0.23, 2.05); p=0.5032	-0.04 (-0.14, 0.07); p=0.4819	
>= 65 years	25/ 29 (86.2)	7/ 12 (58.3)	1.48 (0.90, 2.44); p=0.1256	4.46 (0.94, 21.23); p=0.0600	0.28 (-0.03, 0.58); p=0.0741	
Age at PBC diagnosis						0.6132
< 50 years	55/ 61 (90.2)	29/ 32 (90.6)	0.99 (0.87, 1.14); p=0.9426	0.95 (0.22, 4.07); p=0.9430	-0.00 (-0.13, 0.12); p=0.9427	
>= 50 years	56/ 67 (83.6)	26/ 33 (78.8)	1.06 (0.86, 1.30); p=0.5749	1.37 (0.48, 3.94); p=0.5583	0.05 (-0.12, 0.21); p=0.5697	
Sex						0.9428
female	107/ 123 (87.0)	51/ 60 (85.0)	1.02 (0.90, 1.16); p=0.7194	1.18 (0.49, 2.85); p=0.7129	0.02 (-0.09, 0.13); p=0.7181	
male	4/ 5 (80.0)	4/ 5 (80.0)	1.00 (0.54, 1.86); p=1.0000	1.00 (0.05, 22.18); p=1.0000	0.00 (-0.50, 0.50); p=1.0000	
Race						
white	100/ 114 (87.7)	48/ 56 (85.7)				
black	1/ 2 (50.0)	2/ 2 (100.0)				
asian	6/ 7 (85.7)	3/ 4 (75.0)				
other	4/ 5 (80.0)	2/ 3 (66.7)				
Region						0.0993
North America	39/ 50 (78.0)	12/ 13 (92.3)	0.85 (0.68, 1.05); p=0.1250	0.30 (0.03, 2.53); p=0.2657	-0.14 (-0.33, 0.04); p=0.1292	
Europe	35/ 39 (89.7)	19/ 24 (79.2)	1.13 (0.90, 1.43); p=0.2874	2.30 (0.55, 9.61); p=0.2525	0.11 (-0.08, 0.29); p=0.2710	
Rest-of-World	37/ 39 (94.9)	24/ 28 (85.7)	1.11 (0.94, 1.31); p=0.2360	3.08 (0.52, 18.16); p=0.2133	0.09 (-0.06, 0.24); p=0.2219	
Cirrhosis						0.8584
yes	16/ 18 (88.9)	8/ 9 (88.9)	1.00 (0.75, 1.33); p=1.0000	1.00 (0.08, 12.76); p=1.0000	0.00 (-0.25, 0.25); p=1.0000	
no	95/ 110 (86.4)	47/ 56 (83.9)	1.03 (0.90, 1.18); p=0.6815	1.21 (0.49, 2.97); p=0.6735	0.02 (-0.09, 0.14); p=0.6797	
UDCA						0.0637
UDCA Use	106/ 120 (88.3)	52/ 62 (83.9)	1.05 (0.93, 1.20); p=0.4239	1.46 (0.61, 3.50); p=0.4009	0.04 (-0.06, 0.15); p=0.4184	
UDCA Intolerance	5/ 8 (62.5)	3/ 3 (100.0)	0.63 (0.37, 1.07); p=0.0861	0.22 (0.01, 5.80); p=0.3679	-0.38 (-0.71, -0.04); p=0.0285	
Prior Use of OCA and/or Fibrates						0.8868
yes	17/ 20 (85.0)	11/ 13 (84.6)	1.00 (0.75, 1.35); p=0.9760	1.03 (0.15, 7.19); p=0.9760	0.00 (-0.25, 0.25); p=0.9760	
no	94/ 108 (87.0)	44/ 52 (84.6)	1.03 (0.90, 1.18); p=0.6861	1.22 (0.48, 3.12); p=0.6773	0.02 (-0.09, 0.14); p=0.6843	
Therapy						0.0623
Monotherapy (SEL)	5/ 8 (62.5)	4/ 4 (100.0)	0.63 (0.37, 1.07); p=0.0861	0.17 (0.01, 4.35); p=0.2873	-0.38 (-0.71, -0.04); p=0.0285	
Combinationtherapy (SEL + UDCA)	106/ 120 (88.3)	51/ 61 (83.6)	1.06 (0.93, 1.20); p=0.4025	1.48 (0.62, 3.57); p=0.3775	0.05 (-0.06, 0.16); p=0.3963	
Stratification variable: Baseline Pruritus NRS						0.4038
< 4	68/ 79 (86.1)	34/ 42 (81.0)	1.06 (0.90, 1.26); p=0.4829	1.45 (0.54, 3.95); p=0.4625	0.05 (-0.09, 0.19); p=0.4769	
>= 4	43/ 49 (87.8)	21/ 23 (91.3)	0.96 (0.82, 1.13); p=0.6353	0.68 (0.13, 3.67); p=0.6565	-0.04 (-0.18, 0.11); p=0.6366	
Stratification variable: Baseline ALP Level						0.9723
< 350 U/L	81/ 93 (87.1)	40/ 47 (85.1)	1.02 (0.89, 1.18); p=0.7512	1.18 (0.43, 3.23); p=0.7456	0.02 (-0.10, 0.14); p=0.7501	
>= 350 U/L	30/ 35 (85.7)	15/ 18 (83.3)	1.03 (0.80, 1.32); p=0.8231	1.20 (0.25, 5.71); p=0.8188	0.02 (-0.18, 0.23); p=0.8221	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with Adverse Events - Subgroup analysis
Safety

Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	OR (95% CI); p-Value	RD (95% CI); p-Value	Interaction p-Value
Gamma-GT (GGT)						0.5087
<= 3 x ULN	29/ 33 (87.9)	11/ 14 (78.6)	1.12 (0.83, 1.51); p=0.4667	1.98 (0.38, 10.30); p=0.4181	0.09 (-0.15, 0.34); p=0.4511	
> 3 x ULN	82/ 95 (86.3)	44/ 51 (86.3)	1.00 (0.87, 1.15); p=0.9945	1.00 (0.37, 2.70); p=0.9945	0.00 (-0.12, 0.12); p=0.9945	
Total Bilirubin I						0.3999
<= 1 x ULN	92/ 108 (85.2)	50/ 60 (83.3)	1.02 (0.89, 1.17); p=0.7546	1.15 (0.49, 2.72); p=0.7506	0.02 (-0.10, 0.13); p=0.7537	
> 1 x ULN	19/ 20 (95.0)	5/ 5 (100.0)	0.95 (0.86, 1.05); p=0.3174	1.18 (0.04, 33.27); p=0.9219	-0.05 (-0.15, 0.05); p=0.3049	
Total Bilirubin II						0.2530
< 0.6 x ULN	53/ 59 (89.8)	26/ 32 (81.3)	1.11 (0.92, 1.33); p=0.2934	2.04 (0.60, 6.94); p=0.2545	0.09 (-0.07, 0.24); p=0.2800	
>= 0.6 x ULN	58/ 69 (84.1)	29/ 33 (87.9)	0.96 (0.81, 1.13); p=0.5933	0.73 (0.21, 2.48); p=0.6113	-0.04 (-0.18, 0.10); p=0.5951	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with Adverse Events excluding disease-related events
Safety

	Seladelpar 10 mg	Placebo
Number of subjects with event, n/N (%)	111/128 (86.7)	54/ 65 (83.1)
Analysis Seladelpar 10 mg vs. Placebo		
Relative Risk (95% CI)	1.04 (0.92, 1.19)	
p-value	0.5144	
Odds Ratio (95% CI)	1.33 (0.58, 3.04)	
p-value	0.4981	
Peto Odds Ratio (95% CI)	1.34 (0.58, 3.12)	
p-value	0.4983	
Risk Difference (95% CI)	0.04 (-0.07, 0.14)	
p-value	0.5105	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
RR, OR and RD estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with Adverse Events excluding disease-related events - Subgroup analysis
Safety

Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	OR (95% CI); p-Value	RD (95% CI); p-Value	Interaction p-Value
Age at screening						0.1174
< 65 years	86/ 99 (86.9)	47/ 53 (88.7)	0.98 (0.87, 1.11); p=0.7423	0.84 (0.30, 2.37); p=0.7479	-0.02 (-0.13, 0.09); p=0.7429	
>= 65 years	25/ 29 (86.2)	7/ 12 (58.3)	1.48 (0.90, 2.44); p=0.1256	4.46 (0.94, 21.23); p=0.0600	0.28 (-0.03, 0.58); p=0.0741	
Age at PBC diagnosis						0.4364
< 50 years	55/ 61 (90.2)	29/ 32 (90.6)	0.99 (0.87, 1.14); p=0.9426	0.95 (0.22, 4.07); p=0.9430	-0.00 (-0.13, 0.12); p=0.9427	
>= 50 years	56/ 67 (83.6)	25/ 33 (75.8)	1.10 (0.89, 1.38); p=0.3818	1.63 (0.58, 4.54); p=0.3510	0.08 (-0.09, 0.25); p=0.3699	
Sex						0.8943
female	107/ 123 (87.0)	50/ 60 (83.3)	1.04 (0.91, 1.19); p=0.5241	1.34 (0.57, 3.16); p=0.5067	0.04 (-0.07, 0.15); p=0.5201	
male	4/ 5 (80.0)	4/ 5 (80.0)	1.00 (0.54, 1.86); p=1.0000	1.00 (0.05, 22.18); p=1.0000	0.00 (-0.50, 0.50); p=1.0000	
Race						
white	100/ 114 (87.7)	47/ 56 (83.9)				
black	1/ 2 (50.0)	2/ 2 (100.0)				
asian	6/ 7 (85.7)	3/ 4 (75.0)				
other	4/ 5 (80.0)	2/ 3 (66.7)				
Region						0.0702
North America	39/ 50 (78.0)	12/ 13 (92.3)	0.85 (0.68, 1.05); p=0.1250	0.30 (0.03, 2.53); p=0.2657	-0.14 (-0.33, 0.04); p=0.1292	
Europe	35/ 39 (89.7)	19/ 24 (79.2)	1.13 (0.90, 1.43); p=0.2874	2.30 (0.55, 9.61); p=0.2525	0.11 (-0.08, 0.29); p=0.2710	
Rest-of-World	37/ 39 (94.9)	23/ 28 (82.1)	1.15 (0.96, 1.39); p=0.1320	4.02 (0.72, 22.47); p=0.1129	0.13 (-0.03, 0.29); p=0.1140	
Cirrhosis						0.7567
yes	16/ 18 (88.9)	8/ 9 (88.9)	1.00 (0.75, 1.33); p=1.0000	1.00 (0.08, 12.76); p=1.0000	0.00 (-0.25, 0.25); p=1.0000	
no	95/ 110 (86.4)	46/ 56 (82.1)	1.05 (0.91, 1.21); p=0.4920	1.38 (0.57, 3.30); p=0.4734	0.04 (-0.08, 0.16); p=0.4872	
UDCA						0.0550
UDCA Use	106/ 120 (88.3)	51/ 62 (82.3)	1.07 (0.94, 1.23); p=0.2924	1.63 (0.69, 3.85); p=0.2622	0.06 (-0.05, 0.17); p=0.2838	
UDCA Intolerance	5/ 8 (62.5)	3/ 3 (100.0)	0.63 (0.37, 1.07); p=0.0861	0.22 (0.01, 5.80); p=0.3679	-0.38 (-0.71, -0.04); p=0.0285	
Prior Use of OCA and/or Fibrates						0.7811
yes	17/ 20 (85.0)	11/ 13 (84.6)	1.00 (0.75, 1.35); p=0.9760	1.03 (0.15, 7.19); p=0.9760	0.00 (-0.25, 0.25); p=0.9760	
no	94/ 108 (87.0)	43/ 52 (82.7)	1.05 (0.91, 1.22); p=0.4861	1.41 (0.56, 3.50); p=0.4645	0.04 (-0.08, 0.16); p=0.4808	
Therapy						0.0536
Monotherapy (SEL)	5/ 8 (62.5)	4/ 4 (100.0)	0.63 (0.37, 1.07); p=0.0861	0.17 (0.01, 4.35); p=0.2873	-0.38 (-0.71, -0.04); p=0.0285	
Combinationtherapy (SEL + UDCA)	106/ 120 (88.3)	50/ 61 (82.0)	1.08 (0.94, 1.23); p=0.2756	1.67 (0.71, 3.93); p=0.2439	0.06 (-0.05, 0.18); p=0.2665	
Stratification variable: Baseline Pruritus NRS						0.6889
< 4	68/ 79 (86.1)	34/ 42 (81.0)	1.06 (0.90, 1.26); p=0.4829	1.45 (0.54, 3.95); p=0.4625	0.05 (-0.09, 0.19); p=0.4769	
>= 4	43/ 49 (87.8)	20/ 23 (87.0)	1.01 (0.83, 1.22); p=0.9248	1.08 (0.24, 4.74); p=0.9239	0.01 (-0.16, 0.17); p=0.9246	
Stratification variable: Baseline ALP Level						0.6458
< 350 U/L	81/ 93 (87.1)	40/ 47 (85.1)	1.02 (0.89, 1.18); p=0.7512	1.18 (0.43, 3.23); p=0.7456	0.02 (-0.10, 0.14); p=0.7501	
>= 350 U/L	30/ 35 (85.7)	14/ 18 (77.8)	1.10 (0.83, 1.46); p=0.4988	1.71 (0.40, 7.38); p=0.4693	0.08 (-0.14, 0.30); p=0.4881	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with Adverse Events excluding disease-related events - Subgroup analysis
Safety

Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	OR (95% CI); p-Value	RD (95% CI); p-Value	Interaction p-Value
Gamma-GT (GGT)						0.6032
<= 3 x ULN	29/ 33 (87.9)	11/ 14 (78.6)	1.12 (0.83, 1.51); p=0.4667	1.98 (0.38, 10.30); p=0.4181	0.09 (-0.15, 0.34); p=0.4511	
> 3 x ULN	82/ 95 (86.3)	43/ 51 (84.3)	1.02 (0.89, 1.18); p=0.7476	1.17 (0.45, 3.05); p=0.7426	0.02 (-0.10, 0.14); p=0.7465	
Total Bilirubin I						0.2955
<= 1 x ULN	92/ 108 (85.2)	49/ 60 (81.7)	1.04 (0.90, 1.20); p=0.5642	1.29 (0.56, 3.00); p=0.5525	0.04 (-0.08, 0.15); p=0.5610	
> 1 x ULN	19/ 20 (95.0)	5/ 5 (100.0)	0.95 (0.86, 1.05); p=0.3174	1.18 (0.04, 33.27); p=0.9219	-0.05 (-0.15, 0.05); p=0.3049	
Total Bilirubin II						0.4039
< 0.6 x ULN	53/ 59 (89.8)	26/ 32 (81.3)	1.11 (0.92, 1.33); p=0.2934	2.04 (0.60, 6.94); p=0.2545	0.09 (-0.07, 0.24); p=0.2800	
>= 0.6 x ULN	58/ 69 (84.1)	28/ 33 (84.8)	0.99 (0.83, 1.18); p=0.9175	0.94 (0.30, 2.97); p=0.9182	-0.01 (-0.16, 0.14); p=0.9176	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with Serious Adverse Events
Safety

	Seladelpar 10 mg	Placebo
Number of subjects with event, n/N (%)	9/128 (7.0)	4/ 65 (6.2)
Analysis Seladelpar 10 mg vs. Placebo		
Relative Risk (95% CI)	1.14 (0.37, 3.57)	
p-value	0.8186	
Odds Ratio (95% CI)	1.15 (0.34, 3.90)	
p-value	0.8183	
Peto Odds Ratio (95% CI)	1.15 (0.35, 3.77)	
p-value	0.8187	
Risk Difference (95% CI)	0.01 (-0.06, 0.08)	
p-value	0.8145	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
RR, OR and RD estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with Serious Adverse Events - Subgroup analysis
Safety

Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	OR (95% CI); p-Value	RD (95% CI); p-Value	Interaction p-Value
Age at screening						
< 65 years	4/ 99 (4.0)	4/ 53 (7.5)				
>= 65 years	5/ 29 (17.2)	0/ 12 (0.0)				
Age at PBC diagnosis						
< 50 years	3/ 61 (4.9)	2/ 32 (6.3)				
>= 50 years	6/ 67 (9.0)	2/ 33 (6.1)				
Sex						0.3726
female	9/ 123 (7.3)	3/ 60 (5.0)	1.46 (0.41, 5.21); p=0.5567	1.50 (0.39, 5.76); p=0.5546	0.02 (-0.05, 0.09); p=0.5272	
male	0/ 5 (0.0)	1/ 5 (20.0)	0.33 (0.02, 6.65); p=0.4720	0.27 (0.01, 8.46); p=0.4584	-0.20 (-0.55, 0.15); p=0.2636	
Race						
white	8/ 114 (7.0)	4/ 56 (7.1)				
black	0/ 2 (0.0)	0/ 2 (0.0)				
asian	0/ 7 (0.0)	0/ 4 (0.0)				
other	1/ 5 (20.0)	0/ 3 (0.0)				
Region						
North America	1/ 50 (2.0)	0/ 13 (0.0)				
Europe	6/ 39 (15.4)	2/ 24 (8.3)				
Rest-of-World	2/ 39 (5.1)	2/ 28 (7.1)				
Cirrhosis						0.8974
yes	2/ 18 (11.1)	1/ 9 (11.1)	1.00 (0.10, 9.61); p=1.0000	1.00 (0.08, 12.76); p=1.0000	0.00 (-0.25, 0.25); p=1.0000	
no	7/ 110 (6.4)	3/ 56 (5.4)	1.19 (0.32, 4.42); p=0.7973	1.20 (0.30, 4.83); p=0.7969	0.01 (-0.06, 0.08); p=0.7913	
UDCA						NE
UDCA Use	9/ 120 (7.5)	4/ 62 (6.5)	1.16 (0.37, 3.62); p=0.7952	1.18 (0.35, 3.98); p=0.7948	0.01 (-0.07, 0.09); p=0.7901	
UDCA Intolerance	0/ 8 (0.0)	0/ 3 (0.0)	NE	NE	NE	
Prior Use of OCA and/or Fibrates						0.6537
yes	1/ 20 (5.0)	1/ 13 (7.7)	0.65 (0.04, 9.50); p=0.7529	0.63 (0.04, 11.08); p=0.7532	-0.03 (-0.20, 0.15); p=0.7610	
no	8/ 108 (7.4)	3/ 52 (5.8)	1.28 (0.36, 4.64); p=0.7030	1.31 (0.33, 5.14); p=0.7020	0.02 (-0.06, 0.10); p=0.6894	
Therapy						NE
Monotherapy (SEL)	0/ 8 (0.0)	0/ 4 (0.0)	NE	NE	NE	
Combinationtherapy (SEL + UDCA)	9/ 120 (7.5)	4/ 61 (6.6)	1.14 (0.37, 3.56); p=0.8169	1.16 (0.34, 3.91); p=0.8165	0.01 (-0.07, 0.09); p=0.8127	
Stratification variable: Baseline Pruritus NRS						
< 4	5/ 79 (6.3)	3/ 42 (7.1)				
>= 4	4/ 49 (8.2)	1/ 23 (4.3)				
Stratification variable: Baseline ALP Level						
< 350 U/L	6/ 93 (6.5)	3/ 47 (6.4)				
>= 350 U/L	3/ 35 (8.6)	1/ 18 (5.6)				

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with Serious Adverse Events - Subgroup analysis
Safety

Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	OR (95% CI); p-Value	RD (95% CI); p-Value	Interaction p-Value
Gamma-GT (GGT)						
<= 3 x ULN	3/ 33 (9.1)	3/ 14 (21.4)				
> 3 x ULN	6/ 95 (6.3)	1/ 51 (2.0)				
Total Bilirubin I						0.4650
<= 1 x ULN	7/ 108 (6.5)	3/ 60 (5.0)	1.30 (0.35, 4.83); p=0.6989	1.32 (0.33, 5.29); p=0.6981	0.01 (-0.06, 0.09); p=0.6871	
> 1 x ULN	2/ 20 (10.0)	1/ 5 (20.0)	0.50 (0.06, 4.47); p=0.5353	0.44 (0.03, 6.19); p=0.5462	-0.10 (-0.47, 0.27); p=0.6007	
Total Bilirubin II						
< 0.6 x ULN	3/ 59 (5.1)	3/ 32 (9.4)				
>= 0.6 x ULN	6/ 69 (8.7)	1/ 33 (3.0)				

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with Serious Adverse Events excluding disease-related events
Safety

	Seladelpar 10 mg	Placebo
Number of subjects with event, n/N (%)	9/128 (7.0)	4/ 65 (6.2)
Analysis Seladelpar 10 mg vs. Placebo		
Relative Risk (95% CI)	1.14 (0.37, 3.57)	
p-value	0.8186	
Odds Ratio (95% CI)	1.15 (0.34, 3.90)	
p-value	0.8183	
Peto Odds Ratio (95% CI)	1.15 (0.35, 3.77)	
p-value	0.8187	
Risk Difference (95% CI)	0.01 (-0.06, 0.08)	
p-value	0.8145	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
RR, OR and RD estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with Serious Adverse Events excluding disease-related events - Subgroup analysis
Safety

Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	OR (95% CI); p-Value	RD (95% CI); p-Value	Interaction p-Value
Age at screening						
< 65 years	4/ 99 (4.0)	4/ 53 (7.5)				
>= 65 years	5/ 29 (17.2)	0/ 12 (0.0)				
Age at PBC diagnosis						
< 50 years	3/ 61 (4.9)	2/ 32 (6.3)				
>= 50 years	6/ 67 (9.0)	2/ 33 (6.1)				
Sex						0.3726
female	9/ 123 (7.3)	3/ 60 (5.0)	1.46 (0.41, 5.21); p=0.5567	1.50 (0.39, 5.76); p=0.5546	0.02 (-0.05, 0.09); p=0.5272	
male	0/ 5 (0.0)	1/ 5 (20.0)	0.33 (0.02, 6.65); p=0.4720	0.27 (0.01, 8.46); p=0.4584	-0.20 (-0.55, 0.15); p=0.2636	
Race						
white	8/ 114 (7.0)	4/ 56 (7.1)				
black	0/ 2 (0.0)	0/ 2 (0.0)				
asian	0/ 7 (0.0)	0/ 4 (0.0)				
other	1/ 5 (20.0)	0/ 3 (0.0)				
Region						
North America	1/ 50 (2.0)	0/ 13 (0.0)				
Europe	6/ 39 (15.4)	2/ 24 (8.3)				
Rest-of-World	2/ 39 (5.1)	2/ 28 (7.1)				
Cirrhosis						0.8974
yes	2/ 18 (11.1)	1/ 9 (11.1)	1.00 (0.10, 9.61); p=1.0000	1.00 (0.08, 12.76); p=1.0000	0.00 (-0.25, 0.25); p=1.0000	
no	7/ 110 (6.4)	3/ 56 (5.4)	1.19 (0.32, 4.42); p=0.7973	1.20 (0.30, 4.83); p=0.7969	0.01 (-0.06, 0.08); p=0.7913	
UDCA						NE
UDCA Use	9/ 120 (7.5)	4/ 62 (6.5)	1.16 (0.37, 3.62); p=0.7952	1.18 (0.35, 3.98); p=0.7948	0.01 (-0.07, 0.09); p=0.7901	
UDCA Intolerance	0/ 8 (0.0)	0/ 3 (0.0)	NE	NE	NE	
Prior Use of OCA and/or Fibrates						0.6537
yes	1/ 20 (5.0)	1/ 13 (7.7)	0.65 (0.04, 9.50); p=0.7529	0.63 (0.04, 11.08); p=0.7532	-0.03 (-0.20, 0.15); p=0.7610	
no	8/ 108 (7.4)	3/ 52 (5.8)	1.28 (0.36, 4.64); p=0.7030	1.31 (0.33, 5.14); p=0.7020	0.02 (-0.06, 0.10); p=0.6894	
Therapy						NE
Monotherapy (SEL)	0/ 8 (0.0)	0/ 4 (0.0)	NE	NE	NE	
Combinationtherapy (SEL + UDCA)	9/ 120 (7.5)	4/ 61 (6.6)	1.14 (0.37, 3.56); p=0.8169	1.16 (0.34, 3.91); p=0.8165	0.01 (-0.07, 0.09); p=0.8127	
Stratification variable: Baseline Pruritus NRS						
< 4	5/ 79 (6.3)	3/ 42 (7.1)				
>= 4	4/ 49 (8.2)	1/ 23 (4.3)				
Stratification variable: Baseline ALP Level						
< 350 U/L	6/ 93 (6.5)	3/ 47 (6.4)				
>= 350 U/L	3/ 35 (8.6)	1/ 18 (5.6)				

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with Serious Adverse Events excluding disease-related events - Subgroup analysis
Safety

Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	OR (95% CI); p-Value	RD (95% CI); p-Value	Interaction p-Value
Gamma-GT (GGT)						
<= 3 x ULN	3/ 33 (9.1)	3/ 14 (21.4)				
> 3 x ULN	6/ 95 (6.3)	1/ 51 (2.0)				
Total Bilirubin I						0.4650
<= 1 x ULN	7/ 108 (6.5)	3/ 60 (5.0)	1.30 (0.35, 4.83); p=0.6989	1.32 (0.33, 5.29); p=0.6981	0.01 (-0.06, 0.09); p=0.6871	
> 1 x ULN	2/ 20 (10.0)	1/ 5 (20.0)	0.50 (0.06, 4.47); p=0.5353	0.44 (0.03, 6.19); p=0.5462	-0.10 (-0.47, 0.27); p=0.6007	
Total Bilirubin II						
< 0.6 x ULN	3/ 59 (5.1)	3/ 32 (9.4)				
>= 0.6 x ULN	6/ 69 (8.7)	1/ 33 (3.0)				

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with Severe Adverse Events
Safety

	Seladelpar 10 mg	Placebo
Number of subjects with event, n/N (%)	14/128 (10.9)	5/ 65 (7.7)
Analysis Seladelpar 10 mg vs. Placebo		
Relative Risk (95% CI)	1.42 (0.54, 3.78)	
p-value	0.4799	
Odds Ratio (95% CI)	1.47 (0.51, 4.29)	
p-value	0.4767	
Peto Odds Ratio (95% CI)	1.44 (0.53, 3.91)	
p-value	0.4756	
Risk Difference (95% CI)	0.03 (-0.05, 0.12)	
p-value	0.4510	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
RR, OR and RD estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with Severe Adverse Events - Subgroup analysis
Safety

Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	OR (95% CI); p-Value	RD (95% CI); p-Value	Interaction p-Value
Age at screening						0.4764
< 65 years	8/ 99 (8.1)	4/ 53 (7.5)	1.07 (0.34, 3.39); p=0.9075	1.08 (0.31, 3.76); p=0.9075	0.01 (-0.08, 0.09); p=0.9066	
>= 65 years	6/ 29 (20.7)	1/ 12 (8.3)	2.48 (0.33, 18.48); p=0.3746	2.87 (0.31, 26.84); p=0.3554	0.12 (-0.09, 0.34); p=0.2598	
Age at PBC diagnosis						0.9074
< 50 years	5/ 61 (8.2)	2/ 32 (6.3)	1.31 (0.27, 6.39); p=0.7371	1.34 (0.24, 7.32); p=0.7361	0.02 (-0.09, 0.13); p=0.7251	
>= 50 years	9/ 67 (13.4)	3/ 33 (9.1)	1.48 (0.43, 5.10); p=0.5366	1.55 (0.39, 6.16); p=0.5323	0.04 (-0.08, 0.17); p=0.5049	
Sex						0.3138
female	14/ 123 (11.4)	4/ 60 (6.7)	1.71 (0.59, 4.96); p=0.3260	1.80 (0.57, 5.72); p=0.3202	0.05 (-0.04, 0.13); p=0.2739	
male	0/ 5 (0.0)	1/ 5 (20.0)	0.33 (0.02, 6.65); p=0.4720	0.27 (0.01, 8.46); p=0.4584	-0.20 (-0.55, 0.15); p=0.2636	
Race						
white	13/ 114 (11.4)	4/ 56 (7.1)				
black	0/ 2 (0.0)	0/ 2 (0.0)				
asian	0/ 7 (0.0)	1/ 4 (25.0)				
other	1/ 5 (20.0)	0/ 3 (0.0)				
Region						
North America	4/ 50 (8.0)	0/ 13 (0.0)				
Europe	6/ 39 (15.4)	2/ 24 (8.3)				
Rest-of-World	4/ 39 (10.3)	3/ 28 (10.7)				
Cirrhosis						0.2041
yes	2/ 18 (11.1)	2/ 9 (22.2)	0.50 (0.08, 2.99); p=0.4477	0.44 (0.05, 3.76); p=0.4515	-0.11 (-0.42, 0.20); p=0.4795	
no	12/ 110 (10.9)	3/ 56 (5.4)	2.04 (0.60, 6.92); p=0.2546	2.16 (0.58, 8.01); p=0.2478	0.06 (-0.03, 0.14); p=0.1893	
UDCA						NE
UDCA Use	14/ 120 (11.7)	5/ 62 (8.1)	1.45 (0.55, 3.83); p=0.4575	1.51 (0.52, 4.39); p=0.4538	0.04 (-0.05, 0.12); p=0.4268	
UDCA Intolerance	0/ 8 (0.0)	0/ 3 (0.0)	NE	NE	NE	
Prior Use of OCA and/or Fibrates						0.5510
yes	1/ 20 (5.0)	1/ 13 (7.7)	0.65 (0.04, 9.50); p=0.7529	0.63 (0.04, 11.08); p=0.7532	-0.03 (-0.20, 0.15); p=0.7610	
no	13/ 108 (12.0)	4/ 52 (7.7)	1.56 (0.54, 4.57); p=0.4124	1.64 (0.51, 5.31); p=0.4073	0.04 (-0.05, 0.14); p=0.3697	
Therapy						NE
Monotherapy (SEL)	0/ 8 (0.0)	0/ 4 (0.0)	NE	NE	NE	
Combinationtherapy (SEL + UDCA)	14/ 120 (11.7)	5/ 61 (8.2)	1.42 (0.54, 3.77); p=0.4773	1.48 (0.51, 4.32); p=0.4738	0.03 (-0.05, 0.12); p=0.4481	
Stratification variable: Baseline Pruritus NRS						0.2740
< 4	9/ 79 (11.4)	2/ 42 (4.8)	2.39 (0.54, 10.57); p=0.2499	2.57 (0.53, 12.49); p=0.2416	0.07 (-0.03, 0.16); p=0.1721	
>= 4	5/ 49 (10.2)	3/ 23 (13.0)	0.78 (0.20, 3.00); p=0.7201	0.76 (0.16, 3.48); p=0.7214	-0.03 (-0.19, 0.13); p=0.7306	
Stratification variable: Baseline ALP Level						0.4121
< 350 U/L	11/ 93 (11.8)	3/ 47 (6.4)	1.85 (0.54, 6.32); p=0.3247	1.97 (0.52, 7.43); p=0.3179	0.05 (-0.04, 0.15); p=0.2657	
>= 350 U/L	3/ 35 (8.6)	2/ 18 (11.1)	0.77 (0.14, 4.21); p=0.7643	0.75 (0.11, 4.95); p=0.7651	-0.03 (-0.20, 0.15); p=0.7726	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with Severe Adverse Events - Subgroup analysis
Safety

Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	Seladelpar 10 mg vs. Placebo OR (95% CI); p-Value	Seladelpar 10 mg vs. Placebo RD (95% CI); p-Value	Interaction p-Value
Gamma-GT (GGT)						0.8641
<= 3 x ULN	7/ 33 (21.2)	2/ 14 (14.3)	1.48 (0.35, 6.28); p=0.5910	1.62 (0.29, 8.97); p=0.5834	0.07 (-0.16, 0.30); p=0.5556	
> 3 x ULN	7/ 95 (7.4)	3/ 51 (5.9)	1.25 (0.34, 4.64); p=0.7359	1.27 (0.31, 5.15); p=0.7352	0.01 (-0.07, 0.10); p=0.7264	
Total Bilirubin I						0.5474
<= 1 x ULN	11/ 108 (10.2)	4/ 60 (6.7)	1.53 (0.51, 4.59); p=0.4502	1.59 (0.48, 5.22); p=0.4467	0.04 (-0.05, 0.12); p=0.4176	
> 1 x ULN	3/ 20 (15.0)	1/ 5 (20.0)	0.75 (0.10, 5.77); p=0.7822	0.71 (0.06, 8.70); p=0.7858	-0.05 (-0.43, 0.33); p=0.7985	
Total Bilirubin II						0.8105
< 0.6 x ULN	6/ 59 (10.2)	2/ 32 (6.3)	1.63 (0.35, 7.60); p=0.5359	1.70 (0.32, 8.95); p=0.5323	0.04 (-0.07, 0.15); p=0.5002	
>= 0.6 x ULN	8/ 69 (11.6)	3/ 33 (9.1)	1.28 (0.36, 4.50); p=0.7053	1.31 (0.32, 5.30); p=0.7036	0.03 (-0.10, 0.15); p=0.6919	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with Severe Adverse Events excluding disease-related events
Safety

	Seladelpar 10 mg	Placebo
Number of subjects with event, n/N (%)	14/128 (10.9)	4/ 65 (6.2)
Analysis Seladelpar 10 mg vs. Placebo		
Relative Risk (95% CI)	1.78 (0.61, 5.18)	
p-value	0.2923	
Odds Ratio (95% CI)	1.87 (0.59, 5.94)	
p-value	0.2865	
Peto Odds Ratio (95% CI)	1.76 (0.63, 4.89)	
p-value	0.2814	
Risk Difference (95% CI)	0.05 (-0.03, 0.13)	
p-value	0.2389	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
RR, OR and RD estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with Severe Adverse Events excluding disease-related events - Subgroup analysis
Safety

Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	OR (95% CI); p-Value	RD (95% CI); p-Value	Interaction p-Value
Age at screening						0.6490
< 65 years	8/ 99 (8.1)	3/ 53 (5.7)	1.43 (0.40, 5.16); p=0.5869	1.47 (0.37, 5.77); p=0.5850	0.02 (-0.06, 0.11); p=0.5637	
>= 65 years	6/ 29 (20.7)	1/ 12 (8.3)	2.48 (0.33, 18.48); p=0.3746	2.87 (0.31, 26.84); p=0.3554	0.12 (-0.09, 0.34); p=0.2598	
Age at PBC diagnosis						0.6450
< 50 years	5/ 61 (8.2)	1/ 32 (3.1)	2.62 (0.32, 21.50); p=0.3690	2.77 (0.31, 24.77); p=0.3625	0.05 (-0.04, 0.14); p=0.2773	
>= 50 years	9/ 67 (13.4)	3/ 33 (9.1)	1.48 (0.43, 5.10); p=0.5366	1.55 (0.39, 6.16); p=0.5323	0.04 (-0.08, 0.17); p=0.5049	
Sex						0.2435
female	14/ 123 (11.4)	3/ 60 (5.0)	2.28 (0.68, 7.62); p=0.1820	2.44 (0.67, 8.84); p=0.1744	0.06 (-0.01, 0.14); p=0.1119	
male	0/ 5 (0.0)	1/ 5 (20.0)	0.33 (0.02, 6.65); p=0.4720	0.27 (0.01, 8.46); p=0.4584	-0.20 (-0.55, 0.15); p=0.2636	
Race						
white	13/ 114 (11.4)	4/ 56 (7.1)				
black	0/ 2 (0.0)	0/ 2 (0.0)				
asian	0/ 7 (0.0)	0/ 4 (0.0)				
other	1/ 5 (20.0)	0/ 3 (0.0)				
Region						
North America	4/ 50 (8.0)	0/ 13 (0.0)				
Europe	6/ 39 (15.4)	2/ 24 (8.3)				
Rest-of-World	4/ 39 (10.3)	2/ 28 (7.1)				
Cirrhosis						0.1247
yes	2/ 18 (11.1)	2/ 9 (22.2)	0.50 (0.08, 2.99); p=0.4477	0.44 (0.05, 3.76); p=0.4515	-0.11 (-0.42, 0.20); p=0.4795	
no	12/ 110 (10.9)	2/ 56 (3.6)	3.05 (0.71, 13.18); p=0.1344	3.31 (0.71, 15.32); p=0.1264	0.07 (-0.00, 0.15); p=0.0580	
UDCA						NE
UDCA Use	14/ 120 (11.7)	4/ 62 (6.5)	1.81 (0.62, 5.26); p=0.2770	1.92 (0.60, 6.09); p=0.2708	0.05 (-0.03, 0.14); p=0.2231	
UDCA Intolerance	0/ 8 (0.0)	0/ 3 (0.0)	NE	NE	NE	
Prior Use of OCA and/or Fibrates						0.4374
yes	1/ 20 (5.0)	1/ 13 (7.7)	0.65 (0.04, 9.50); p=0.7529	0.63 (0.04, 11.08); p=0.7532	-0.03 (-0.20, 0.15); p=0.7610	
no	13/ 108 (12.0)	3/ 52 (5.8)	2.09 (0.62, 7.00); p=0.2339	2.24 (0.61, 8.22); p=0.2259	0.06 (-0.03, 0.15); p=0.1638	
Therapy						NE
Monotherapy (SEL)	0/ 8 (0.0)	0/ 4 (0.0)	NE	NE	NE	
Combinationtherapy (SEL + UDCA)	14/ 120 (11.7)	4/ 61 (6.6)	1.78 (0.61, 5.17); p=0.2902	1.88 (0.59, 5.99); p=0.2840	0.05 (-0.03, 0.14); p=0.2366	
Stratification variable: Baseline Pruritus NRS						0.5174
< 4	9/ 79 (11.4)	2/ 42 (4.8)	2.39 (0.54, 10.57); p=0.2499	2.57 (0.53, 12.49); p=0.2416	0.07 (-0.03, 0.16); p=0.1721	
>= 4	5/ 49 (10.2)	2/ 23 (8.7)	1.17 (0.25, 5.60); p=0.8410	1.19 (0.21, 6.67); p=0.8405	0.02 (-0.13, 0.16); p=0.8362	
Stratification variable: Baseline ALP Level						0.8863
< 350 U/L	11/ 93 (11.8)	3/ 47 (6.4)	1.85 (0.54, 6.32); p=0.3247	1.97 (0.52, 7.43); p=0.3179	0.05 (-0.04, 0.15); p=0.2657	
>= 350 U/L	3/ 35 (8.6)	1/ 18 (5.6)	1.54 (0.17, 13.79); p=0.6980	1.59 (0.15, 16.52); p=0.6960	0.03 (-0.11, 0.17); p=0.6744	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with Severe Adverse Events excluding disease-related events - Subgroup analysis
Safety

Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	OR (95% CI); p-Value	RD (95% CI); p-Value	Interaction p-Value
Gamma-GT (GGT)						
<= 3 x ULN	7/ 33 (21.2)	2/ 14 (14.3)				
> 3 x ULN	7/ 95 (7.4)	2/ 51 (3.9)				
Total Bilirubin I						0.4117
<= 1 x ULN	11/ 108 (10.2)	3/ 60 (5.0)	2.04 (0.59, 7.02); p=0.2596	2.15 (0.58, 8.05); p=0.2536	0.05 (-0.03, 0.13); p=0.2002	
> 1 x ULN	3/ 20 (15.0)	1/ 5 (20.0)	0.75 (0.10, 5.77); p=0.7822	0.71 (0.06, 8.70); p=0.7858	-0.05 (-0.43, 0.33); p=0.7985	
Total Bilirubin II						0.8825
< 0.6 x ULN	6/ 59 (10.2)	2/ 32 (6.3)	1.63 (0.35, 7.60); p=0.5359	1.70 (0.32, 8.95); p=0.5323	0.04 (-0.07, 0.15); p=0.5002	
>= 0.6 x ULN	8/ 69 (11.6)	2/ 33 (6.1)	1.91 (0.43, 8.51); p=0.3944	2.03 (0.41, 10.16); p=0.3874	0.06 (-0.06, 0.17); p=0.3288	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with Adverse Events leading to discontinuation of study drug
Safety

	Seladelpar 10 mg	Placebo
Number of subjects with event, n/N (%)	4/128 (3.1)	3/ 65 (4.6)
Analysis Seladelpar 10 mg vs. Placebo		
Relative Risk (95% CI)	0.68 (0.16, 2.94)	
p-value	0.6023	
Odds Ratio (95% CI)	0.67 (0.14, 3.07)	
p-value	0.6029	
Peto Odds Ratio (95% CI)	0.65 (0.13, 3.22)	
p-value	0.6016	
Risk Difference (95% CI)	-0.01 (-0.07, 0.04)	
p-value	0.6220	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
RR, OR and RD estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with Adverse Events leading to discontinuation of study drug - Subgroup analysis
Safety

Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	OR (95% CI); p-Value	RD (95% CI); p-Value	Interaction p-Value
Age at screening						
< 65 years	4/ 99 (4.0)	3/ 53 (5.7)				
>= 65 years	0/ 29 (0.0)	0/ 12 (0.0)				
Age at PBC diagnosis						
< 50 years	3/ 61 (4.9)	3/ 32 (9.4)				
>= 50 years	1/ 67 (1.5)	0/ 33 (0.0)				
Sex						
female	4/ 123 (3.3)	3/ 60 (5.0)				
male	0/ 5 (0.0)	0/ 5 (0.0)				
Race						
white	4/ 114 (3.5)	3/ 56 (5.4)				
black	0/ 2 (0.0)	0/ 2 (0.0)				
asian	0/ 7 (0.0)	0/ 4 (0.0)				
other	0/ 5 (0.0)	0/ 3 (0.0)				
Region						
North America	1/ 50 (2.0)	1/ 13 (7.7)				
Europe	2/ 39 (5.1)	2/ 24 (8.3)				
Rest-of-World	1/ 39 (2.6)	0/ 28 (0.0)				
Cirrhosis						
yes	0/ 18 (0.0)	2/ 9 (22.2)				
no	4/ 110 (3.6)	1/ 56 (1.8)				
UDCA						
UDCA Use	4/ 120 (3.3)	3/ 62 (4.8)				
UDCA Intolerance	0/ 8 (0.0)	0/ 3 (0.0)				
Prior Use of OCA and/or Fibrates						
yes	1/ 20 (5.0)	1/ 13 (7.7)				
no	3/ 108 (2.8)	2/ 52 (3.8)				
Therapy						
Monotherapy (SEL)	0/ 8 (0.0)	0/ 4 (0.0)				
Combinationtherapy (SEL + UDCA)	4/ 120 (3.3)	3/ 61 (4.9)				
Stratification variable: Baseline Pruritus NRS						
< 4	1/ 79 (1.3)	1/ 42 (2.4)				
>= 4	3/ 49 (6.1)	2/ 23 (8.7)				
Stratification variable: Baseline ALP Level						
< 350 U/L	1/ 93 (1.1)	2/ 47 (4.3)				
>= 350 U/L	3/ 35 (8.6)	1/ 18 (5.6)				

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with Adverse Events leading to discontinuation of study drug - Subgroup analysis
Safety

Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	Seladelpar 10 mg vs. Placebo OR (95% CI); p-Value	Seladelpar 10 mg vs. Placebo RD (95% CI); p-Value	Interaction p-Value
Gamma-GT (GGT)						
<= 3 x ULN	2/ 33 (6.1)	1/ 14 (7.1)				
> 3 x ULN	2/ 95 (2.1)	2/ 51 (3.9)				
Total Bilirubin I						
<= 1 x ULN	3/ 108 (2.8)	2/ 60 (3.3)				
> 1 x ULN	1/ 20 (5.0)	1/ 5 (20.0)				
Total Bilirubin II						
< 0.6 x ULN	0/ 59 (0.0)	1/ 32 (3.1)				
>= 0.6 x ULN	4/ 69 (5.8)	2/ 33 (6.1)				

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with Adverse Events leading to death
Safety

	Seladelpar 10 mg	Placebo
Number of subjects with event, n/N (%)	0/128 (0.0)	0/ 65 (0.0)
Analysis Seladelpar 10 mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Peto Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
RR, OR and RD estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with Adverse Events leading to death - Subgroup analysis
Safety

Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	OR (95% CI); p-Value	RD (95% CI); p-Value	Interaction p-Value
Age at screening						
< 65 years	0/ 99 (0.0)	0/ 53 (0.0)				
>= 65 years	0/ 29 (0.0)	0/ 12 (0.0)				
Age at PBC diagnosis						
< 50 years	0/ 61 (0.0)	0/ 32 (0.0)				
>= 50 years	0/ 67 (0.0)	0/ 33 (0.0)				
Sex						
female	0/ 123 (0.0)	0/ 60 (0.0)				
male	0/ 5 (0.0)	0/ 5 (0.0)				
Race						
white	0/ 114 (0.0)	0/ 56 (0.0)				
black	0/ 2 (0.0)	0/ 2 (0.0)				
asian	0/ 7 (0.0)	0/ 4 (0.0)				
other	0/ 5 (0.0)	0/ 3 (0.0)				
Region						
North America	0/ 50 (0.0)	0/ 13 (0.0)				
Europe	0/ 39 (0.0)	0/ 24 (0.0)				
Rest-of-World	0/ 39 (0.0)	0/ 28 (0.0)				
Cirrhosis						
yes	0/ 18 (0.0)	0/ 9 (0.0)				
no	0/ 110 (0.0)	0/ 56 (0.0)				
UDCA						
UDCA Use	0/ 120 (0.0)	0/ 62 (0.0)				
UDCA Intolerance	0/ 8 (0.0)	0/ 3 (0.0)				
Prior Use of OCA and/or Fibrates						
yes	0/ 20 (0.0)	0/ 13 (0.0)				
no	0/ 108 (0.0)	0/ 52 (0.0)				
Therapy						
Monotherapy (SEL)	0/ 8 (0.0)	0/ 4 (0.0)				
Combinationtherapy (SEL + UDCA)	0/ 120 (0.0)	0/ 61 (0.0)				
Stratification variable: Baseline Pruritus NRS						
< 4	0/ 79 (0.0)	0/ 42 (0.0)				
>= 4	0/ 49 (0.0)	0/ 23 (0.0)				
Stratification variable: Baseline ALP Level						
< 350 U/L	0/ 93 (0.0)	0/ 47 (0.0)				
>= 350 U/L	0/ 35 (0.0)	0/ 18 (0.0)				

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with Adverse Events leading to death - Subgroup analysis
Safety

Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	Seladelpar 10 mg vs. Placebo OR (95% CI); p-Value	Seladelpar 10 mg vs. Placebo RD (95% CI); p-Value	Interaction p-Value
Gamma-GT (GGT)						
<= 3 x ULN	0/ 33 (0.0)	0/ 14 (0.0)				
> 3 x ULN	0/ 95 (0.0)	0/ 51 (0.0)				
Total Bilirubin I						
<= 1 x ULN	0/ 108 (0.0)	0/ 60 (0.0)				
> 1 x ULN	0/ 20 (0.0)	0/ 5 (0.0)				
Total Bilirubin II						
< 0.6 x ULN	0/ 59 (0.0)	0/ 32 (0.0)				
>= 0.6 x ULN	0/ 69 (0.0)	0/ 33 (0.0)				

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with AESI Pruritus-related TEAE
Safety

	Seladelpar 10 mg	Placebo
Number of subjects with event, n/N (%)	7/128 (5.5)	10/ 65 (15.4)
Analysis Seladelpar 10 mg vs. Placebo		
Relative Risk (95% CI)	0.36 (0.14, 0.89)	
p-value	0.0273	
Odds Ratio (95% CI)	0.32 (0.12, 0.88)	
p-value	0.0273	
Peto Odds Ratio (95% CI)	0.29 (0.10, 0.84)	
p-value	0.0220	
Risk Difference (95% CI)	-0.10 (-0.20, -0.00)	
p-value	0.0433	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
RR, OR and RD estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with AESI Pruritus-related TEAE - Subgroup analysis
Safety

Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	OR (95% CI); p-Value	RD (95% CI); p-Value	Interaction p-Value
Age at screening						0.8448
< 65 years	5/ 99 (5.1)	8/ 53 (15.1)	0.33 (0.12, 0.97); p=0.0442	0.30 (0.09, 0.97); p=0.0437	-0.10 (-0.21, 0.01); p=0.0623	
>= 65 years	2/ 29 (6.9)	2/ 12 (16.7)	0.41 (0.07, 2.61); p=0.3475	0.37 (0.05, 2.99); p=0.3516	-0.10 (-0.33, 0.13); p=0.4054	
Age at PBC diagnosis						
< 50 years	2/ 61 (3.3)	6/ 32 (18.8)				
>= 50 years	5/ 67 (7.5)	4/ 33 (12.1)				
Sex						0.9355
female	7/ 123 (5.7)	9/ 60 (15.0)	0.38 (0.15, 0.97); p=0.0429	0.34 (0.12, 0.97); p=0.0434	-0.09 (-0.19, 0.01); p=0.0659	
male	0/ 5 (0.0)	1/ 5 (20.0)	0.33 (0.02, 6.65); p=0.4720	0.27 (0.01, 8.46); p=0.4584	-0.20 (-0.55, 0.15); p=0.2636	
Race						
white	6/ 114 (5.3)	8/ 56 (14.3)				
black	0/ 2 (0.0)	1/ 2 (50.0)				
asian	1/ 7 (14.3)	1/ 4 (25.0)				
other	0/ 5 (0.0)	0/ 3 (0.0)				
Region						
North America	2/ 50 (4.0)	2/ 13 (15.4)				
Europe	3/ 39 (7.7)	3/ 24 (12.5)				
Rest-of-World	2/ 39 (5.1)	5/ 28 (17.9)				
Cirrhosis						0.6709
yes	2/ 18 (11.1)	2/ 9 (22.2)	0.50 (0.08, 2.99); p=0.4477	0.44 (0.05, 3.76); p=0.4515	-0.11 (-0.42, 0.20); p=0.4795	
no	5/ 110 (4.5)	8/ 56 (14.3)	0.32 (0.11, 0.93); p=0.0359	0.29 (0.09, 0.92); p=0.0356	-0.10 (-0.20, 0.00); p=0.0552	
UDCA						NE
UDCA Use	7/ 120 (5.8)	10/ 62 (16.1)	0.36 (0.14, 0.90); p=0.0295	0.32 (0.12, 0.89); p=0.0295	-0.10 (-0.20, -0.00); p=0.0451	
UDCA Intolerance	0/ 8 (0.0)	0/ 3 (0.0)	NE	NE	NE	
Prior Use of OCA and/or Fibrates						0.4764
yes	2/ 20 (10.0)	2/ 13 (15.4)	0.65 (0.10, 4.06); p=0.6448	0.61 (0.07, 4.98); p=0.6456	-0.05 (-0.29, 0.18); p=0.6549	
no	5/ 108 (4.6)	8/ 52 (15.4)	0.30 (0.10, 0.87); p=0.0274	0.27 (0.08, 0.86); p=0.0272	-0.11 (-0.21, -0.00); p=0.0463	
Therapy						0.6371
Monotherapy (SEL)	0/ 8 (0.0)	1/ 4 (25.0)	0.19 (0.01, 3.75); p=0.2719	0.14 (0.00, 4.26); p=0.2570	-0.25 (-0.67, 0.17); p=0.2482	
Combinationtherapy (SEL + UDCA)	7/ 120 (5.8)	9/ 61 (14.8)	0.40 (0.15, 1.01); p=0.0526	0.36 (0.13, 1.01); p=0.0530	-0.09 (-0.19, 0.01); p=0.0755	
Stratification variable: Baseline Pruritus NRS						0.8520
< 4	5/ 79 (6.3)	7/ 42 (16.7)	0.38 (0.13, 1.12); p=0.0802	0.34 (0.10, 1.14); p=0.0803	-0.10 (-0.23, 0.02); p=0.1046	
>= 4	2/ 49 (4.1)	3/ 23 (13.0)	0.31 (0.06, 1.75); p=0.1854	0.28 (0.04, 1.83); p=0.1853	-0.09 (-0.24, 0.06); p=0.2365	
Stratification variable: Baseline ALP Level						0.2855
< 350 U/L	4/ 93 (4.3)	8/ 47 (17.0)	0.25 (0.08, 0.80); p=0.0188	0.22 (0.06, 0.77); p=0.0180	-0.13 (-0.24, -0.01); p=0.0303	
>= 350 U/L	3/ 35 (8.6)	2/ 18 (11.1)	0.77 (0.14, 4.21); p=0.7643	0.75 (0.11, 4.95); p=0.7651	-0.03 (-0.20, 0.15); p=0.7726	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with AESI Pruritus-related TEAE - Subgroup analysis
Safety

Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	OR (95% CI); p-Value	RD (95% CI); p-Value	Interaction p-Value
Gamma-GT (GGT)						0.3371
<= 3 x ULN	1/ 33 (3.0)	3/ 14 (21.4)	0.14 (0.02, 1.24); p=0.0780	0.11 (0.01, 1.22); p=0.0725	-0.18 (-0.41, 0.04); p=0.1055	
> 3 x ULN	6/ 95 (6.3)	7/ 51 (13.7)	0.46 (0.16, 1.30); p=0.1420	0.42 (0.13, 1.34); p=0.1429	-0.07 (-0.18, 0.03); p=0.1721	
Total Bilirubin I						NE
<= 1 x ULN	7/ 108 (6.5)	10/ 60 (16.7)	0.39 (0.16, 0.97); p=0.0426	0.35 (0.12, 0.96); p=0.0424	-0.10 (-0.21, 0.00); p=0.0575	
> 1 x ULN	0/ 20 (0.0)	0/ 5 (0.0)	NE	NE	NE	
Total Bilirubin II						
< 0.6 x ULN	3/ 59 (5.1)	5/ 32 (15.6)				
>= 0.6 x ULN	4/ 69 (5.8)	5/ 33 (15.2)				

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with Serious AESI Pruritus-related TEAE
Safety

	Seladelpar 10 mg	Placebo
Number of subjects with event, n/N (%)	0/128 (0.0)	0/ 65 (0.0)
Analysis Seladelpar 10 mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Peto Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
RR, OR and RD estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with Serious AESI Pruritus-related TEAE - Subgroup analysis
Safety

Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	OR (95% CI); p-Value	RD (95% CI); p-Value	Interaction p-Value
Age at screening						
< 65 years	0/ 99 (0.0)	0/ 53 (0.0)				
>= 65 years	0/ 29 (0.0)	0/ 12 (0.0)				
Age at PBC diagnosis						
< 50 years	0/ 61 (0.0)	0/ 32 (0.0)				
>= 50 years	0/ 67 (0.0)	0/ 33 (0.0)				
Sex						
female	0/ 123 (0.0)	0/ 60 (0.0)				
male	0/ 5 (0.0)	0/ 5 (0.0)				
Race						
white	0/ 114 (0.0)	0/ 56 (0.0)				
black	0/ 2 (0.0)	0/ 2 (0.0)				
asian	0/ 7 (0.0)	0/ 4 (0.0)				
other	0/ 5 (0.0)	0/ 3 (0.0)				
Region						
North America	0/ 50 (0.0)	0/ 13 (0.0)				
Europe	0/ 39 (0.0)	0/ 24 (0.0)				
Rest-of-World	0/ 39 (0.0)	0/ 28 (0.0)				
Cirrhosis						
yes	0/ 18 (0.0)	0/ 9 (0.0)				
no	0/ 110 (0.0)	0/ 56 (0.0)				
UDCA						
UDCA Use	0/ 120 (0.0)	0/ 62 (0.0)				
UDCA Intolerance	0/ 8 (0.0)	0/ 3 (0.0)				
Prior Use of OCA and/or Fibrates						
yes	0/ 20 (0.0)	0/ 13 (0.0)				
no	0/ 108 (0.0)	0/ 52 (0.0)				
Therapy						
Monotherapy (SEL)	0/ 8 (0.0)	0/ 4 (0.0)				
Combinationtherapy (SEL + UDCA)	0/ 120 (0.0)	0/ 61 (0.0)				
Stratification variable: Baseline Pruritus NRS						
< 4	0/ 79 (0.0)	0/ 42 (0.0)				
>= 4	0/ 49 (0.0)	0/ 23 (0.0)				
Stratification variable: Baseline ALP Level						
< 350 U/L	0/ 93 (0.0)	0/ 47 (0.0)				
>= 350 U/L	0/ 35 (0.0)	0/ 18 (0.0)				

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with Serious AESI Pruritus-related TEAE - Subgroup analysis
Safety

Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	Seladelpar 10 mg vs. Placebo OR (95% CI); p-Value	Seladelpar 10 mg vs. Placebo RD (95% CI); p-Value	Interaction p-Value
Gamma-GT (GGT)						
<= 3 x ULN	0/ 33 (0.0)	0/ 14 (0.0)				
> 3 x ULN	0/ 95 (0.0)	0/ 51 (0.0)				
Total Bilirubin I						
<= 1 x ULN	0/ 108 (0.0)	0/ 60 (0.0)				
> 1 x ULN	0/ 20 (0.0)	0/ 5 (0.0)				
Total Bilirubin II						
< 0.6 x ULN	0/ 59 (0.0)	0/ 32 (0.0)				
>= 0.6 x ULN	0/ 69 (0.0)	0/ 33 (0.0)				

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with Severe AESI Pruritus-related TEAE
Safety

	Seladelpar 10 mg	Placebo
Number of subjects with event, n/N (%)	0/128 (0.0)	1/ 65 (1.5)
Analysis Seladelpar 10 mg vs. Placebo		
Relative Risk (95% CI)	0.17 (0.01, 4.13)	
p-value	0.2767	
Odds Ratio (95% CI)	0.17 (0.01, 4.16)	
p-value	0.2757	
Peto Odds Ratio (95% CI)	0.05 (0.00, 3.25)	
p-value	0.1605	
Risk Difference (95% CI)	-0.02 (-0.05, 0.01)	
p-value	0.3136	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
RR, OR and RD estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with Severe AESI Pruritus-related TEAE - Subgroup analysis
Safety

Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	OR (95% CI); p-Value	RD (95% CI); p-Value	Interaction p-Value
Age at screening						
< 65 years	0/ 99 (0.0)	1/ 53 (1.9)				
>= 65 years	0/ 29 (0.0)	0/ 12 (0.0)				
Age at PBC diagnosis						
< 50 years	0/ 61 (0.0)	1/ 32 (3.1)				
>= 50 years	0/ 67 (0.0)	0/ 33 (0.0)				
Sex						
female	0/ 123 (0.0)	1/ 60 (1.7)				
male	0/ 5 (0.0)	0/ 5 (0.0)				
Race						
white	0/ 114 (0.0)	0/ 56 (0.0)				
black	0/ 2 (0.0)	0/ 2 (0.0)				
asian	0/ 7 (0.0)	1/ 4 (25.0)				
other	0/ 5 (0.0)	0/ 3 (0.0)				
Region						
North America	0/ 50 (0.0)	0/ 13 (0.0)				
Europe	0/ 39 (0.0)	0/ 24 (0.0)				
Rest-of-World	0/ 39 (0.0)	1/ 28 (3.6)				
Cirrhosis						
yes	0/ 18 (0.0)	0/ 9 (0.0)				
no	0/ 110 (0.0)	1/ 56 (1.8)				
UDCA						
UDCA Use	0/ 120 (0.0)	1/ 62 (1.6)				
UDCA Intolerance	0/ 8 (0.0)	0/ 3 (0.0)				
Prior Use of OCA and/or Fibrates						
yes	0/ 20 (0.0)	0/ 13 (0.0)				
no	0/ 108 (0.0)	1/ 52 (1.9)				
Therapy						
Monotherapy (SEL)	0/ 8 (0.0)	0/ 4 (0.0)				
Combinationtherapy (SEL + UDCA)	0/ 120 (0.0)	1/ 61 (1.6)				
Stratification variable: Baseline Pruritus NRS						
< 4	0/ 79 (0.0)	0/ 42 (0.0)				
>= 4	0/ 49 (0.0)	1/ 23 (4.3)				
Stratification variable: Baseline ALP Level						
< 350 U/L	0/ 93 (0.0)	0/ 47 (0.0)				
>= 350 U/L	0/ 35 (0.0)	1/ 18 (5.6)				

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with Severe AESI Pruritus-related TEAE - Subgroup analysis
Safety

Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	Seladelpar 10 mg vs. Placebo OR (95% CI); p-Value	Seladelpar 10 mg vs. Placebo RD (95% CI); p-Value	Interaction p-Value
Gamma-GT (GGT)						
<= 3 x ULN	0/ 33 (0.0)	0/ 14 (0.0)				
> 3 x ULN	0/ 95 (0.0)	1/ 51 (2.0)				
Total Bilirubin I						
<= 1 x ULN	0/ 108 (0.0)	1/ 60 (1.7)				
> 1 x ULN	0/ 20 (0.0)	0/ 5 (0.0)				
Total Bilirubin II						
< 0.6 x ULN	0/ 59 (0.0)	0/ 32 (0.0)				
>= 0.6 x ULN	0/ 69 (0.0)	1/ 33 (3.0)				

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with AESI Liver-related toxicity
Safety

	Seladelpar 10 mg	Placebo
Number of subjects with event, n/N (%)	8/128 (6.3)	6/ 65 (9.2)
Analysis Seladelpar 10 mg vs. Placebo		
Relative Risk (95% CI)	0.68 (0.25, 1.87)	
p-value	0.4517	
Odds Ratio (95% CI)	0.66 (0.22, 1.98)	
p-value	0.4532	
Peto Odds Ratio (95% CI)	0.64 (0.20, 2.03)	
p-value	0.4517	
Risk Difference (95% CI)	-0.03 (-0.11, 0.05)	
p-value	0.4757	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
RR, OR and RD estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with AESI Liver-related toxicity - Subgroup analysis
Safety

Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	OR (95% CI); p-Value	RD (95% CI); p-Value	Interaction p-Value
Age at screening						0.8469
< 65 years	6/ 99 (6.1)	5/ 53 (9.4)	0.64 (0.21, 2.01); p=0.4464	0.62 (0.18, 2.13); p=0.4478	-0.03 (-0.13, 0.06); p=0.4707	
>= 65 years	2/ 29 (6.9)	1/ 12 (8.3)	0.83 (0.08, 8.29); p=0.8721	0.81 (0.07, 9.93); p=0.8725	-0.01 (-0.20, 0.17); p=0.8767	
Age at PBC diagnosis						
< 50 years	4/ 61 (6.6)	3/ 32 (9.4)				
>= 50 years	4/ 67 (6.0)	3/ 33 (9.1)				
Sex						0.3080
female	8/ 123 (6.5)	4/ 60 (6.7)	0.98 (0.31, 3.11); p=0.9667	0.97 (0.28, 3.37); p=0.9667	-0.00 (-0.08, 0.08); p=0.9669	
male	0/ 5 (0.0)	2/ 5 (40.0)	0.20 (0.01, 3.35); p=0.2629	0.13 (0.00, 3.52); p=0.2235	-0.40 (-0.83, 0.03); p=0.0679	
Race						
white	8/ 114 (7.0)	6/ 56 (10.7)				
black	0/ 2 (0.0)	0/ 2 (0.0)				
asian	0/ 7 (0.0)	0/ 4 (0.0)				
other	0/ 5 (0.0)	0/ 3 (0.0)				
Region						
North America	3/ 50 (6.0)	2/ 13 (15.4)				
Europe	2/ 39 (5.1)	3/ 24 (12.5)				
Rest-of-World	3/ 39 (7.7)	1/ 28 (3.6)				
Cirrhosis						0.7018
yes	2/ 18 (11.1)	2/ 9 (22.2)	0.50 (0.08, 2.99); p=0.4477	0.44 (0.05, 3.76); p=0.4515	-0.11 (-0.42, 0.20); p=0.4795	
no	6/ 110 (5.5)	4/ 56 (7.1)	0.76 (0.22, 2.60); p=0.6658	0.75 (0.20, 2.77); p=0.6665	-0.02 (-0.10, 0.06); p=0.6780	
UDCA						0.6300
UDCA Use	7/ 120 (5.8)	5/ 62 (8.1)	0.72 (0.24, 2.19); p=0.5660	0.71 (0.21, 2.32); p=0.5670	-0.02 (-0.10, 0.06); p=0.5832	
UDCA Intolerance	1/ 8 (12.5)	1/ 3 (33.3)	0.38 (0.03, 4.27); p=0.4296	0.29 (0.01, 6.91); p=0.4409	-0.21 (-0.79, 0.37); p=0.4819	
Prior Use of OCA and/or Fibrates						0.5353
yes	2/ 20 (10.0)	1/ 13 (7.7)	1.30 (0.13, 12.92); p=0.8228	1.33 (0.11, 16.39); p=0.8222	0.02 (-0.17, 0.22); p=0.8172	
no	6/ 108 (5.6)	5/ 52 (9.6)	0.58 (0.18, 1.81); p=0.3455	0.55 (0.16, 1.90); p=0.3475	-0.04 (-0.13, 0.05); p=0.3821	
Therapy						0.2989
Monotherapy (SEL)	1/ 8 (12.5)	2/ 4 (50.0)	0.25 (0.03, 2.00); p=0.1912	0.14 (0.01, 2.52); p=0.1837	-0.38 (-0.92, 0.17); p=0.1742	
Combinationtherapy (SEL + UDCA)	7/ 120 (5.8)	4/ 61 (6.6)	0.89 (0.27, 2.92); p=0.8471	0.88 (0.25, 3.14); p=0.8473	-0.01 (-0.08, 0.07); p=0.8498	
Stratification variable: Baseline Pruritus NRS						0.6441
< 4	6/ 79 (7.6)	4/ 42 (9.5)	0.80 (0.24, 2.67); p=0.7136	0.78 (0.21, 2.94); p=0.7143	-0.02 (-0.13, 0.09); p=0.7220	
>= 4	2/ 49 (4.1)	2/ 23 (8.7)	0.47 (0.07, 3.13); p=0.4344	0.45 (0.06, 3.39); p=0.4358	-0.05 (-0.17, 0.08); p=0.4791	
Stratification variable: Baseline ALP Level						
< 350 U/L	5/ 93 (5.4)	4/ 47 (8.5)				
>= 350 U/L	3/ 35 (8.6)	2/ 18 (11.1)				

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with AESI Liver-related toxicity - Subgroup analysis
Safety

Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	OR (95% CI); p-Value	RD (95% CI); p-Value	Interaction p-Value
Gamma-GT (GGT)						0.6576
<= 3 x ULN	1/ 33 (3.0)	0/ 14 (0.0)	1.32 (0.06, 30.65); p=0.8612	1.34 (0.05, 34.86); p=0.8609	0.03 (-0.03, 0.09); p=0.3099	
> 3 x ULN	7/ 95 (7.4)	6/ 51 (11.8)	0.63 (0.22, 1.76); p=0.3760	0.60 (0.19, 1.88); p=0.3779	-0.04 (-0.15, 0.06); p=0.4022	
Total Bilirubin I						0.4298
<= 1 x ULN	7/ 108 (6.5)	5/ 60 (8.3)	0.78 (0.26, 2.34); p=0.6553	0.76 (0.23, 2.52); p=0.6560	-0.02 (-0.10, 0.07); p=0.6655	
> 1 x ULN	1/ 20 (5.0)	1/ 5 (20.0)	0.25 (0.02, 3.34); p=0.2947	0.21 (0.01, 4.12); p=0.3045	-0.15 (-0.51, 0.21); p=0.4185	
Total Bilirubin II						
< 0.6 x ULN	4/ 59 (6.8)	3/ 32 (9.4)				
>= 0.6 x ULN	4/ 69 (5.8)	3/ 33 (9.1)				

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with Serious AESI Liver-related toxicity
Safety

	Seladelpar 10 mg	Placebo
Number of subjects with event, n/N (%)	1/128 (0.8)	0/ 65 (0.0)
Analysis Seladelpar 10 mg vs. Placebo		
Relative Risk (95% CI)	1.53 (0.06, 37.16)	
p-value	0.7922	
Odds Ratio (95% CI)	1.54 (0.06, 38.36)	
p-value	0.7920	
Peto Odds Ratio (95% CI)	4.52 (0.07, 285.69)	
p-value	0.4761	
Risk Difference (95% CI)	0.01 (-0.01, 0.02)	
p-value	0.3154	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
RR, OR and RD estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with Serious AESI Liver-related toxicity - Subgroup analysis
Safety

Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	OR (95% CI); p-Value	RD (95% CI); p-Value	Interaction p-Value
Age at screening						
< 65 years	0/ 99 (0.0)	0/ 53 (0.0)				
>= 65 years	1/ 29 (3.4)	0/ 12 (0.0)				
Age at PBC diagnosis						
< 50 years	0/ 61 (0.0)	0/ 32 (0.0)				
>= 50 years	1/ 67 (1.5)	0/ 33 (0.0)				
Sex						
female	1/ 123 (0.8)	0/ 60 (0.0)				
male	0/ 5 (0.0)	0/ 5 (0.0)				
Race						
white	1/ 114 (0.9)	0/ 56 (0.0)				
black	0/ 2 (0.0)	0/ 2 (0.0)				
asian	0/ 7 (0.0)	0/ 4 (0.0)				
other	0/ 5 (0.0)	0/ 3 (0.0)				
Region						
North America	0/ 50 (0.0)	0/ 13 (0.0)				
Europe	0/ 39 (0.0)	0/ 24 (0.0)				
Rest-of-World	1/ 39 (2.6)	0/ 28 (0.0)				
Cirrhosis						
yes	1/ 18 (5.6)	0/ 9 (0.0)				
no	0/ 110 (0.0)	0/ 56 (0.0)				
UDCA						
UDCA Use	1/ 120 (0.8)	0/ 62 (0.0)				
UDCA Intolerance	0/ 8 (0.0)	0/ 3 (0.0)				
Prior Use of OCA and/or Fibrates						
yes	0/ 20 (0.0)	0/ 13 (0.0)				
no	1/ 108 (0.9)	0/ 52 (0.0)				
Therapy						
Monotherapy (SEL)	0/ 8 (0.0)	0/ 4 (0.0)				
Combinationtherapy (SEL + UDCA)	1/ 120 (0.8)	0/ 61 (0.0)				
Stratification variable: Baseline Pruritus NRS						
< 4	1/ 79 (1.3)	0/ 42 (0.0)				
>= 4	0/ 49 (0.0)	0/ 23 (0.0)				
Stratification variable: Baseline ALP Level						
< 350 U/L	1/ 93 (1.1)	0/ 47 (0.0)				
>= 350 U/L	0/ 35 (0.0)	0/ 18 (0.0)				

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with Serious AESI Liver-related toxicity - Subgroup analysis
Safety

Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	OR (95% CI); p-Value	RD (95% CI); p-Value	Interaction p-Value
Gamma-GT (GGT)						
<= 3 x ULN	0/ 33 (0.0)	0/ 14 (0.0)				
> 3 x ULN	1/ 95 (1.1)	0/ 51 (0.0)				
Total Bilirubin I						
<= 1 x ULN	1/ 108 (0.9)	0/ 60 (0.0)				
> 1 x ULN	0/ 20 (0.0)	0/ 5 (0.0)				
Total Bilirubin II						
< 0.6 x ULN	1/ 59 (1.7)	0/ 32 (0.0)				
>= 0.6 x ULN	0/ 69 (0.0)	0/ 33 (0.0)				

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with Severe AESI Liver-related toxicity
Safety

	Seladelpar 10 mg	Placebo
Number of subjects with event, n/N (%)	1/128 (0.8)	0/ 65 (0.0)
Analysis Seladelpar 10 mg vs. Placebo		
Relative Risk (95% CI)	1.53 (0.06, 37.16)	
p-value	0.7922	
Odds Ratio (95% CI)	1.54 (0.06, 38.36)	
p-value	0.7920	
Peto Odds Ratio (95% CI)	4.52 (0.07, 285.69)	
p-value	0.4761	
Risk Difference (95% CI)	0.01 (-0.01, 0.02)	
p-value	0.3154	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
RR, OR and RD estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with Severe AESI Liver-related toxicity - Subgroup analysis
Safety

Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	OR (95% CI); p-Value	RD (95% CI); p-Value	Interaction p-Value
Age at screening						
< 65 years	0/ 99 (0.0)	0/ 53 (0.0)				
>= 65 years	1/ 29 (3.4)	0/ 12 (0.0)				
Age at PBC diagnosis						
< 50 years	0/ 61 (0.0)	0/ 32 (0.0)				
>= 50 years	1/ 67 (1.5)	0/ 33 (0.0)				
Sex						
female	1/ 123 (0.8)	0/ 60 (0.0)				
male	0/ 5 (0.0)	0/ 5 (0.0)				
Race						
white	1/ 114 (0.9)	0/ 56 (0.0)				
black	0/ 2 (0.0)	0/ 2 (0.0)				
asian	0/ 7 (0.0)	0/ 4 (0.0)				
other	0/ 5 (0.0)	0/ 3 (0.0)				
Region						
North America	0/ 50 (0.0)	0/ 13 (0.0)				
Europe	0/ 39 (0.0)	0/ 24 (0.0)				
Rest-of-World	1/ 39 (2.6)	0/ 28 (0.0)				
Cirrhosis						
yes	1/ 18 (5.6)	0/ 9 (0.0)				
no	0/ 110 (0.0)	0/ 56 (0.0)				
UDCA						
UDCA Use	1/ 120 (0.8)	0/ 62 (0.0)				
UDCA Intolerance	0/ 8 (0.0)	0/ 3 (0.0)				
Prior Use of OCA and/or Fibrates						
yes	0/ 20 (0.0)	0/ 13 (0.0)				
no	1/ 108 (0.9)	0/ 52 (0.0)				
Therapy						
Monotherapy (SEL)	0/ 8 (0.0)	0/ 4 (0.0)				
Combinationtherapy (SEL + UDCA)	1/ 120 (0.8)	0/ 61 (0.0)				
Stratification variable: Baseline Pruritus NRS						
< 4	1/ 79 (1.3)	0/ 42 (0.0)				
>= 4	0/ 49 (0.0)	0/ 23 (0.0)				
Stratification variable: Baseline ALP Level						
< 350 U/L	1/ 93 (1.1)	0/ 47 (0.0)				
>= 350 U/L	0/ 35 (0.0)	0/ 18 (0.0)				

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with Severe AESI Liver-related toxicity - Subgroup analysis
Safety

Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	OR (95% CI); p-Value	RD (95% CI); p-Value	Interaction p-Value
Gamma-GT (GGT)						
<= 3 x ULN	0/ 33 (0.0)	0/ 14 (0.0)				
> 3 x ULN	1/ 95 (1.1)	0/ 51 (0.0)				
Total Bilirubin I						
<= 1 x ULN	1/ 108 (0.9)	0/ 60 (0.0)				
> 1 x ULN	0/ 20 (0.0)	0/ 5 (0.0)				
Total Bilirubin II						
< 0.6 x ULN	1/ 59 (1.7)	0/ 32 (0.0)				
>= 0.6 x ULN	0/ 69 (0.0)	0/ 33 (0.0)				

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with AESI Muscle-related toxicity
Safety

	Seladelpar 10 mg	Placebo
Number of subjects with event, n/N (%)	8/128 (6.3)	5/ 65 (7.7)
Analysis Seladelpar 10 mg vs. Placebo		
Relative Risk (95% CI)	0.81 (0.28, 2.38)	
p-value	0.7055	
Odds Ratio (95% CI)	0.80 (0.25, 2.55)	
p-value	0.7060	
Peto Odds Ratio (95% CI)	0.80 (0.24, 2.61)	
p-value	0.7063	
Risk Difference (95% CI)	-0.01 (-0.09, 0.06)	
p-value	0.7141	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
RR, OR and RD estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with AESI Muscle-related toxicity - Subgroup analysis
Safety

Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	OR (95% CI); p-Value	RD (95% CI); p-Value	Interaction p-Value
Age at screening						
< 65 years	6/ 99 (6.1)	2/ 53 (3.8)				
>= 65 years	2/ 29 (6.9)	3/ 12 (25.0)				
Age at PBC diagnosis						
< 50 years	4/ 61 (6.6)	2/ 32 (6.3)				
>= 50 years	4/ 67 (6.0)	3/ 33 (9.1)				
Sex						NE
female	8/ 123 (6.5)	5/ 60 (8.3)	0.78 (0.27, 2.28); p=0.6510	0.77 (0.24, 2.45); p=0.6519	-0.02 (-0.10, 0.06); p=0.6635	
male	0/ 5 (0.0)	0/ 5 (0.0)	NE	NE	NE	
Race						
white	7/ 114 (6.1)	5/ 56 (8.9)				
black	0/ 2 (0.0)	0/ 2 (0.0)				
asian	0/ 7 (0.0)	0/ 4 (0.0)				
other	1/ 5 (20.0)	0/ 3 (0.0)				
Region						
North America	1/ 50 (2.0)	1/ 13 (7.7)				
Europe	3/ 39 (7.7)	2/ 24 (8.3)				
Rest-of-World	4/ 39 (10.3)	2/ 28 (7.1)				
Cirrhosis						0.2986
yes	0/ 18 (0.0)	1/ 9 (11.1)	0.18 (0.01, 3.92); p=0.2723	0.15 (0.01, 4.16); p=0.2654	-0.11 (-0.32, 0.09); p=0.2888	
no	8/ 110 (7.3)	4/ 56 (7.1)	1.02 (0.32, 3.24); p=0.9756	1.02 (0.29, 3.54); p=0.9756	0.00 (-0.08, 0.08); p=0.9756	
UDCA						0.7058
UDCA Use	7/ 120 (5.8)	5/ 62 (8.1)	0.72 (0.24, 2.19); p=0.5660	0.71 (0.21, 2.32); p=0.5670	-0.02 (-0.10, 0.06); p=0.5832	
UDCA Intolerance	1/ 8 (12.5)	0/ 3 (0.0)	1.33 (0.07, 26.15); p=0.8497	1.40 (0.04, 43.79); p=0.8481	0.13 (-0.10, 0.35); p=0.2850	
Prior Use of OCA and/or Fibrates						0.1689
yes	0/ 20 (0.0)	2/ 13 (15.4)	0.13 (0.01, 2.57); p=0.1822	0.11 (0.00, 2.54); p=0.1695	-0.15 (-0.35, 0.04); p=0.1242	
no	8/ 108 (7.4)	3/ 52 (5.8)	1.28 (0.36, 4.64); p=0.7030	1.31 (0.33, 5.14); p=0.7020	0.02 (-0.06, 0.10); p=0.6894	
Therapy						0.6028
Monotherapy (SEL)	1/ 8 (12.5)	0/ 4 (0.0)	1.67 (0.08, 33.75); p=0.7393	1.80 (0.06, 54.33); p=0.7353	0.13 (-0.10, 0.35); p=0.2850	
Combinationtherapy (SEL + UDCA)	7/ 120 (5.8)	5/ 61 (8.2)	0.71 (0.24, 2.15); p=0.5465	0.69 (0.21, 2.28); p=0.5476	-0.02 (-0.10, 0.06); p=0.5655	
Stratification variable: Baseline Pruritus NRS						
< 4	6/ 79 (7.6)	2/ 42 (4.8)				
>= 4	2/ 49 (4.1)	3/ 23 (13.0)				
Stratification variable: Baseline ALP Level						0.3070
< 350 U/L	8/ 93 (8.6)	4/ 47 (8.5)	1.01 (0.32, 3.19); p=0.9854	1.01 (0.29, 3.55); p=0.9854	0.00 (-0.10, 0.10); p=0.9854	
>= 350 U/L	0/ 35 (0.0)	1/ 18 (5.6)	0.18 (0.01, 4.11); p=0.2799	0.16 (0.01, 4.24); p=0.2763	-0.06 (-0.16, 0.05); p=0.3035	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with AESI Muscle-related toxicity - Subgroup analysis
Safety

Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	Seladelpar 10 mg vs. Placebo OR (95% CI); p-Value	Seladelpar 10 mg vs. Placebo RD (95% CI); p-Value	Interaction p-Value
Gamma-GT (GGT)						0.7389
<= 3 x ULN	1/ 33 (3.0)	0/ 14 (0.0)	1.32 (0.06, 30.65); p=0.8612	1.34 (0.05, 34.86); p=0.8609	0.03 (-0.03, 0.09); p=0.3099	
> 3 x ULN	7/ 95 (7.4)	5/ 51 (9.8)	0.75 (0.25, 2.25); p=0.6096	0.73 (0.22, 2.43); p=0.6106	-0.02 (-0.12, 0.07); p=0.6229	
Total Bilirubin I						NE
<= 1 x ULN	8/ 108 (7.4)	5/ 60 (8.3)	0.89 (0.30, 2.60); p=0.8295	0.88 (0.27, 2.82); p=0.8297	-0.01 (-0.09, 0.08); p=0.8321	
> 1 x ULN	0/ 20 (0.0)	0/ 5 (0.0)	NE	NE	NE	
Total Bilirubin II						
< 0.6 x ULN	3/ 59 (5.1)	2/ 32 (6.3)				
>= 0.6 x ULN	5/ 69 (7.2)	3/ 33 (9.1)				

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with Serious AESI Muscle-related toxicity
Safety

	Seladelpar 10 mg	Placebo
Number of subjects with event, n/N (%)	0/128 (0.0)	0/ 65 (0.0)
Analysis Seladelpar 10 mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Peto Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
RR, OR and RD estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with Serious AESI Muscle-related toxicity - Subgroup analysis
Safety

Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	OR (95% CI); p-Value	RD (95% CI); p-Value	Interaction p-Value
Age at screening						
< 65 years	0/ 99 (0.0)	0/ 53 (0.0)				
>= 65 years	0/ 29 (0.0)	0/ 12 (0.0)				
Age at PBC diagnosis						
< 50 years	0/ 61 (0.0)	0/ 32 (0.0)				
>= 50 years	0/ 67 (0.0)	0/ 33 (0.0)				
Sex						
female	0/ 123 (0.0)	0/ 60 (0.0)				
male	0/ 5 (0.0)	0/ 5 (0.0)				
Race						
white	0/ 114 (0.0)	0/ 56 (0.0)				
black	0/ 2 (0.0)	0/ 2 (0.0)				
asian	0/ 7 (0.0)	0/ 4 (0.0)				
other	0/ 5 (0.0)	0/ 3 (0.0)				
Region						
North America	0/ 50 (0.0)	0/ 13 (0.0)				
Europe	0/ 39 (0.0)	0/ 24 (0.0)				
Rest-of-World	0/ 39 (0.0)	0/ 28 (0.0)				
Cirrhosis						
yes	0/ 18 (0.0)	0/ 9 (0.0)				
no	0/ 110 (0.0)	0/ 56 (0.0)				
UDCA						
UDCA Use	0/ 120 (0.0)	0/ 62 (0.0)				
UDCA Intolerance	0/ 8 (0.0)	0/ 3 (0.0)				
Prior Use of OCA and/or Fibrates						
yes	0/ 20 (0.0)	0/ 13 (0.0)				
no	0/ 108 (0.0)	0/ 52 (0.0)				
Therapy						
Monotherapy (SEL)	0/ 8 (0.0)	0/ 4 (0.0)				
Combinationtherapy (SEL + UDCA)	0/ 120 (0.0)	0/ 61 (0.0)				
Stratification variable: Baseline Pruritus NRS						
< 4	0/ 79 (0.0)	0/ 42 (0.0)				
>= 4	0/ 49 (0.0)	0/ 23 (0.0)				
Stratification variable: Baseline ALP Level						
< 350 U/L	0/ 93 (0.0)	0/ 47 (0.0)				
>= 350 U/L	0/ 35 (0.0)	0/ 18 (0.0)				

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with Serious AESI Muscle-related toxicity - Subgroup analysis
Safety

Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	OR (95% CI); p-Value	RD (95% CI); p-Value	Interaction p-Value
Gamma-GT (GGT)						
<= 3 x ULN	0/ 33 (0.0)	0/ 14 (0.0)				
> 3 x ULN	0/ 95 (0.0)	0/ 51 (0.0)				
Total Bilirubin I						
<= 1 x ULN	0/ 108 (0.0)	0/ 60 (0.0)				
> 1 x ULN	0/ 20 (0.0)	0/ 5 (0.0)				
Total Bilirubin II						
< 0.6 x ULN	0/ 59 (0.0)	0/ 32 (0.0)				
>= 0.6 x ULN	0/ 69 (0.0)	0/ 33 (0.0)				

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with Severe AESI Muscle-related toxicity
Safety

	Seladelpar 10 mg	Placebo
Number of subjects with event, n/N (%)	0/128 (0.0)	1/ 65 (1.5)
Analysis Seladelpar 10 mg vs. Placebo		
Relative Risk (95% CI)	0.17 (0.01, 4.13)	
p-value	0.2767	
Odds Ratio (95% CI)	0.17 (0.01, 4.16)	
p-value	0.2757	
Peto Odds Ratio (95% CI)	0.05 (0.00, 3.25)	
p-value	0.1605	
Risk Difference (95% CI)	-0.02 (-0.05, 0.01)	
p-value	0.3136	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
RR, OR and RD estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with Severe AESI Muscle-related toxicity - Subgroup analysis
Safety

Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	OR (95% CI); p-Value	RD (95% CI); p-Value	Interaction p-Value
Age at screening						
< 65 years	0/ 99 (0.0)	0/ 53 (0.0)				
>= 65 years	0/ 29 (0.0)	1/ 12 (8.3)				
Age at PBC diagnosis						
< 50 years	0/ 61 (0.0)	0/ 32 (0.0)				
>= 50 years	0/ 67 (0.0)	1/ 33 (3.0)				
Sex						
female	0/ 123 (0.0)	1/ 60 (1.7)				
male	0/ 5 (0.0)	0/ 5 (0.0)				
Race						
white	0/ 114 (0.0)	1/ 56 (1.8)				
black	0/ 2 (0.0)	0/ 2 (0.0)				
asian	0/ 7 (0.0)	0/ 4 (0.0)				
other	0/ 5 (0.0)	0/ 3 (0.0)				
Region						
North America	0/ 50 (0.0)	0/ 13 (0.0)				
Europe	0/ 39 (0.0)	0/ 24 (0.0)				
Rest-of-World	0/ 39 (0.0)	1/ 28 (3.6)				
Cirrhosis						
yes	0/ 18 (0.0)	1/ 9 (11.1)				
no	0/ 110 (0.0)	0/ 56 (0.0)				
UDCA						
UDCA Use	0/ 120 (0.0)	1/ 62 (1.6)				
UDCA Intolerance	0/ 8 (0.0)	0/ 3 (0.0)				
Prior Use of OCA and/or Fibrates						
yes	0/ 20 (0.0)	0/ 13 (0.0)				
no	0/ 108 (0.0)	1/ 52 (1.9)				
Therapy						
Monotherapy (SEL)	0/ 8 (0.0)	0/ 4 (0.0)				
Combinationtherapy (SEL + UDCA)	0/ 120 (0.0)	1/ 61 (1.6)				
Stratification variable: Baseline Pruritus NRS						
< 4	0/ 79 (0.0)	0/ 42 (0.0)				
>= 4	0/ 49 (0.0)	1/ 23 (4.3)				
Stratification variable: Baseline ALP Level						
< 350 U/L	0/ 93 (0.0)	1/ 47 (2.1)				
>= 350 U/L	0/ 35 (0.0)	0/ 18 (0.0)				

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with Severe AESI Muscle-related toxicity - Subgroup analysis
Safety

Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	Seladelpar 10 mg vs. Placebo OR (95% CI); p-Value	Seladelpar 10 mg vs. Placebo RD (95% CI); p-Value	Interaction p-Value
Gamma-GT (GGT)						
<= 3 x ULN	0/ 33 (0.0)	0/ 14 (0.0)				
> 3 x ULN	0/ 95 (0.0)	1/ 51 (2.0)				
Total Bilirubin I						
<= 1 x ULN	0/ 108 (0.0)	1/ 60 (1.7)				
> 1 x ULN	0/ 20 (0.0)	0/ 5 (0.0)				
Total Bilirubin II						
< 0.6 x ULN	0/ 59 (0.0)	0/ 32 (0.0)				
>= 0.6 x ULN	0/ 69 (0.0)	1/ 33 (3.0)				

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with AESI Renal-related toxicity
Safety

	Seladelpar 10 mg	Placebo
Number of subjects with event, n/N (%)	0/128 (0.0)	0/ 65 (0.0)
Analysis Seladelpar 10 mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Peto Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
RR, OR and RD estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with AESI Renal-related toxicity - Subgroup analysis
Safety

Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	OR (95% CI); p-Value	RD (95% CI); p-Value	Interaction p-Value
Age at screening						
< 65 years	0/ 99 (0.0)	0/ 53 (0.0)				
>= 65 years	0/ 29 (0.0)	0/ 12 (0.0)				
Age at PBC diagnosis						
< 50 years	0/ 61 (0.0)	0/ 32 (0.0)				
>= 50 years	0/ 67 (0.0)	0/ 33 (0.0)				
Sex						
female	0/ 123 (0.0)	0/ 60 (0.0)				
male	0/ 5 (0.0)	0/ 5 (0.0)				
Race						
white	0/ 114 (0.0)	0/ 56 (0.0)				
black	0/ 2 (0.0)	0/ 2 (0.0)				
asian	0/ 7 (0.0)	0/ 4 (0.0)				
other	0/ 5 (0.0)	0/ 3 (0.0)				
Region						
North America	0/ 50 (0.0)	0/ 13 (0.0)				
Europe	0/ 39 (0.0)	0/ 24 (0.0)				
Rest-of-World	0/ 39 (0.0)	0/ 28 (0.0)				
Cirrhosis						
yes	0/ 18 (0.0)	0/ 9 (0.0)				
no	0/ 110 (0.0)	0/ 56 (0.0)				
UDCA						
UDCA Use	0/ 120 (0.0)	0/ 62 (0.0)				
UDCA Intolerance	0/ 8 (0.0)	0/ 3 (0.0)				
Prior Use of OCA and/or Fibrates						
yes	0/ 20 (0.0)	0/ 13 (0.0)				
no	0/ 108 (0.0)	0/ 52 (0.0)				
Therapy						
Monotherapy (SEL)	0/ 8 (0.0)	0/ 4 (0.0)				
Combinationtherapy (SEL + UDCA)	0/ 120 (0.0)	0/ 61 (0.0)				
Stratification variable: Baseline Pruritus NRS						
< 4	0/ 79 (0.0)	0/ 42 (0.0)				
>= 4	0/ 49 (0.0)	0/ 23 (0.0)				
Stratification variable: Baseline ALP Level						
< 350 U/L	0/ 93 (0.0)	0/ 47 (0.0)				
>= 350 U/L	0/ 35 (0.0)	0/ 18 (0.0)				

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with AESI Renal-related toxicity - Subgroup analysis
Safety

Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	Seladelpar 10 mg vs. Placebo OR (95% CI); p-Value	Seladelpar 10 mg vs. Placebo RD (95% CI); p-Value	Interaction p-Value
Gamma-GT (GGT)						
<= 3 x ULN	0/ 33 (0.0)	0/ 14 (0.0)				
> 3 x ULN	0/ 95 (0.0)	0/ 51 (0.0)				
Total Bilirubin I						
<= 1 x ULN	0/ 108 (0.0)	0/ 60 (0.0)				
> 1 x ULN	0/ 20 (0.0)	0/ 5 (0.0)				
Total Bilirubin II						
< 0.6 x ULN	0/ 59 (0.0)	0/ 32 (0.0)				
>= 0.6 x ULN	0/ 69 (0.0)	0/ 33 (0.0)				

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with Serious AESI Renal-related toxicity
Safety

	Seladelpar 10 mg	Placebo
Number of subjects with event, n/N (%)	0/128 (0.0)	0/ 65 (0.0)
Analysis Seladelpar 10 mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Peto Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
RR, OR and RD estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with Serious AESI Renal-related toxicity - Subgroup analysis
Safety

Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	OR (95% CI); p-Value	RD (95% CI); p-Value	Interaction p-Value
Age at screening						
< 65 years	0/ 99 (0.0)	0/ 53 (0.0)				
>= 65 years	0/ 29 (0.0)	0/ 12 (0.0)				
Age at PBC diagnosis						
< 50 years	0/ 61 (0.0)	0/ 32 (0.0)				
>= 50 years	0/ 67 (0.0)	0/ 33 (0.0)				
Sex						
female	0/ 123 (0.0)	0/ 60 (0.0)				
male	0/ 5 (0.0)	0/ 5 (0.0)				
Race						
white	0/ 114 (0.0)	0/ 56 (0.0)				
black	0/ 2 (0.0)	0/ 2 (0.0)				
asian	0/ 7 (0.0)	0/ 4 (0.0)				
other	0/ 5 (0.0)	0/ 3 (0.0)				
Region						
North America	0/ 50 (0.0)	0/ 13 (0.0)				
Europe	0/ 39 (0.0)	0/ 24 (0.0)				
Rest-of-World	0/ 39 (0.0)	0/ 28 (0.0)				
Cirrhosis						
yes	0/ 18 (0.0)	0/ 9 (0.0)				
no	0/ 110 (0.0)	0/ 56 (0.0)				
UDCA						
UDCA Use	0/ 120 (0.0)	0/ 62 (0.0)				
UDCA Intolerance	0/ 8 (0.0)	0/ 3 (0.0)				
Prior Use of OCA and/or Fibrates						
yes	0/ 20 (0.0)	0/ 13 (0.0)				
no	0/ 108 (0.0)	0/ 52 (0.0)				
Therapy						
Monotherapy (SEL)	0/ 8 (0.0)	0/ 4 (0.0)				
Combinationtherapy (SEL + UDCA)	0/ 120 (0.0)	0/ 61 (0.0)				
Stratification variable: Baseline Pruritus NRS						
< 4	0/ 79 (0.0)	0/ 42 (0.0)				
>= 4	0/ 49 (0.0)	0/ 23 (0.0)				
Stratification variable: Baseline ALP Level						
< 350 U/L	0/ 93 (0.0)	0/ 47 (0.0)				
>= 350 U/L	0/ 35 (0.0)	0/ 18 (0.0)				

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with Serious AESI Renal-related toxicity - Subgroup analysis
Safety

Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	OR (95% CI); p-Value	RD (95% CI); p-Value	Interaction p-Value
Gamma-GT (GGT)						
<= 3 x ULN	0/ 33 (0.0)	0/ 14 (0.0)				
> 3 x ULN	0/ 95 (0.0)	0/ 51 (0.0)				
Total Bilirubin I						
<= 1 x ULN	0/ 108 (0.0)	0/ 60 (0.0)				
> 1 x ULN	0/ 20 (0.0)	0/ 5 (0.0)				
Total Bilirubin II						
< 0.6 x ULN	0/ 59 (0.0)	0/ 32 (0.0)				
>= 0.6 x ULN	0/ 69 (0.0)	0/ 33 (0.0)				

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with Severe AESI Renal-related toxicity
Safety

	Seladelpar 10 mg	Placebo
Number of subjects with event, n/N (%)	0/128 (0.0)	0/ 65 (0.0)
Analysis Seladelpar 10 mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Peto Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
RR, OR and RD estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with Severe AESI Renal-related toxicity - Subgroup analysis
Safety

Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	OR (95% CI); p-Value	RD (95% CI); p-Value	Interaction p-Value
Age at screening						
< 65 years	0/ 99 (0.0)	0/ 53 (0.0)				
>= 65 years	0/ 29 (0.0)	0/ 12 (0.0)				
Age at PBC diagnosis						
< 50 years	0/ 61 (0.0)	0/ 32 (0.0)				
>= 50 years	0/ 67 (0.0)	0/ 33 (0.0)				
Sex						
female	0/ 123 (0.0)	0/ 60 (0.0)				
male	0/ 5 (0.0)	0/ 5 (0.0)				
Race						
white	0/ 114 (0.0)	0/ 56 (0.0)				
black	0/ 2 (0.0)	0/ 2 (0.0)				
asian	0/ 7 (0.0)	0/ 4 (0.0)				
other	0/ 5 (0.0)	0/ 3 (0.0)				
Region						
North America	0/ 50 (0.0)	0/ 13 (0.0)				
Europe	0/ 39 (0.0)	0/ 24 (0.0)				
Rest-of-World	0/ 39 (0.0)	0/ 28 (0.0)				
Cirrhosis						
yes	0/ 18 (0.0)	0/ 9 (0.0)				
no	0/ 110 (0.0)	0/ 56 (0.0)				
UDCA						
UDCA Use	0/ 120 (0.0)	0/ 62 (0.0)				
UDCA Intolerance	0/ 8 (0.0)	0/ 3 (0.0)				
Prior Use of OCA and/or Fibrates						
yes	0/ 20 (0.0)	0/ 13 (0.0)				
no	0/ 108 (0.0)	0/ 52 (0.0)				
Therapy						
Monotherapy (SEL)	0/ 8 (0.0)	0/ 4 (0.0)				
Combinationtherapy (SEL + UDCA)	0/ 120 (0.0)	0/ 61 (0.0)				
Stratification variable: Baseline Pruritus NRS						
< 4	0/ 79 (0.0)	0/ 42 (0.0)				
>= 4	0/ 49 (0.0)	0/ 23 (0.0)				
Stratification variable: Baseline ALP Level						
< 350 U/L	0/ 93 (0.0)	0/ 47 (0.0)				
>= 350 U/L	0/ 35 (0.0)	0/ 18 (0.0)				

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with Severe AESI Renal-related toxicity - Subgroup analysis
Safety

Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	OR (95% CI); p-Value	RD (95% CI); p-Value	Interaction p-Value
Gamma-GT (GGT)						
<= 3 x ULN	0/ 33 (0.0)	0/ 14 (0.0)				
> 3 x ULN	0/ 95 (0.0)	0/ 51 (0.0)				
Total Bilirubin I						
<= 1 x ULN	0/ 108 (0.0)	0/ 60 (0.0)				
> 1 x ULN	0/ 20 (0.0)	0/ 5 (0.0)				
Total Bilirubin II						
< 0.6 x ULN	0/ 59 (0.0)	0/ 32 (0.0)				
>= 0.6 x ULN	0/ 69 (0.0)	0/ 33 (0.0)				

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with AESI Pancreatic-related toxicity
Safety

	Seladelpar 10 mg	Placebo
Number of subjects with event, n/N (%)	2/128 (1.6)	1/ 65 (1.5)
Analysis Seladelpar 10 mg vs. Placebo		
Relative Risk (95% CI)	1.02 (0.09, 10.99)	
p-value	0.9898	
Odds Ratio (95% CI)	1.02 (0.09, 11.42)	
p-value	0.9898	
Peto Odds Ratio (95% CI)	1.02 (0.09, 11.27)	
p-value	0.9898	
Risk Difference (95% CI)	0.00 (-0.04, 0.04)	
p-value	0.9898	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
RR, OR and RD estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with AESI Pancreatic-related toxicity - Subgroup analysis
Safety

Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	OR (95% CI); p-Value	RD (95% CI); p-Value	Interaction p-Value
Age at screening						
< 65 years	2/ 99 (2.0)	1/ 53 (1.9)				
>= 65 years	0/ 29 (0.0)	0/ 12 (0.0)				
Age at PBC diagnosis						
< 50 years	1/ 61 (1.6)	1/ 32 (3.1)				
>= 50 years	1/ 67 (1.5)	0/ 33 (0.0)				
Sex						
female	1/ 123 (0.8)	1/ 60 (1.7)				
male	1/ 5 (20.0)	0/ 5 (0.0)				
Race						
white	2/ 114 (1.8)	1/ 56 (1.8)				
black	0/ 2 (0.0)	0/ 2 (0.0)				
asian	0/ 7 (0.0)	0/ 4 (0.0)				
other	0/ 5 (0.0)	0/ 3 (0.0)				
Region						
North America	1/ 50 (2.0)	0/ 13 (0.0)				
Europe	0/ 39 (0.0)	0/ 24 (0.0)				
Rest-of-World	1/ 39 (2.6)	1/ 28 (3.6)				
Cirrhosis						
yes	0/ 18 (0.0)	0/ 9 (0.0)				
no	2/ 110 (1.8)	1/ 56 (1.8)				
UDCA						
UDCA Use	2/ 120 (1.7)	1/ 62 (1.6)				
UDCA Intolerance	0/ 8 (0.0)	0/ 3 (0.0)				
Prior Use of OCA and/or Fibrates						
yes	1/ 20 (5.0)	0/ 13 (0.0)				
no	1/ 108 (0.9)	1/ 52 (1.9)				
Therapy						
Monotherapy (SEL)	0/ 8 (0.0)	0/ 4 (0.0)				
Combinationtherapy (SEL + UDCA)	2/ 120 (1.7)	1/ 61 (1.6)				
Stratification variable: Baseline Pruritus NRS						
< 4	1/ 79 (1.3)	1/ 42 (2.4)				
>= 4	1/ 49 (2.0)	0/ 23 (0.0)				
Stratification variable: Baseline ALP Level						
< 350 U/L	2/ 93 (2.2)	1/ 47 (2.1)				
>= 350 U/L	0/ 35 (0.0)	0/ 18 (0.0)				

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with AESI Pancreatic-related toxicity - Subgroup analysis
Safety

Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	OR (95% CI); p-Value	RD (95% CI); p-Value	Interaction p-Value
Gamma-GT (GGT)						
<= 3 x ULN	0/ 33 (0.0)	0/ 14 (0.0)				
> 3 x ULN	2/ 95 (2.1)	1/ 51 (2.0)				
Total Bilirubin I						
<= 1 x ULN	1/ 108 (0.9)	1/ 60 (1.7)				
> 1 x ULN	1/ 20 (5.0)	0/ 5 (0.0)				
Total Bilirubin II						
< 0.6 x ULN	1/ 59 (1.7)	1/ 32 (3.1)				
>= 0.6 x ULN	1/ 69 (1.4)	0/ 33 (0.0)				

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with Serious AESI Pancreatic-related toxicity
Safety

	Seladelpar 10 mg	Placebo
Number of subjects with event, n/N (%)	0/128 (0.0)	0/ 65 (0.0)
Analysis Seladelpar 10 mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Peto Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
RR, OR and RD estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with Serious AESI Pancreatic-related toxicity - Subgroup analysis
Safety

Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	OR (95% CI); p-Value	RD (95% CI); p-Value	Interaction p-Value
Age at screening						
< 65 years	0/ 99 (0.0)	0/ 53 (0.0)				
>= 65 years	0/ 29 (0.0)	0/ 12 (0.0)				
Age at PBC diagnosis						
< 50 years	0/ 61 (0.0)	0/ 32 (0.0)				
>= 50 years	0/ 67 (0.0)	0/ 33 (0.0)				
Sex						
female	0/ 123 (0.0)	0/ 60 (0.0)				
male	0/ 5 (0.0)	0/ 5 (0.0)				
Race						
white	0/ 114 (0.0)	0/ 56 (0.0)				
black	0/ 2 (0.0)	0/ 2 (0.0)				
asian	0/ 7 (0.0)	0/ 4 (0.0)				
other	0/ 5 (0.0)	0/ 3 (0.0)				
Region						
North America	0/ 50 (0.0)	0/ 13 (0.0)				
Europe	0/ 39 (0.0)	0/ 24 (0.0)				
Rest-of-World	0/ 39 (0.0)	0/ 28 (0.0)				
Cirrhosis						
yes	0/ 18 (0.0)	0/ 9 (0.0)				
no	0/ 110 (0.0)	0/ 56 (0.0)				
UDCA						
UDCA Use	0/ 120 (0.0)	0/ 62 (0.0)				
UDCA Intolerance	0/ 8 (0.0)	0/ 3 (0.0)				
Prior Use of OCA and/or Fibrates						
yes	0/ 20 (0.0)	0/ 13 (0.0)				
no	0/ 108 (0.0)	0/ 52 (0.0)				
Therapy						
Monotherapy (SEL)	0/ 8 (0.0)	0/ 4 (0.0)				
Combinationtherapy (SEL + UDCA)	0/ 120 (0.0)	0/ 61 (0.0)				
Stratification variable: Baseline Pruritus NRS						
< 4	0/ 79 (0.0)	0/ 42 (0.0)				
>= 4	0/ 49 (0.0)	0/ 23 (0.0)				
Stratification variable: Baseline ALP Level						
< 350 U/L	0/ 93 (0.0)	0/ 47 (0.0)				
>= 350 U/L	0/ 35 (0.0)	0/ 18 (0.0)				

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with Serious AESI Pancreatic-related toxicity - Subgroup analysis
Safety

Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	OR (95% CI); p-Value	RD (95% CI); p-Value	Interaction p-Value
Gamma-GT (GGT)						
<= 3 x ULN	0/ 33 (0.0)	0/ 14 (0.0)				
> 3 x ULN	0/ 95 (0.0)	0/ 51 (0.0)				
Total Bilirubin I						
<= 1 x ULN	0/ 108 (0.0)	0/ 60 (0.0)				
> 1 x ULN	0/ 20 (0.0)	0/ 5 (0.0)				
Total Bilirubin II						
< 0.6 x ULN	0/ 59 (0.0)	0/ 32 (0.0)				
>= 0.6 x ULN	0/ 69 (0.0)	0/ 33 (0.0)				

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with Severe AESI Pancreatic-related toxicity
Safety

	Seladelpar 10 mg	Placebo
Number of subjects with event, n/N (%)	0/128 (0.0)	0/ 65 (0.0)
Analysis Seladelpar 10 mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Peto Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
RR, OR and RD estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with Severe AESI Pancreatic-related toxicity - Subgroup analysis
Safety

Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	OR (95% CI); p-Value	RD (95% CI); p-Value	Interaction p-Value
Age at screening						
< 65 years	0/ 99 (0.0)	0/ 53 (0.0)				
>= 65 years	0/ 29 (0.0)	0/ 12 (0.0)				
Age at PBC diagnosis						
< 50 years	0/ 61 (0.0)	0/ 32 (0.0)				
>= 50 years	0/ 67 (0.0)	0/ 33 (0.0)				
Sex						
female	0/ 123 (0.0)	0/ 60 (0.0)				
male	0/ 5 (0.0)	0/ 5 (0.0)				
Race						
white	0/ 114 (0.0)	0/ 56 (0.0)				
black	0/ 2 (0.0)	0/ 2 (0.0)				
asian	0/ 7 (0.0)	0/ 4 (0.0)				
other	0/ 5 (0.0)	0/ 3 (0.0)				
Region						
North America	0/ 50 (0.0)	0/ 13 (0.0)				
Europe	0/ 39 (0.0)	0/ 24 (0.0)				
Rest-of-World	0/ 39 (0.0)	0/ 28 (0.0)				
Cirrhosis						
yes	0/ 18 (0.0)	0/ 9 (0.0)				
no	0/ 110 (0.0)	0/ 56 (0.0)				
UDCA						
UDCA Use	0/ 120 (0.0)	0/ 62 (0.0)				
UDCA Intolerance	0/ 8 (0.0)	0/ 3 (0.0)				
Prior Use of OCA and/or Fibrates						
yes	0/ 20 (0.0)	0/ 13 (0.0)				
no	0/ 108 (0.0)	0/ 52 (0.0)				
Therapy						
Monotherapy (SEL)	0/ 8 (0.0)	0/ 4 (0.0)				
Combinationtherapy (SEL + UDCA)	0/ 120 (0.0)	0/ 61 (0.0)				
Stratification variable: Baseline Pruritus NRS						
< 4	0/ 79 (0.0)	0/ 42 (0.0)				
>= 4	0/ 49 (0.0)	0/ 23 (0.0)				
Stratification variable: Baseline ALP Level						
< 350 U/L	0/ 93 (0.0)	0/ 47 (0.0)				
>= 350 U/L	0/ 35 (0.0)	0/ 18 (0.0)				

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with Severe AESI Pancreatic-related toxicity - Subgroup analysis
Safety

Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	Seladelpar 10 mg vs. Placebo OR (95% CI); p-Value	Seladelpar 10 mg vs. Placebo RD (95% CI); p-Value	Interaction p-Value
Gamma-GT (GGT)						
<= 3 x ULN	0/ 33 (0.0)	0/ 14 (0.0)				
> 3 x ULN	0/ 95 (0.0)	0/ 51 (0.0)				
Total Bilirubin I						
<= 1 x ULN	0/ 108 (0.0)	0/ 60 (0.0)				
> 1 x ULN	0/ 20 (0.0)	0/ 5 (0.0)				
Total Bilirubin II						
< 0.6 x ULN	0/ 59 (0.0)	0/ 32 (0.0)				
>= 0.6 x ULN	0/ 69 (0.0)	0/ 33 (0.0)				

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with AESI Cardiovascular-related toxicity
Safety

	Seladelpar 10 mg	Placebo
Number of subjects with event, n/N (%)	13/128 (10.2)	5/ 65 (7.7)
Analysis Seladelpar 10 mg vs. Placebo		
Relative Risk (95% CI)	1.32 (0.49, 3.54)	
p-value	0.5812	
Odds Ratio (95% CI)	1.36 (0.46, 3.98)	
p-value	0.5792	
Peto Odds Ratio (95% CI)	1.34 (0.48, 3.72)	
p-value	0.5790	
Risk Difference (95% CI)	0.02 (-0.06, 0.11)	
p-value	0.5620	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
RR, OR and RD estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with AESI Cardiovascular-related toxicity - Subgroup analysis
Safety

Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	OR (95% CI); p-Value	RD (95% CI); p-Value	Interaction p-Value
Age at screening						0.5171
< 65 years	9/ 99 (9.1)	3/ 53 (5.7)	1.61 (0.45, 5.68); p=0.4623	1.67 (0.43, 6.44); p=0.4588	0.03 (-0.05, 0.12); p=0.4242	
>= 65 years	4/ 29 (13.8)	2/ 12 (16.7)	0.83 (0.17, 3.93); p=0.8119	0.80 (0.13, 5.08); p=0.8130	-0.03 (-0.27, 0.22); p=0.8185	
Age at PBC diagnosis						0.1855
< 50 years	7/ 61 (11.5)	1/ 32 (3.1)	3.67 (0.47, 28.56); p=0.2139	4.02 (0.47, 34.20); p=0.2030	0.08 (-0.02, 0.18); p=0.1022	
>= 50 years	6/ 67 (9.0)	4/ 33 (12.1)	0.74 (0.22, 2.44); p=0.6194	0.71 (0.19, 2.72); p=0.6210	-0.03 (-0.16, 0.10); p=0.6349	
Sex						NE
female	13/ 123 (10.6)	5/ 60 (8.3)	1.27 (0.47, 3.39); p=0.6360	1.30 (0.44, 3.83); p=0.6343	0.02 (-0.07, 0.11); p=0.6207	
male	0/ 5 (0.0)	0/ 5 (0.0)	NE	NE	NE	
Race						
white	13/ 114 (11.4)	5/ 56 (8.9)				
black	0/ 2 (0.0)	0/ 2 (0.0)				
asian	0/ 7 (0.0)	0/ 4 (0.0)				
other	0/ 5 (0.0)	0/ 3 (0.0)				
Region						
North America	2/ 50 (4.0)	0/ 13 (0.0)				
Europe	4/ 39 (10.3)	3/ 24 (12.5)				
Rest-of-World	7/ 39 (17.9)	2/ 28 (7.1)				
Cirrhosis						0.8929
yes	3/ 18 (16.7)	1/ 9 (11.1)	1.50 (0.18, 12.46); p=0.7074	1.60 (0.14, 18.00); p=0.7035	0.06 (-0.21, 0.32); p=0.6845	
no	10/ 110 (9.1)	4/ 56 (7.1)	1.27 (0.42, 3.88); p=0.6713	1.30 (0.39, 4.35); p=0.6701	0.02 (-0.07, 0.11); p=0.6579	
UDCA						0.9639
UDCA Use	12/ 120 (10.0)	5/ 62 (8.1)	1.24 (0.46, 3.36); p=0.6725	1.27 (0.43, 3.77); p=0.6712	0.02 (-0.07, 0.11); p=0.6608	
UDCA Intolerance	1/ 8 (12.5)	0/ 3 (0.0)	1.33 (0.07, 26.15); p=0.8497	1.40 (0.04, 43.79); p=0.8481	0.13 (-0.10, 0.35); p=0.2850	
Prior Use of OCA and/or Fibrates						0.9887
yes	2/ 20 (10.0)	1/ 13 (7.7)	1.30 (0.13, 12.92); p=0.8228	1.33 (0.11, 16.39); p=0.8222	0.02 (-0.17, 0.22); p=0.8172	
no	11/ 108 (10.2)	4/ 52 (7.7)	1.32 (0.44, 3.96); p=0.6155	1.36 (0.41, 4.50); p=0.6135	0.02 (-0.07, 0.12); p=0.5961	
Therapy						0.8470
Monotherapy (SEL)	1/ 8 (12.5)	0/ 4 (0.0)	1.67 (0.08, 33.75); p=0.7393	1.80 (0.06, 54.33); p=0.7353	0.13 (-0.10, 0.35); p=0.2850	
Combinationtherapy (SEL + UDCA)	12/ 120 (10.0)	5/ 61 (8.2)	1.22 (0.45, 3.31); p=0.6958	1.24 (0.42, 3.71); p=0.6947	0.02 (-0.07, 0.11); p=0.6856	
Stratification variable: Baseline Pruritus NRS						0.7138
< 4	9/ 79 (11.4)	4/ 42 (9.5)	1.20 (0.39, 3.65); p=0.7532	1.22 (0.35, 4.23); p=0.7523	0.02 (-0.09, 0.13); p=0.7461	
>= 4	4/ 49 (8.2)	1/ 23 (4.3)	1.88 (0.22, 15.87); p=0.5630	1.96 (0.21, 18.55); p=0.5590	0.04 (-0.08, 0.15); p=0.5090	
Stratification variable: Baseline ALP Level						0.0964
< 350 U/L	6/ 93 (6.5)	5/ 47 (10.6)	0.61 (0.20, 1.88); p=0.3873	0.58 (0.17, 2.01); p=0.3892	-0.04 (-0.14, 0.06); p=0.4179	
>= 350 U/L	7/ 35 (20.0)	0/ 18 (0.0)	7.92 (0.48, 131.26); p=0.1487	9.74 (0.52, 180.88); p=0.1268	0.20 (0.07, 0.33); p=0.0031	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with AESI Cardiovascular-related toxicity - Subgroup analysis
Safety

Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	OR (95% CI); p-Value	RD (95% CI); p-Value	Interaction p-Value
Gamma-GT (GGT)						0.0458
<= 3 x ULN	0/ 33 (0.0)	2/ 14 (14.3)	0.09 (0.00, 1.73); p=0.1097	0.07 (0.00, 1.66); p=0.1014	-0.14 (-0.33, 0.04); p=0.1266	
> 3 x ULN	13/ 95 (13.7)	3/ 51 (5.9)	2.33 (0.69, 7.79); p=0.1709	2.54 (0.69, 9.35); p=0.1621	0.08 (-0.02, 0.17); p=0.1059	
Total Bilirubin I						0.5328
<= 1 x ULN	9/ 108 (8.3)	5/ 60 (8.3)	1.00 (0.35, 2.85); p=1.0000	1.00 (0.32, 3.13); p=1.0000	0.00 (-0.09, 0.09); p=1.0000	
> 1 x ULN	4/ 20 (20.0)	0/ 5 (0.0)	2.57 (0.16, 41.34); p=0.5051	3.00 (0.14, 65.08); p=0.4841	0.20 (0.02, 0.38); p=0.0253	
Total Bilirubin II						
< 0.6 x ULN	6/ 59 (10.2)	3/ 32 (9.4)				
>= 0.6 x ULN	7/ 69 (10.1)	2/ 33 (6.1)				

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with Serious AESI Cardiovascular-related toxicity
Safety

	Seladelpar 10 mg	Placebo
Number of subjects with event, n/N (%)	1/128 (0.8)	0/ 65 (0.0)
Analysis Seladelpar 10 mg vs. Placebo		
Relative Risk (95% CI)	1.53 (0.06, 37.16)	
p-value	0.7922	
Odds Ratio (95% CI)	1.54 (0.06, 38.36)	
p-value	0.7920	
Peto Odds Ratio (95% CI)	4.52 (0.07, 285.69)	
p-value	0.4761	
Risk Difference (95% CI)	0.01 (-0.01, 0.02)	
p-value	0.3154	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
RR, OR and RD estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with Serious AESI Cardiovascular-related toxicity - Subgroup analysis
Safety

Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	OR (95% CI); p-Value	RD (95% CI); p-Value	Interaction p-Value
Age at screening						
< 65 years	0/ 99 (0.0)	0/ 53 (0.0)				
>= 65 years	1/ 29 (3.4)	0/ 12 (0.0)				
Age at PBC diagnosis						
< 50 years	0/ 61 (0.0)	0/ 32 (0.0)				
>= 50 years	1/ 67 (1.5)	0/ 33 (0.0)				
Sex						
female	1/ 123 (0.8)	0/ 60 (0.0)				
male	0/ 5 (0.0)	0/ 5 (0.0)				
Race						
white	1/ 114 (0.9)	0/ 56 (0.0)				
black	0/ 2 (0.0)	0/ 2 (0.0)				
asian	0/ 7 (0.0)	0/ 4 (0.0)				
other	0/ 5 (0.0)	0/ 3 (0.0)				
Region						
North America	0/ 50 (0.0)	0/ 13 (0.0)				
Europe	0/ 39 (0.0)	0/ 24 (0.0)				
Rest-of-World	1/ 39 (2.6)	0/ 28 (0.0)				
Cirrhosis						
yes	1/ 18 (5.6)	0/ 9 (0.0)				
no	0/ 110 (0.0)	0/ 56 (0.0)				
UDCA						
UDCA Use	1/ 120 (0.8)	0/ 62 (0.0)				
UDCA Intolerance	0/ 8 (0.0)	0/ 3 (0.0)				
Prior Use of OCA and/or Fibrates						
yes	0/ 20 (0.0)	0/ 13 (0.0)				
no	1/ 108 (0.9)	0/ 52 (0.0)				
Therapy						
Monotherapy (SEL)	0/ 8 (0.0)	0/ 4 (0.0)				
Combinationtherapy (SEL + UDCA)	1/ 120 (0.8)	0/ 61 (0.0)				
Stratification variable: Baseline Pruritus NRS						
< 4	1/ 79 (1.3)	0/ 42 (0.0)				
>= 4	0/ 49 (0.0)	0/ 23 (0.0)				
Stratification variable: Baseline ALP Level						
< 350 U/L	1/ 93 (1.1)	0/ 47 (0.0)				
>= 350 U/L	0/ 35 (0.0)	0/ 18 (0.0)				

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with Serious AESI Cardiovascular-related toxicity - Subgroup analysis
Safety

Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	OR (95% CI); p-Value	RD (95% CI); p-Value	Interaction p-Value
Gamma-GT (GGT)						
<= 3 x ULN	0/ 33 (0.0)	0/ 14 (0.0)				
> 3 x ULN	1/ 95 (1.1)	0/ 51 (0.0)				
Total Bilirubin I						
<= 1 x ULN	1/ 108 (0.9)	0/ 60 (0.0)				
> 1 x ULN	0/ 20 (0.0)	0/ 5 (0.0)				
Total Bilirubin II						
< 0.6 x ULN	1/ 59 (1.7)	0/ 32 (0.0)				
>= 0.6 x ULN	0/ 69 (0.0)	0/ 33 (0.0)				

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with Severe AESI Cardiovascular-related toxicity
Safety

	Seladelpar 10 mg	Placebo
Number of subjects with event, n/N (%)	1/128 (0.8)	0/ 65 (0.0)
Analysis Seladelpar 10 mg vs. Placebo		
Relative Risk (95% CI)	1.53 (0.06, 37.16)	
p-value	0.7922	
Odds Ratio (95% CI)	1.54 (0.06, 38.36)	
p-value	0.7920	
Peto Odds Ratio (95% CI)	4.52 (0.07, 285.69)	
p-value	0.4761	
Risk Difference (95% CI)	0.01 (-0.01, 0.02)	
p-value	0.3154	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
RR, OR and RD estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with Severe AESI Cardiovascular-related toxicity - Subgroup analysis
Safety

Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	OR (95% CI); p-Value	RD (95% CI); p-Value	Interaction p-Value
Age at screening						
< 65 years	0/ 99 (0.0)	0/ 53 (0.0)				
>= 65 years	1/ 29 (3.4)	0/ 12 (0.0)				
Age at PBC diagnosis						
< 50 years	0/ 61 (0.0)	0/ 32 (0.0)				
>= 50 years	1/ 67 (1.5)	0/ 33 (0.0)				
Sex						
female	1/ 123 (0.8)	0/ 60 (0.0)				
male	0/ 5 (0.0)	0/ 5 (0.0)				
Race						
white	1/ 114 (0.9)	0/ 56 (0.0)				
black	0/ 2 (0.0)	0/ 2 (0.0)				
asian	0/ 7 (0.0)	0/ 4 (0.0)				
other	0/ 5 (0.0)	0/ 3 (0.0)				
Region						
North America	0/ 50 (0.0)	0/ 13 (0.0)				
Europe	0/ 39 (0.0)	0/ 24 (0.0)				
Rest-of-World	1/ 39 (2.6)	0/ 28 (0.0)				
Cirrhosis						
yes	1/ 18 (5.6)	0/ 9 (0.0)				
no	0/ 110 (0.0)	0/ 56 (0.0)				
UDCA						
UDCA Use	1/ 120 (0.8)	0/ 62 (0.0)				
UDCA Intolerance	0/ 8 (0.0)	0/ 3 (0.0)				
Prior Use of OCA and/or Fibrates						
yes	0/ 20 (0.0)	0/ 13 (0.0)				
no	1/ 108 (0.9)	0/ 52 (0.0)				
Therapy						
Monotherapy (SEL)	0/ 8 (0.0)	0/ 4 (0.0)				
Combinationtherapy (SEL + UDCA)	1/ 120 (0.8)	0/ 61 (0.0)				
Stratification variable: Baseline Pruritus NRS						
< 4	1/ 79 (1.3)	0/ 42 (0.0)				
>= 4	0/ 49 (0.0)	0/ 23 (0.0)				
Stratification variable: Baseline ALP Level						
< 350 U/L	1/ 93 (1.1)	0/ 47 (0.0)				
>= 350 U/L	0/ 35 (0.0)	0/ 18 (0.0)				

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with Severe AESI Cardiovascular-related toxicity - Subgroup analysis
Safety

Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	OR (95% CI); p-Value	RD (95% CI); p-Value	Interaction p-Value
Gamma-GT (GGT)						
<= 3 x ULN	0/ 33 (0.0)	0/ 14 (0.0)				
> 3 x ULN	1/ 95 (1.1)	0/ 51 (0.0)				
Total Bilirubin I						
<= 1 x ULN	1/ 108 (0.9)	0/ 60 (0.0)				
> 1 x ULN	0/ 20 (0.0)	0/ 5 (0.0)				
Total Bilirubin II						
< 0.6 x ULN	1/ 59 (1.7)	0/ 32 (0.0)				
>= 0.6 x ULN	0/ 69 (0.0)	0/ 33 (0.0)				

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with AESI Cardiac arrhythmias
Safety

	Seladelpar 10 mg	Placebo
Number of subjects with event, n/N (%)	3/128 (2.3)	2/ 65 (3.1)
Analysis Seladelpar 10 mg vs. Placebo		
Relative Risk (95% CI)	0.76 (0.13, 4.45)	
p-value	0.7624	
Odds Ratio (95% CI)	0.76 (0.12, 4.64)	
p-value	0.7626	
Peto Odds Ratio (95% CI)	0.75 (0.11, 4.88)	
p-value	0.7625	
Risk Difference (95% CI)	-0.01 (-0.06, 0.04)	
p-value	0.7715	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
RR, OR and RD estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with AESI Cardiac arrhythmias - Subgroup analysis
Safety

Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	OR (95% CI); p-Value	RD (95% CI); p-Value	Interaction p-Value
Age at screening						
< 65 years	3/ 99 (3.0)	2/ 53 (3.8)				
>= 65 years	0/ 29 (0.0)	0/ 12 (0.0)				
Age at PBC diagnosis						
< 50 years	2/ 61 (3.3)	0/ 32 (0.0)				
>= 50 years	1/ 67 (1.5)	2/ 33 (6.1)				
Sex						
female	3/ 123 (2.4)	2/ 60 (3.3)				
male	0/ 5 (0.0)	0/ 5 (0.0)				
Race						
white	3/ 114 (2.6)	2/ 56 (3.6)				
black	0/ 2 (0.0)	0/ 2 (0.0)				
asian	0/ 7 (0.0)	0/ 4 (0.0)				
other	0/ 5 (0.0)	0/ 3 (0.0)				
Region						
North America	0/ 50 (0.0)	0/ 13 (0.0)				
Europe	1/ 39 (2.6)	1/ 24 (4.2)				
Rest-of-World	2/ 39 (5.1)	1/ 28 (3.6)				
Cirrhosis						
yes	0/ 18 (0.0)	0/ 9 (0.0)				
no	3/ 110 (2.7)	2/ 56 (3.6)				
UDCA						
UDCA Use	3/ 120 (2.5)	2/ 62 (3.2)				
UDCA Intolerance	0/ 8 (0.0)	0/ 3 (0.0)				
Prior Use of OCA and/or Fibrates						
yes	1/ 20 (5.0)	0/ 13 (0.0)				
no	2/ 108 (1.9)	2/ 52 (3.8)				
Therapy						
Monotherapy (SEL)	0/ 8 (0.0)	0/ 4 (0.0)				
Combinationtherapy (SEL + UDCA)	3/ 120 (2.5)	2/ 61 (3.3)				
Stratification variable: Baseline Pruritus NRS						
< 4	3/ 79 (3.8)	2/ 42 (4.8)				
>= 4	0/ 49 (0.0)	0/ 23 (0.0)				
Stratification variable: Baseline ALP Level						
< 350 U/L	1/ 93 (1.1)	2/ 47 (4.3)				
>= 350 U/L	2/ 35 (5.7)	0/ 18 (0.0)				

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with AESI Cardiac arrhythmias - Subgroup analysis
Safety

Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	Seladelpar 10 mg vs. Placebo OR (95% CI); p-Value	Seladelpar 10 mg vs. Placebo RD (95% CI); p-Value	Interaction p-Value
Gamma-GT (GGT)						
<= 3 x ULN	0/ 33 (0.0)	2/ 14 (14.3)				
> 3 x ULN	3/ 95 (3.2)	0/ 51 (0.0)				
Total Bilirubin I						
<= 1 x ULN	3/ 108 (2.8)	2/ 60 (3.3)				
> 1 x ULN	0/ 20 (0.0)	0/ 5 (0.0)				
Total Bilirubin II						
< 0.6 x ULN	2/ 59 (3.4)	2/ 32 (6.3)				
>= 0.6 x ULN	1/ 69 (1.4)	0/ 33 (0.0)				

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with Serious AESI Cardiac arrhythmias
Safety

	Seladelpar 10 mg	Placebo
Number of subjects with event, n/N (%)	0/128 (0.0)	0/ 65 (0.0)
Analysis Seladelpar 10 mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Peto Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
RR, OR and RD estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with Serious AESI Cardiac arrhythmias - Subgroup analysis
Safety

Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	OR (95% CI); p-Value	RD (95% CI); p-Value	Interaction p-Value
Age at screening						
< 65 years	0/ 99 (0.0)	0/ 53 (0.0)				
>= 65 years	0/ 29 (0.0)	0/ 12 (0.0)				
Age at PBC diagnosis						
< 50 years	0/ 61 (0.0)	0/ 32 (0.0)				
>= 50 years	0/ 67 (0.0)	0/ 33 (0.0)				
Sex						
female	0/ 123 (0.0)	0/ 60 (0.0)				
male	0/ 5 (0.0)	0/ 5 (0.0)				
Race						
white	0/ 114 (0.0)	0/ 56 (0.0)				
black	0/ 2 (0.0)	0/ 2 (0.0)				
asian	0/ 7 (0.0)	0/ 4 (0.0)				
other	0/ 5 (0.0)	0/ 3 (0.0)				
Region						
North America	0/ 50 (0.0)	0/ 13 (0.0)				
Europe	0/ 39 (0.0)	0/ 24 (0.0)				
Rest-of-World	0/ 39 (0.0)	0/ 28 (0.0)				
Cirrhosis						
yes	0/ 18 (0.0)	0/ 9 (0.0)				
no	0/ 110 (0.0)	0/ 56 (0.0)				
UDCA						
UDCA Use	0/ 120 (0.0)	0/ 62 (0.0)				
UDCA Intolerance	0/ 8 (0.0)	0/ 3 (0.0)				
Prior Use of OCA and/or Fibrates						
yes	0/ 20 (0.0)	0/ 13 (0.0)				
no	0/ 108 (0.0)	0/ 52 (0.0)				
Therapy						
Monotherapy (SEL)	0/ 8 (0.0)	0/ 4 (0.0)				
Combinationtherapy (SEL + UDCA)	0/ 120 (0.0)	0/ 61 (0.0)				
Stratification variable: Baseline Pruritus NRS						
< 4	0/ 79 (0.0)	0/ 42 (0.0)				
>= 4	0/ 49 (0.0)	0/ 23 (0.0)				
Stratification variable: Baseline ALP Level						
< 350 U/L	0/ 93 (0.0)	0/ 47 (0.0)				
>= 350 U/L	0/ 35 (0.0)	0/ 18 (0.0)				

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with Serious AESI Cardiac arrhythmias - Subgroup analysis
Safety

Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	Seladelpar 10 mg vs. Placebo OR (95% CI); p-Value	Seladelpar 10 mg vs. Placebo RD (95% CI); p-Value	Interaction p-Value
Gamma-GT (GGT)						
<= 3 x ULN	0/ 33 (0.0)	0/ 14 (0.0)				
> 3 x ULN	0/ 95 (0.0)	0/ 51 (0.0)				
Total Bilirubin I						
<= 1 x ULN	0/ 108 (0.0)	0/ 60 (0.0)				
> 1 x ULN	0/ 20 (0.0)	0/ 5 (0.0)				
Total Bilirubin II						
< 0.6 x ULN	0/ 59 (0.0)	0/ 32 (0.0)				
>= 0.6 x ULN	0/ 69 (0.0)	0/ 33 (0.0)				

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with Severe AESI Cardiac arrhythmias
Safety

	Seladelpar 10 mg	Placebo
Number of subjects with event, n/N (%)	0/128 (0.0)	0/ 65 (0.0)
Analysis Seladelpar 10 mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Peto Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
RR, OR and RD estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with Severe AESI Cardiac arrhythmias - Subgroup analysis
Safety

Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	OR (95% CI); p-Value	RD (95% CI); p-Value	Interaction p-Value
Age at screening						
< 65 years	0/ 99 (0.0)	0/ 53 (0.0)				
>= 65 years	0/ 29 (0.0)	0/ 12 (0.0)				
Age at PBC diagnosis						
< 50 years	0/ 61 (0.0)	0/ 32 (0.0)				
>= 50 years	0/ 67 (0.0)	0/ 33 (0.0)				
Sex						
female	0/ 123 (0.0)	0/ 60 (0.0)				
male	0/ 5 (0.0)	0/ 5 (0.0)				
Race						
white	0/ 114 (0.0)	0/ 56 (0.0)				
black	0/ 2 (0.0)	0/ 2 (0.0)				
asian	0/ 7 (0.0)	0/ 4 (0.0)				
other	0/ 5 (0.0)	0/ 3 (0.0)				
Region						
North America	0/ 50 (0.0)	0/ 13 (0.0)				
Europe	0/ 39 (0.0)	0/ 24 (0.0)				
Rest-of-World	0/ 39 (0.0)	0/ 28 (0.0)				
Cirrhosis						
yes	0/ 18 (0.0)	0/ 9 (0.0)				
no	0/ 110 (0.0)	0/ 56 (0.0)				
UDCA						
UDCA Use	0/ 120 (0.0)	0/ 62 (0.0)				
UDCA Intolerance	0/ 8 (0.0)	0/ 3 (0.0)				
Prior Use of OCA and/or Fibrates						
yes	0/ 20 (0.0)	0/ 13 (0.0)				
no	0/ 108 (0.0)	0/ 52 (0.0)				
Therapy						
Monotherapy (SEL)	0/ 8 (0.0)	0/ 4 (0.0)				
Combinationtherapy (SEL + UDCA)	0/ 120 (0.0)	0/ 61 (0.0)				
Stratification variable: Baseline Pruritus NRS						
< 4	0/ 79 (0.0)	0/ 42 (0.0)				
>= 4	0/ 49 (0.0)	0/ 23 (0.0)				
Stratification variable: Baseline ALP Level						
< 350 U/L	0/ 93 (0.0)	0/ 47 (0.0)				
>= 350 U/L	0/ 35 (0.0)	0/ 18 (0.0)				

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with Severe AESI Cardiac arrhythmias - Subgroup analysis
Safety

Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	Seladelpar 10 mg vs. Placebo OR (95% CI); p-Value	Seladelpar 10 mg vs. Placebo RD (95% CI); p-Value	Interaction p-Value
Gamma-GT (GGT)						
<= 3 x ULN	0/ 33 (0.0)	0/ 14 (0.0)				
> 3 x ULN	0/ 95 (0.0)	0/ 51 (0.0)				
Total Bilirubin I						
<= 1 x ULN	0/ 108 (0.0)	0/ 60 (0.0)				
> 1 x ULN	0/ 20 (0.0)	0/ 5 (0.0)				
Total Bilirubin II						
< 0.6 x ULN	0/ 59 (0.0)	0/ 32 (0.0)				
>= 0.6 x ULN	0/ 69 (0.0)	0/ 33 (0.0)				

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with AESI Cardiac failure
Safety

	Seladelpar 10 mg	Placebo
Number of subjects with event, n/N (%)	3/128 (2.3)	1/ 65 (1.5)
Analysis Seladelpar 10 mg vs. Placebo		
Relative Risk (95% CI)	1.52 (0.16, 14.36)	
p-value	0.7130	
Odds Ratio (95% CI)	1.54 (0.16, 15.06)	
p-value	0.7126	
Peto Odds Ratio (95% CI)	1.48 (0.18, 12.00)	
p-value	0.7113	
Risk Difference (95% CI)	0.01 (-0.03, 0.05)	
p-value	0.6915	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
RR, OR and RD estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with AESI Cardiac failure - Subgroup analysis
Safety

Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	OR (95% CI); p-Value	RD (95% CI); p-Value	Interaction p-Value
Age at screening						
< 65 years	2/ 99 (2.0)	0/ 53 (0.0)				
>= 65 years	1/ 29 (3.4)	1/ 12 (8.3)				
Age at PBC diagnosis						
< 50 years	2/ 61 (3.3)	0/ 32 (0.0)				
>= 50 years	1/ 67 (1.5)	1/ 33 (3.0)				
Sex						
female	3/ 123 (2.4)	1/ 60 (1.7)				
male	0/ 5 (0.0)	0/ 5 (0.0)				
Race						
white	3/ 114 (2.6)	1/ 56 (1.8)				
black	0/ 2 (0.0)	0/ 2 (0.0)				
asian	0/ 7 (0.0)	0/ 4 (0.0)				
other	0/ 5 (0.0)	0/ 3 (0.0)				
Region						
North America	1/ 50 (2.0)	0/ 13 (0.0)				
Europe	1/ 39 (2.6)	0/ 24 (0.0)				
Rest-of-World	1/ 39 (2.6)	1/ 28 (3.6)				
Cirrhosis						
yes	1/ 18 (5.6)	1/ 9 (11.1)				
no	2/ 110 (1.8)	0/ 56 (0.0)				
UDCA						
UDCA Use	2/ 120 (1.7)	1/ 62 (1.6)				
UDCA Intolerance	1/ 8 (12.5)	0/ 3 (0.0)				
Prior Use of OCA and/or Fibrates						
yes	0/ 20 (0.0)	0/ 13 (0.0)				
no	3/ 108 (2.8)	1/ 52 (1.9)				
Therapy						
Monotherapy (SEL)	1/ 8 (12.5)	0/ 4 (0.0)				
Combinationtherapy (SEL + UDCA)	2/ 120 (1.7)	1/ 61 (1.6)				
Stratification variable: Baseline Pruritus NRS						
< 4	1/ 79 (1.3)	0/ 42 (0.0)				
>= 4	2/ 49 (4.1)	1/ 23 (4.3)				
Stratification variable: Baseline ALP Level						
< 350 U/L	1/ 93 (1.1)	1/ 47 (2.1)				
>= 350 U/L	2/ 35 (5.7)	0/ 18 (0.0)				

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with AESI Cardiac failure - Subgroup analysis
Safety

Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	Seladelpar 10 mg vs. Placebo OR (95% CI); p-Value	Seladelpar 10 mg vs. Placebo RD (95% CI); p-Value	Interaction p-Value
Gamma-GT (GGT)						
<= 3 x ULN	0/ 33 (0.0)	0/ 14 (0.0)				
> 3 x ULN	3/ 95 (3.2)	1/ 51 (2.0)				
Total Bilirubin I						
<= 1 x ULN	1/ 108 (0.9)	1/ 60 (1.7)				
> 1 x ULN	2/ 20 (10.0)	0/ 5 (0.0)				
Total Bilirubin II						
< 0.6 x ULN	0/ 59 (0.0)	0/ 32 (0.0)				
>= 0.6 x ULN	3/ 69 (4.3)	1/ 33 (3.0)				

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with Serious AESI Cardiac failure
Safety

	Seladelpar 10 mg	Placebo
Number of subjects with event, n/N (%)	0/128 (0.0)	0/ 65 (0.0)
Analysis Seladelpar 10 mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Peto Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
RR, OR and RD estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with Serious AESI Cardiac failure - Subgroup analysis
Safety

Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	OR (95% CI); p-Value	RD (95% CI); p-Value	Interaction p-Value
Age at screening						
< 65 years	0/ 99 (0.0)	0/ 53 (0.0)				
>= 65 years	0/ 29 (0.0)	0/ 12 (0.0)				
Age at PBC diagnosis						
< 50 years	0/ 61 (0.0)	0/ 32 (0.0)				
>= 50 years	0/ 67 (0.0)	0/ 33 (0.0)				
Sex						
female	0/ 123 (0.0)	0/ 60 (0.0)				
male	0/ 5 (0.0)	0/ 5 (0.0)				
Race						
white	0/ 114 (0.0)	0/ 56 (0.0)				
black	0/ 2 (0.0)	0/ 2 (0.0)				
asian	0/ 7 (0.0)	0/ 4 (0.0)				
other	0/ 5 (0.0)	0/ 3 (0.0)				
Region						
North America	0/ 50 (0.0)	0/ 13 (0.0)				
Europe	0/ 39 (0.0)	0/ 24 (0.0)				
Rest-of-World	0/ 39 (0.0)	0/ 28 (0.0)				
Cirrhosis						
yes	0/ 18 (0.0)	0/ 9 (0.0)				
no	0/ 110 (0.0)	0/ 56 (0.0)				
UDCA						
UDCA Use	0/ 120 (0.0)	0/ 62 (0.0)				
UDCA Intolerance	0/ 8 (0.0)	0/ 3 (0.0)				
Prior Use of OCA and/or Fibrates						
yes	0/ 20 (0.0)	0/ 13 (0.0)				
no	0/ 108 (0.0)	0/ 52 (0.0)				
Therapy						
Monotherapy (SEL)	0/ 8 (0.0)	0/ 4 (0.0)				
Combinationtherapy (SEL + UDCA)	0/ 120 (0.0)	0/ 61 (0.0)				
Stratification variable: Baseline Pruritus NRS						
< 4	0/ 79 (0.0)	0/ 42 (0.0)				
>= 4	0/ 49 (0.0)	0/ 23 (0.0)				
Stratification variable: Baseline ALP Level						
< 350 U/L	0/ 93 (0.0)	0/ 47 (0.0)				
>= 350 U/L	0/ 35 (0.0)	0/ 18 (0.0)				

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with Serious AESI Cardiac failure - Subgroup analysis
Safety

Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	Seladelpar 10 mg vs. Placebo OR (95% CI); p-Value	Seladelpar 10 mg vs. Placebo RD (95% CI); p-Value	Interaction p-Value
Gamma-GT (GGT)						
<= 3 x ULN	0/ 33 (0.0)	0/ 14 (0.0)				
> 3 x ULN	0/ 95 (0.0)	0/ 51 (0.0)				
Total Bilirubin I						
<= 1 x ULN	0/ 108 (0.0)	0/ 60 (0.0)				
> 1 x ULN	0/ 20 (0.0)	0/ 5 (0.0)				
Total Bilirubin II						
< 0.6 x ULN	0/ 59 (0.0)	0/ 32 (0.0)				
>= 0.6 x ULN	0/ 69 (0.0)	0/ 33 (0.0)				

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with Severe AESI Cardiac failure
Safety

	Seladelpar 10 mg	Placebo
Number of subjects with event, n/N (%)	0/128 (0.0)	0/ 65 (0.0)
Analysis Seladelpar 10 mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Peto Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
RR, OR and RD estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with Severe AESI Cardiac failure - Subgroup analysis
Safety

Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	OR (95% CI); p-Value	RD (95% CI); p-Value	Interaction p-Value
Age at screening						
< 65 years	0/ 99 (0.0)	0/ 53 (0.0)				
>= 65 years	0/ 29 (0.0)	0/ 12 (0.0)				
Age at PBC diagnosis						
< 50 years	0/ 61 (0.0)	0/ 32 (0.0)				
>= 50 years	0/ 67 (0.0)	0/ 33 (0.0)				
Sex						
female	0/ 123 (0.0)	0/ 60 (0.0)				
male	0/ 5 (0.0)	0/ 5 (0.0)				
Race						
white	0/ 114 (0.0)	0/ 56 (0.0)				
black	0/ 2 (0.0)	0/ 2 (0.0)				
asian	0/ 7 (0.0)	0/ 4 (0.0)				
other	0/ 5 (0.0)	0/ 3 (0.0)				
Region						
North America	0/ 50 (0.0)	0/ 13 (0.0)				
Europe	0/ 39 (0.0)	0/ 24 (0.0)				
Rest-of-World	0/ 39 (0.0)	0/ 28 (0.0)				
Cirrhosis						
yes	0/ 18 (0.0)	0/ 9 (0.0)				
no	0/ 110 (0.0)	0/ 56 (0.0)				
UDCA						
UDCA Use	0/ 120 (0.0)	0/ 62 (0.0)				
UDCA Intolerance	0/ 8 (0.0)	0/ 3 (0.0)				
Prior Use of OCA and/or Fibrates						
yes	0/ 20 (0.0)	0/ 13 (0.0)				
no	0/ 108 (0.0)	0/ 52 (0.0)				
Therapy						
Monotherapy (SEL)	0/ 8 (0.0)	0/ 4 (0.0)				
Combinationtherapy (SEL + UDCA)	0/ 120 (0.0)	0/ 61 (0.0)				
Stratification variable: Baseline Pruritus NRS						
< 4	0/ 79 (0.0)	0/ 42 (0.0)				
>= 4	0/ 49 (0.0)	0/ 23 (0.0)				
Stratification variable: Baseline ALP Level						
< 350 U/L	0/ 93 (0.0)	0/ 47 (0.0)				
>= 350 U/L	0/ 35 (0.0)	0/ 18 (0.0)				

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with Severe AESI Cardiac failure - Subgroup analysis
Safety

Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	Seladelpar 10 mg vs. Placebo OR (95% CI); p-Value	Seladelpar 10 mg vs. Placebo RD (95% CI); p-Value	Interaction p-Value
Gamma-GT (GGT)						
<= 3 x ULN	0/ 33 (0.0)	0/ 14 (0.0)				
> 3 x ULN	0/ 95 (0.0)	0/ 51 (0.0)				
Total Bilirubin I						
<= 1 x ULN	0/ 108 (0.0)	0/ 60 (0.0)				
> 1 x ULN	0/ 20 (0.0)	0/ 5 (0.0)				
Total Bilirubin II						
< 0.6 x ULN	0/ 59 (0.0)	0/ 32 (0.0)				
>= 0.6 x ULN	0/ 69 (0.0)	0/ 33 (0.0)				

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with AESI Cardiomyopathy
Safety

	Seladelpar 10 mg	Placebo
Number of subjects with event, n/N (%)	5/128 (3.9)	0/ 65 (0.0)
Analysis Seladelpar 10 mg vs. Placebo		
Relative Risk (95% CI)	5.63 (0.32, 100.24)	
p-value	0.2396	
Odds Ratio (95% CI)	5.83 (0.32, 107.15)	
p-value	0.2350	
Peto Odds Ratio (95% CI)	4.66 (0.72, 30.39)	
p-value	0.1073	
Risk Difference (95% CI)	0.04 (0.01, 0.07)	
p-value	0.0225	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
RR, OR and RD estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with AESI Cardiomyopathy - Subgroup analysis
Safety

Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	OR (95% CI); p-Value	RD (95% CI); p-Value	Interaction p-Value
Age at screening						
< 65 years	4/ 99 (4.0)	0/ 53 (0.0)				
>= 65 years	1/ 29 (3.4)	0/ 12 (0.0)				
Age at PBC diagnosis						
< 50 years	3/ 61 (4.9)	0/ 32 (0.0)				
>= 50 years	2/ 67 (3.0)	0/ 33 (0.0)				
Sex						
female	5/ 123 (4.1)	0/ 60 (0.0)				
male	0/ 5 (0.0)	0/ 5 (0.0)				
Race						
white	5/ 114 (4.4)	0/ 56 (0.0)				
black	0/ 2 (0.0)	0/ 2 (0.0)				
asian	0/ 7 (0.0)	0/ 4 (0.0)				
other	0/ 5 (0.0)	0/ 3 (0.0)				
Region						
North America	0/ 50 (0.0)	0/ 13 (0.0)				
Europe	2/ 39 (5.1)	0/ 24 (0.0)				
Rest-of-World	3/ 39 (7.7)	0/ 28 (0.0)				
Cirrhosis						
yes	2/ 18 (11.1)	0/ 9 (0.0)				
no	3/ 110 (2.7)	0/ 56 (0.0)				
UDCA						
UDCA Use	5/ 120 (4.2)	0/ 62 (0.0)				
UDCA Intolerance	0/ 8 (0.0)	0/ 3 (0.0)				
Prior Use of OCA and/or Fibrates						
yes	0/ 20 (0.0)	0/ 13 (0.0)				
no	5/ 108 (4.6)	0/ 52 (0.0)				
Therapy						
Monotherapy (SEL)	0/ 8 (0.0)	0/ 4 (0.0)				
Combinationtherapy (SEL + UDCA)	5/ 120 (4.2)	0/ 61 (0.0)				
Stratification variable: Baseline Pruritus NRS						
< 4	4/ 79 (5.1)	0/ 42 (0.0)				
>= 4	1/ 49 (2.0)	0/ 23 (0.0)				
Stratification variable: Baseline ALP Level						
< 350 U/L	2/ 93 (2.2)	0/ 47 (0.0)				
>= 350 U/L	3/ 35 (8.6)	0/ 18 (0.0)				

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with AESI Cardiomyopathy - Subgroup analysis
Safety

Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	Seladelpar 10 mg vs. Placebo OR (95% CI); p-Value	Seladelpar 10 mg vs. Placebo RD (95% CI); p-Value	Interaction p-Value
Gamma-GT (GGT)						
<= 3 x ULN	0/ 33 (0.0)	0/ 14 (0.0)				
> 3 x ULN	5/ 95 (5.3)	0/ 51 (0.0)				
Total Bilirubin I						
<= 1 x ULN	3/ 108 (2.8)	0/ 60 (0.0)				
> 1 x ULN	2/ 20 (10.0)	0/ 5 (0.0)				
Total Bilirubin II						
< 0.6 x ULN	2/ 59 (3.4)	0/ 32 (0.0)				
>= 0.6 x ULN	3/ 69 (4.3)	0/ 33 (0.0)				

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with Serious AESI Cardiomyopathy
Safety

	Seladelpar 10 mg	Placebo
Number of subjects with event, n/N (%)	0/128 (0.0)	0/ 65 (0.0)
Analysis Seladelpar 10 mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Peto Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
RR, OR and RD estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with Serious AESI Cardiomyopathy - Subgroup analysis
Safety

Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	OR (95% CI); p-Value	RD (95% CI); p-Value	Interaction p-Value
Age at screening						
< 65 years	0/ 99 (0.0)	0/ 53 (0.0)				
>= 65 years	0/ 29 (0.0)	0/ 12 (0.0)				
Age at PBC diagnosis						
< 50 years	0/ 61 (0.0)	0/ 32 (0.0)				
>= 50 years	0/ 67 (0.0)	0/ 33 (0.0)				
Sex						
female	0/ 123 (0.0)	0/ 60 (0.0)				
male	0/ 5 (0.0)	0/ 5 (0.0)				
Race						
white	0/ 114 (0.0)	0/ 56 (0.0)				
black	0/ 2 (0.0)	0/ 2 (0.0)				
asian	0/ 7 (0.0)	0/ 4 (0.0)				
other	0/ 5 (0.0)	0/ 3 (0.0)				
Region						
North America	0/ 50 (0.0)	0/ 13 (0.0)				
Europe	0/ 39 (0.0)	0/ 24 (0.0)				
Rest-of-World	0/ 39 (0.0)	0/ 28 (0.0)				
Cirrhosis						
yes	0/ 18 (0.0)	0/ 9 (0.0)				
no	0/ 110 (0.0)	0/ 56 (0.0)				
UDCA						
UDCA Use	0/ 120 (0.0)	0/ 62 (0.0)				
UDCA Intolerance	0/ 8 (0.0)	0/ 3 (0.0)				
Prior Use of OCA and/or Fibrates						
yes	0/ 20 (0.0)	0/ 13 (0.0)				
no	0/ 108 (0.0)	0/ 52 (0.0)				
Therapy						
Monotherapy (SEL)	0/ 8 (0.0)	0/ 4 (0.0)				
Combinationtherapy (SEL + UDCA)	0/ 120 (0.0)	0/ 61 (0.0)				
Stratification variable: Baseline Pruritus NRS						
< 4	0/ 79 (0.0)	0/ 42 (0.0)				
>= 4	0/ 49 (0.0)	0/ 23 (0.0)				
Stratification variable: Baseline ALP Level						
< 350 U/L	0/ 93 (0.0)	0/ 47 (0.0)				
>= 350 U/L	0/ 35 (0.0)	0/ 18 (0.0)				

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with Serious AESI Cardiomyopathy - Subgroup analysis
Safety

Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	OR (95% CI); p-Value	RD (95% CI); p-Value	Interaction p-Value
Gamma-GT (GGT)						
<= 3 x ULN	0/ 33 (0.0)	0/ 14 (0.0)				
> 3 x ULN	0/ 95 (0.0)	0/ 51 (0.0)				
Total Bilirubin I						
<= 1 x ULN	0/ 108 (0.0)	0/ 60 (0.0)				
> 1 x ULN	0/ 20 (0.0)	0/ 5 (0.0)				
Total Bilirubin II						
< 0.6 x ULN	0/ 59 (0.0)	0/ 32 (0.0)				
>= 0.6 x ULN	0/ 69 (0.0)	0/ 33 (0.0)				

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with Severe AESI Cardiomyopathy
Safety

	Seladelpar 10 mg	Placebo
Number of subjects with event, n/N (%)	0/128 (0.0)	0/ 65 (0.0)
Analysis Seladelpar 10 mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Peto Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
RR, OR and RD estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with Severe AESI Cardiomyopathy - Subgroup analysis
Safety

Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	OR (95% CI); p-Value	RD (95% CI); p-Value	Interaction p-Value
Age at screening						
< 65 years	0/ 99 (0.0)	0/ 53 (0.0)				
>= 65 years	0/ 29 (0.0)	0/ 12 (0.0)				
Age at PBC diagnosis						
< 50 years	0/ 61 (0.0)	0/ 32 (0.0)				
>= 50 years	0/ 67 (0.0)	0/ 33 (0.0)				
Sex						
female	0/ 123 (0.0)	0/ 60 (0.0)				
male	0/ 5 (0.0)	0/ 5 (0.0)				
Race						
white	0/ 114 (0.0)	0/ 56 (0.0)				
black	0/ 2 (0.0)	0/ 2 (0.0)				
asian	0/ 7 (0.0)	0/ 4 (0.0)				
other	0/ 5 (0.0)	0/ 3 (0.0)				
Region						
North America	0/ 50 (0.0)	0/ 13 (0.0)				
Europe	0/ 39 (0.0)	0/ 24 (0.0)				
Rest-of-World	0/ 39 (0.0)	0/ 28 (0.0)				
Cirrhosis						
yes	0/ 18 (0.0)	0/ 9 (0.0)				
no	0/ 110 (0.0)	0/ 56 (0.0)				
UDCA						
UDCA Use	0/ 120 (0.0)	0/ 62 (0.0)				
UDCA Intolerance	0/ 8 (0.0)	0/ 3 (0.0)				
Prior Use of OCA and/or Fibrates						
yes	0/ 20 (0.0)	0/ 13 (0.0)				
no	0/ 108 (0.0)	0/ 52 (0.0)				
Therapy						
Monotherapy (SEL)	0/ 8 (0.0)	0/ 4 (0.0)				
Combinationtherapy (SEL + UDCA)	0/ 120 (0.0)	0/ 61 (0.0)				
Stratification variable: Baseline Pruritus NRS						
< 4	0/ 79 (0.0)	0/ 42 (0.0)				
>= 4	0/ 49 (0.0)	0/ 23 (0.0)				
Stratification variable: Baseline ALP Level						
< 350 U/L	0/ 93 (0.0)	0/ 47 (0.0)				
>= 350 U/L	0/ 35 (0.0)	0/ 18 (0.0)				

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with Severe AESI Cardiomyopathy - Subgroup analysis
Safety

Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	OR (95% CI); p-Value	RD (95% CI); p-Value	Interaction p-Value
Gamma-GT (GGT)						
<= 3 x ULN	0/ 33 (0.0)	0/ 14 (0.0)				
> 3 x ULN	0/ 95 (0.0)	0/ 51 (0.0)				
Total Bilirubin I						
<= 1 x ULN	0/ 108 (0.0)	0/ 60 (0.0)				
> 1 x ULN	0/ 20 (0.0)	0/ 5 (0.0)				
Total Bilirubin II						
< 0.6 x ULN	0/ 59 (0.0)	0/ 32 (0.0)				
>= 0.6 x ULN	0/ 69 (0.0)	0/ 33 (0.0)				

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with AESI Ischaemic heart disease
Safety

	Seladelpar 10 mg	Placebo
Number of subjects with event, n/N (%)	5/128 (3.9)	2/ 65 (3.1)
Analysis Seladelpar 10 mg vs. Placebo		
Relative Risk (95% CI)	1.27 (0.25, 6.37)	
p-value	0.7718	
Odds Ratio (95% CI)	1.28 (0.24, 6.79)	
p-value	0.7714	
Peto Odds Ratio (95% CI)	1.27 (0.26, 6.22)	
p-value	0.7714	
Risk Difference (95% CI)	0.01 (-0.05, 0.06)	
p-value	0.7623	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
RR, OR and RD estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with AESI Ischaemic heart disease - Subgroup analysis
Safety

Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	Seladelpar 10 mg vs. Placebo OR (95% CI); p-Value	Seladelpar 10 mg vs. Placebo RD (95% CI); p-Value	Interaction p-Value
Age at screening						
< 65 years	2/ 99 (2.0)	1/ 53 (1.9)				
>= 65 years	3/ 29 (10.3)	1/ 12 (8.3)				
Age at PBC diagnosis						
< 50 years	1/ 61 (1.6)	1/ 32 (3.1)				
>= 50 years	4/ 67 (6.0)	1/ 33 (3.0)				
Sex						
female	5/ 123 (4.1)	2/ 60 (3.3)				
male	0/ 5 (0.0)	0/ 5 (0.0)				
Race						
white	5/ 114 (4.4)	2/ 56 (3.6)				
black	0/ 2 (0.0)	0/ 2 (0.0)				
asian	0/ 7 (0.0)	0/ 4 (0.0)				
other	0/ 5 (0.0)	0/ 3 (0.0)				
Region						
North America	1/ 50 (2.0)	0/ 13 (0.0)				
Europe	1/ 39 (2.6)	2/ 24 (8.3)				
Rest-of-World	3/ 39 (7.7)	0/ 28 (0.0)				
Cirrhosis						
yes	1/ 18 (5.6)	0/ 9 (0.0)				
no	4/ 110 (3.6)	2/ 56 (3.6)				
UDCA						
UDCA Use	5/ 120 (4.2)	2/ 62 (3.2)				
UDCA Intolerance	0/ 8 (0.0)	0/ 3 (0.0)				
Prior Use of OCA and/or Fibrates						
yes	1/ 20 (5.0)	1/ 13 (7.7)				
no	4/ 108 (3.7)	1/ 52 (1.9)				
Therapy						
Monotherapy (SEL)	0/ 8 (0.0)	0/ 4 (0.0)				
Combinationtherapy (SEL + UDCA)	5/ 120 (4.2)	2/ 61 (3.3)				
Stratification variable: Baseline Pruritus NRS						
< 4	4/ 79 (5.1)	2/ 42 (4.8)				
>= 4	1/ 49 (2.0)	0/ 23 (0.0)				
Stratification variable: Baseline ALP Level						
< 350 U/L	4/ 93 (4.3)	2/ 47 (4.3)				
>= 350 U/L	1/ 35 (2.9)	0/ 18 (0.0)				

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with AESI Ischaemic heart disease - Subgroup analysis
Safety

Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	Seladelpar 10 mg vs. Placebo OR (95% CI); p-Value	Seladelpar 10 mg vs. Placebo RD (95% CI); p-Value	Interaction p-Value
Gamma-GT (GGT)						
<= 3 x ULN	0/ 33 (0.0)	0/ 14 (0.0)				
> 3 x ULN	5/ 95 (5.3)	2/ 51 (3.9)				
Total Bilirubin I						
<= 1 x ULN	5/ 108 (4.6)	2/ 60 (3.3)				
> 1 x ULN	0/ 20 (0.0)	0/ 5 (0.0)				
Total Bilirubin II						
< 0.6 x ULN	4/ 59 (6.8)	1/ 32 (3.1)				
>= 0.6 x ULN	1/ 69 (1.4)	1/ 33 (3.0)				

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with Serious AESI Ischaemic heart disease
Safety

	Seladelpar 10 mg	Placebo
Number of subjects with event, n/N (%)	1/128 (0.8)	0/ 65 (0.0)
Analysis Seladelpar 10 mg vs. Placebo		
Relative Risk (95% CI)	1.53 (0.06, 37.16)	
p-value	0.7922	
Odds Ratio (95% CI)	1.54 (0.06, 38.36)	
p-value	0.7920	
Peto Odds Ratio (95% CI)	4.52 (0.07, 285.69)	
p-value	0.4761	
Risk Difference (95% CI)	0.01 (-0.01, 0.02)	
p-value	0.3154	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
RR, OR and RD estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with Serious AESI Ischaemic heart disease - Subgroup analysis
Safety

Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	OR (95% CI); p-Value	RD (95% CI); p-Value	Interaction p-Value
Age at screening						
< 65 years	0/ 99 (0.0)	0/ 53 (0.0)				
>= 65 years	1/ 29 (3.4)	0/ 12 (0.0)				
Age at PBC diagnosis						
< 50 years	0/ 61 (0.0)	0/ 32 (0.0)				
>= 50 years	1/ 67 (1.5)	0/ 33 (0.0)				
Sex						
female	1/ 123 (0.8)	0/ 60 (0.0)				
male	0/ 5 (0.0)	0/ 5 (0.0)				
Race						
white	1/ 114 (0.9)	0/ 56 (0.0)				
black	0/ 2 (0.0)	0/ 2 (0.0)				
asian	0/ 7 (0.0)	0/ 4 (0.0)				
other	0/ 5 (0.0)	0/ 3 (0.0)				
Region						
North America	0/ 50 (0.0)	0/ 13 (0.0)				
Europe	0/ 39 (0.0)	0/ 24 (0.0)				
Rest-of-World	1/ 39 (2.6)	0/ 28 (0.0)				
Cirrhosis						
yes	1/ 18 (5.6)	0/ 9 (0.0)				
no	0/ 110 (0.0)	0/ 56 (0.0)				
UDCA						
UDCA Use	1/ 120 (0.8)	0/ 62 (0.0)				
UDCA Intolerance	0/ 8 (0.0)	0/ 3 (0.0)				
Prior Use of OCA and/or Fibrates						
yes	0/ 20 (0.0)	0/ 13 (0.0)				
no	1/ 108 (0.9)	0/ 52 (0.0)				
Therapy						
Monotherapy (SEL)	0/ 8 (0.0)	0/ 4 (0.0)				
Combinationtherapy (SEL + UDCA)	1/ 120 (0.8)	0/ 61 (0.0)				
Stratification variable: Baseline Pruritus NRS						
< 4	1/ 79 (1.3)	0/ 42 (0.0)				
>= 4	0/ 49 (0.0)	0/ 23 (0.0)				
Stratification variable: Baseline ALP Level						
< 350 U/L	1/ 93 (1.1)	0/ 47 (0.0)				
>= 350 U/L	0/ 35 (0.0)	0/ 18 (0.0)				

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with Serious AESI Ischaemic heart disease - Subgroup analysis
Safety

Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	Seladelpar 10 mg vs. Placebo OR (95% CI); p-Value	Seladelpar 10 mg vs. Placebo RD (95% CI); p-Value	Interaction p-Value
Gamma-GT (GGT)						
<= 3 x ULN	0/ 33 (0.0)	0/ 14 (0.0)				
> 3 x ULN	1/ 95 (1.1)	0/ 51 (0.0)				
Total Bilirubin I						
<= 1 x ULN	1/ 108 (0.9)	0/ 60 (0.0)				
> 1 x ULN	0/ 20 (0.0)	0/ 5 (0.0)				
Total Bilirubin II						
< 0.6 x ULN	1/ 59 (1.7)	0/ 32 (0.0)				
>= 0.6 x ULN	0/ 69 (0.0)	0/ 33 (0.0)				

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with Severe AESI Ischaemic heart disease
Safety

	Seladelpar 10 mg	Placebo
Number of subjects with event, n/N (%)	1/128 (0.8)	0/ 65 (0.0)
Analysis Seladelpar 10 mg vs. Placebo		
Relative Risk (95% CI)	1.53 (0.06, 37.16)	
p-value	0.7922	
Odds Ratio (95% CI)	1.54 (0.06, 38.36)	
p-value	0.7920	
Peto Odds Ratio (95% CI)	4.52 (0.07, 285.69)	
p-value	0.4761	
Risk Difference (95% CI)	0.01 (-0.01, 0.02)	
p-value	0.3154	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
RR, OR and RD estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with Severe AESI Ischaemic heart disease - Subgroup analysis
Safety

Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	OR (95% CI); p-Value	RD (95% CI); p-Value	Interaction p-Value
Age at screening						
< 65 years	0/ 99 (0.0)	0/ 53 (0.0)				
>= 65 years	1/ 29 (3.4)	0/ 12 (0.0)				
Age at PBC diagnosis						
< 50 years	0/ 61 (0.0)	0/ 32 (0.0)				
>= 50 years	1/ 67 (1.5)	0/ 33 (0.0)				
Sex						
female	1/ 123 (0.8)	0/ 60 (0.0)				
male	0/ 5 (0.0)	0/ 5 (0.0)				
Race						
white	1/ 114 (0.9)	0/ 56 (0.0)				
black	0/ 2 (0.0)	0/ 2 (0.0)				
asian	0/ 7 (0.0)	0/ 4 (0.0)				
other	0/ 5 (0.0)	0/ 3 (0.0)				
Region						
North America	0/ 50 (0.0)	0/ 13 (0.0)				
Europe	0/ 39 (0.0)	0/ 24 (0.0)				
Rest-of-World	1/ 39 (2.6)	0/ 28 (0.0)				
Cirrhosis						
yes	1/ 18 (5.6)	0/ 9 (0.0)				
no	0/ 110 (0.0)	0/ 56 (0.0)				
UDCA						
UDCA Use	1/ 120 (0.8)	0/ 62 (0.0)				
UDCA Intolerance	0/ 8 (0.0)	0/ 3 (0.0)				
Prior Use of OCA and/or Fibrates						
yes	0/ 20 (0.0)	0/ 13 (0.0)				
no	1/ 108 (0.9)	0/ 52 (0.0)				
Therapy						
Monotherapy (SEL)	0/ 8 (0.0)	0/ 4 (0.0)				
Combinationtherapy (SEL + UDCA)	1/ 120 (0.8)	0/ 61 (0.0)				
Stratification variable: Baseline Pruritus NRS						
< 4	1/ 79 (1.3)	0/ 42 (0.0)				
>= 4	0/ 49 (0.0)	0/ 23 (0.0)				
Stratification variable: Baseline ALP Level						
< 350 U/L	1/ 93 (1.1)	0/ 47 (0.0)				
>= 350 U/L	0/ 35 (0.0)	0/ 18 (0.0)				

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with Severe AESI Ischaemic heart disease - Subgroup analysis
Safety

Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	Seladelpar 10 mg vs. Placebo OR (95% CI); p-Value	Seladelpar 10 mg vs. Placebo RD (95% CI); p-Value	Interaction p-Value
Gamma-GT (GGT)						
<= 3 x ULN	0/ 33 (0.0)	0/ 14 (0.0)				
> 3 x ULN	1/ 95 (1.1)	0/ 51 (0.0)				
Total Bilirubin I						
<= 1 x ULN	1/ 108 (0.9)	0/ 60 (0.0)				
> 1 x ULN	0/ 20 (0.0)	0/ 5 (0.0)				
Total Bilirubin II						
< 0.6 x ULN	1/ 59 (1.7)	0/ 32 (0.0)				
>= 0.6 x ULN	0/ 69 (0.0)	0/ 33 (0.0)				

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with AESI Fracture
Safety

	Seladelpar 10 mg	Placebo
Number of subjects with event, n/N (%)	7/128 (5.5)	0/ 65 (0.0)
Analysis Seladelpar 10 mg vs. Placebo		
Relative Risk (95% CI)	7.67 (0.45, 132.32)	
p-value	0.1607	
Odds Ratio (95% CI)	8.09 (0.45, 143.83)	
p-value	0.1547	
Peto Odds Ratio (95% CI)	4.74 (0.96, 23.31)	
p-value	0.0554	
Risk Difference (95% CI)	0.05 (0.02, 0.09)	
p-value	0.0065	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
RR, OR and RD estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with AESI Fracture - Subgroup analysis
Safety

Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	OR (95% CI); p-Value	RD (95% CI); p-Value	Interaction p-Value
Age at screening						
< 65 years	4/ 99 (4.0)	0/ 53 (0.0)				
>= 65 years	3/ 29 (10.3)	0/ 12 (0.0)				
Age at PBC diagnosis						
< 50 years	5/ 61 (8.2)	0/ 32 (0.0)				
>= 50 years	2/ 67 (3.0)	0/ 33 (0.0)				
Sex						
female	6/ 123 (4.9)	0/ 60 (0.0)				
male	1/ 5 (20.0)	0/ 5 (0.0)				
Race						
white	7/ 114 (6.1)	0/ 56 (0.0)				
black	0/ 2 (0.0)	0/ 2 (0.0)				
asian	0/ 7 (0.0)	0/ 4 (0.0)				
other	0/ 5 (0.0)	0/ 3 (0.0)				
Region						
North America	5/ 50 (10.0)	0/ 13 (0.0)				
Europe	2/ 39 (5.1)	0/ 24 (0.0)				
Rest-of-World	0/ 39 (0.0)	0/ 28 (0.0)				
Cirrhosis						
yes	3/ 18 (16.7)	0/ 9 (0.0)				
no	4/ 110 (3.6)	0/ 56 (0.0)				
UDCA						
UDCA Use	7/ 120 (5.8)	0/ 62 (0.0)				
UDCA Intolerance	0/ 8 (0.0)	0/ 3 (0.0)				
Prior Use of OCA and/or Fibrates						
yes	2/ 20 (10.0)	0/ 13 (0.0)				
no	5/ 108 (4.6)	0/ 52 (0.0)				
Therapy						
Monotherapy (SEL)	0/ 8 (0.0)	0/ 4 (0.0)				
Combinationtherapy (SEL + UDCA)	7/ 120 (5.8)	0/ 61 (0.0)				
Stratification variable: Baseline Pruritus NRS						
< 4	6/ 79 (7.6)	0/ 42 (0.0)				
>= 4	1/ 49 (2.0)	0/ 23 (0.0)				
Stratification variable: Baseline ALP Level						
< 350 U/L	6/ 93 (6.5)	0/ 47 (0.0)				
>= 350 U/L	1/ 35 (2.9)	0/ 18 (0.0)				

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with AESI Fracture - Subgroup analysis
Safety

Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	Seladelpar 10 mg vs. Placebo OR (95% CI); p-Value	Seladelpar 10 mg vs. Placebo RD (95% CI); p-Value	Interaction p-Value
Gamma-GT (GGT)						
<= 3 x ULN	1/ 33 (3.0)	0/ 14 (0.0)				
> 3 x ULN	6/ 95 (6.3)	0/ 51 (0.0)				
Total Bilirubin I						
<= 1 x ULN	6/ 108 (5.6)	0/ 60 (0.0)				
> 1 x ULN	1/ 20 (5.0)	0/ 5 (0.0)				
Total Bilirubin II						
< 0.6 x ULN	5/ 59 (8.5)	0/ 32 (0.0)				
>= 0.6 x ULN	2/ 69 (2.9)	0/ 33 (0.0)				

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with Serious AESI Fracture
Safety

	Seladelpar 10 mg	Placebo
Number of subjects with event, n/N (%)	1/128 (0.8)	0/ 65 (0.0)
Analysis Seladelpar 10 mg vs. Placebo		
Relative Risk (95% CI)	1.53 (0.06, 37.16)	
p-value	0.7922	
Odds Ratio (95% CI)	1.54 (0.06, 38.36)	
p-value	0.7920	
Peto Odds Ratio (95% CI)	4.52 (0.07, 285.69)	
p-value	0.4761	
Risk Difference (95% CI)	0.01 (-0.01, 0.02)	
p-value	0.3154	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
RR, OR and RD estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with Serious AESI Fracture - Subgroup analysis
Safety

Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	OR (95% CI); p-Value	RD (95% CI); p-Value	Interaction p-Value
Age at screening						
< 65 years	0/ 99 (0.0)	0/ 53 (0.0)				
>= 65 years	1/ 29 (3.4)	0/ 12 (0.0)				
Age at PBC diagnosis						
< 50 years	1/ 61 (1.6)	0/ 32 (0.0)				
>= 50 years	0/ 67 (0.0)	0/ 33 (0.0)				
Sex						
female	1/ 123 (0.8)	0/ 60 (0.0)				
male	0/ 5 (0.0)	0/ 5 (0.0)				
Race						
white	1/ 114 (0.9)	0/ 56 (0.0)				
black	0/ 2 (0.0)	0/ 2 (0.0)				
asian	0/ 7 (0.0)	0/ 4 (0.0)				
other	0/ 5 (0.0)	0/ 3 (0.0)				
Region						
North America	0/ 50 (0.0)	0/ 13 (0.0)				
Europe	1/ 39 (2.6)	0/ 24 (0.0)				
Rest-of-World	0/ 39 (0.0)	0/ 28 (0.0)				
Cirrhosis						
yes	1/ 18 (5.6)	0/ 9 (0.0)				
no	0/ 110 (0.0)	0/ 56 (0.0)				
UDCA						
UDCA Use	1/ 120 (0.8)	0/ 62 (0.0)				
UDCA Intolerance	0/ 8 (0.0)	0/ 3 (0.0)				
Prior Use of OCA and/or Fibrates						
yes	0/ 20 (0.0)	0/ 13 (0.0)				
no	1/ 108 (0.9)	0/ 52 (0.0)				
Therapy						
Monotherapy (SEL)	0/ 8 (0.0)	0/ 4 (0.0)				
Combinationtherapy (SEL + UDCA)	1/ 120 (0.8)	0/ 61 (0.0)				
Stratification variable: Baseline Pruritus NRS						
< 4	1/ 79 (1.3)	0/ 42 (0.0)				
>= 4	0/ 49 (0.0)	0/ 23 (0.0)				
Stratification variable: Baseline ALP Level						
< 350 U/L	0/ 93 (0.0)	0/ 47 (0.0)				
>= 350 U/L	1/ 35 (2.9)	0/ 18 (0.0)				

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with Serious AESI Fracture - Subgroup analysis
Safety

Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	Seladelpar 10 mg vs. Placebo OR (95% CI); p-Value	Seladelpar 10 mg vs. Placebo RD (95% CI); p-Value	Interaction p-Value
Gamma-GT (GGT)						
<= 3 x ULN	0/ 33 (0.0)	0/ 14 (0.0)				
> 3 x ULN	1/ 95 (1.1)	0/ 51 (0.0)				
Total Bilirubin I						
<= 1 x ULN	0/ 108 (0.0)	0/ 60 (0.0)				
> 1 x ULN	1/ 20 (5.0)	0/ 5 (0.0)				
Total Bilirubin II						
< 0.6 x ULN	0/ 59 (0.0)	0/ 32 (0.0)				
>= 0.6 x ULN	1/ 69 (1.4)	0/ 33 (0.0)				

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with Severe AESI Fracture
Safety

	Seladelpar 10 mg	Placebo
Number of subjects with event, n/N (%)	1/128 (0.8)	0/ 65 (0.0)
Analysis Seladelpar 10 mg vs. Placebo		
Relative Risk (95% CI)	1.53 (0.06, 37.16)	
p-value	0.7922	
Odds Ratio (95% CI)	1.54 (0.06, 38.36)	
p-value	0.7920	
Peto Odds Ratio (95% CI)	4.52 (0.07, 285.69)	
p-value	0.4761	
Risk Difference (95% CI)	0.01 (-0.01, 0.02)	
p-value	0.3154	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
RR, OR and RD estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with Severe AESI Fracture - Subgroup analysis
Safety

Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	OR (95% CI); p-Value	RD (95% CI); p-Value	Interaction p-Value
Age at screening						
< 65 years	0/ 99 (0.0)	0/ 53 (0.0)				
>= 65 years	1/ 29 (3.4)	0/ 12 (0.0)				
Age at PBC diagnosis						
< 50 years	1/ 61 (1.6)	0/ 32 (0.0)				
>= 50 years	0/ 67 (0.0)	0/ 33 (0.0)				
Sex						
female	1/ 123 (0.8)	0/ 60 (0.0)				
male	0/ 5 (0.0)	0/ 5 (0.0)				
Race						
white	1/ 114 (0.9)	0/ 56 (0.0)				
black	0/ 2 (0.0)	0/ 2 (0.0)				
asian	0/ 7 (0.0)	0/ 4 (0.0)				
other	0/ 5 (0.0)	0/ 3 (0.0)				
Region						
North America	0/ 50 (0.0)	0/ 13 (0.0)				
Europe	1/ 39 (2.6)	0/ 24 (0.0)				
Rest-of-World	0/ 39 (0.0)	0/ 28 (0.0)				
Cirrhosis						
yes	1/ 18 (5.6)	0/ 9 (0.0)				
no	0/ 110 (0.0)	0/ 56 (0.0)				
UDCA						
UDCA Use	1/ 120 (0.8)	0/ 62 (0.0)				
UDCA Intolerance	0/ 8 (0.0)	0/ 3 (0.0)				
Prior Use of OCA and/or Fibrates						
yes	0/ 20 (0.0)	0/ 13 (0.0)				
no	1/ 108 (0.9)	0/ 52 (0.0)				
Therapy						
Monotherapy (SEL)	0/ 8 (0.0)	0/ 4 (0.0)				
Combinationtherapy (SEL + UDCA)	1/ 120 (0.8)	0/ 61 (0.0)				
Stratification variable: Baseline Pruritus NRS						
< 4	1/ 79 (1.3)	0/ 42 (0.0)				
>= 4	0/ 49 (0.0)	0/ 23 (0.0)				
Stratification variable: Baseline ALP Level						
< 350 U/L	0/ 93 (0.0)	0/ 47 (0.0)				
>= 350 U/L	1/ 35 (2.9)	0/ 18 (0.0)				

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with Severe AESI Fracture - Subgroup analysis
Safety

Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	Seladelpar 10 mg vs. Placebo OR (95% CI); p-Value	Seladelpar 10 mg vs. Placebo RD (95% CI); p-Value	Interaction p-Value
Gamma-GT (GGT)						
<= 3 x ULN	0/ 33 (0.0)	0/ 14 (0.0)				
> 3 x ULN	1/ 95 (1.1)	0/ 51 (0.0)				
Total Bilirubin I						
<= 1 x ULN	0/ 108 (0.0)	0/ 60 (0.0)				
> 1 x ULN	1/ 20 (5.0)	0/ 5 (0.0)				
Total Bilirubin II						
< 0.6 x ULN	0/ 59 (0.0)	0/ 32 (0.0)				
>= 0.6 x ULN	1/ 69 (1.4)	0/ 33 (0.0)				

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety

SOC / PT		Seladelpar 10 mg	Placebo
SOC: Blood and lymphatic system disorders	Number of subjects with events, n/N (%)	15/128 (11.7)	3/ 65 (4.6)
	Analysis Seladelpar 10 mg vs. Placebo		
	Relative Risk (95% CI)	2.54 (0.76, 8.46)	
	p-value	0.1290	
	Odds Ratio (95% CI)	2.74 (0.76, 9.84)	
	p-value	0.1216	
	Peto Odds Ratio (95% CI)	2.31 (0.83, 6.42)	
	p-value	0.1097	
	Risk Difference (95% CI)	0.07 (-0.00, 0.15)	
	p-value	0.0653	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
RR, OR and RD estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety

SOC / PT		Seladelpar 10 mg	Placebo
SOC: Gastrointestinal disorders	Number of subjects with events, n/N (%)	41/128 (32.0)	24/ 65 (36.9)
	Analysis Seladelpar 10 mg vs. Placebo		
	Relative Risk (95% CI)	0.87 (0.58, 1.30)	
	p-value	0.4924	
	Odds Ratio (95% CI)	0.81 (0.43, 1.51)	
	p-value	0.4971	
	Peto Odds Ratio (95% CI)	0.80 (0.43, 1.51)	
	p-value	0.4979	
	Risk Difference (95% CI)	-0.05 (-0.19, 0.09)	
	p-value	0.5010	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
RR, OR and RD estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety

SOC / PT		Seladelpar 10 mg	Placebo
SOC: General disorders and administration site conditions	Number of subjects with events, n/N (%)	23/128 (18.0)	13/ 65 (20.0)
	Analysis Seladelpar 10 mg vs. Placebo		
	Relative Risk (95% CI)	0.90 (0.49, 1.66)	
	p-value	0.7312	
	Odds Ratio (95% CI)	0.88 (0.41, 1.87)	
	p-value	0.7322	
	Peto Odds Ratio (95% CI)	0.88 (0.41, 1.88)	
	p-value	0.7327	
	Risk Difference (95% CI)	-0.02 (-0.14, 0.10)	
	p-value	0.7354	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
RR, OR and RD estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety

SOC / PT		Seladelpar 10 mg	Placebo
SOC: Infections and infestations	Number of subjects with events, n/N (%)	58/128 (45.3)	35/ 65 (53.8)
	Analysis Seladelpar 10 mg vs. Placebo		
	Relative Risk (95% CI)	0.84 (0.63, 1.13)	
	p-value	0.2512	
	Odds Ratio (95% CI)	0.71 (0.39, 1.29)	
	p-value	0.2629	
	Peto Odds Ratio (95% CI)	0.71 (0.39, 1.29)	
	p-value	0.2634	
	Risk Difference (95% CI)	-0.09 (-0.23, 0.06)	
	p-value	0.2608	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
RR, OR and RD estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety

SOC / PT		Seladelpar 10 mg	Placebo
SOC: Infections and infestations, PT: COVID-19	Number of subjects with events, n/N (%)	23/128 (18.0)	10/ 65 (15.4)
	Analysis Seladelpar 10 mg vs. Placebo		
	Relative Risk (95% CI)	1.17 (0.59, 2.30)	
	p-value	0.6544	
	Odds Ratio (95% CI)	1.20 (0.54, 2.71)	
	p-value	0.6525	
	Peto Odds Ratio (95% CI)	1.20 (0.54, 2.64)	
	p-value	0.6531	
	Risk Difference (95% CI)	0.03 (-0.08, 0.14)	
	p-value	0.6454	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
RR, OR and RD estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety

SOC / PT		Seladelpar 10 mg	Placebo
SOC: Injury, poisoning and procedural complications	Number of subjects with events, n/N (%)	17/128 (13.3)	4/ 65 (6.2)
	Analysis Seladelpar 10 mg vs. Placebo		
	Relative Risk (95% CI)	2.16 (0.76, 6.15)	
	p-value	0.1500	
	Odds Ratio (95% CI)	2.34 (0.75, 7.25)	
	p-value	0.1423	
	Peto Odds Ratio (95% CI)	2.08 (0.80, 5.41)	
	p-value	0.1339	
	Risk Difference (95% CI)	0.07 (-0.01, 0.15)	
	p-value	0.0919	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
RR, OR and RD estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety

SOC / PT		Seladelpar 10 mg	Placebo
SOC: Investigations	Number of subjects with events, n/N (%)	18/128 (14.1)	6/ 65 (9.2)
	Analysis Seladelpar 10 mg vs. Placebo		
	Relative Risk (95% CI)	1.52 (0.64, 3.65)	
	p-value	0.3454	
	Odds Ratio (95% CI)	1.61 (0.61, 4.27)	
	p-value	0.3397	
	Peto Odds Ratio (95% CI)	1.55 (0.63, 3.83)	
	p-value	0.3376	
	Risk Difference (95% CI)	0.05 (-0.04, 0.14)	
	p-value	0.3066	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
RR, OR and RD estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety

SOC / PT		Seladelpar 10 mg	Placebo
SOC: Metabolism and nutrition disorders	Number of subjects with events, n/N (%)	15/128 (11.7)	10/ 65 (15.4)
	Analysis Seladelpar 10 mg vs. Placebo		
	Relative Risk (95% CI)	0.76 (0.36, 1.60)	
	p-value	0.4724	
	Odds Ratio (95% CI)	0.73 (0.31, 1.73)	
	p-value	0.4747	
	Peto Odds Ratio (95% CI)	0.72 (0.30, 1.76)	
	p-value	0.4747	
	Risk Difference (95% CI)	-0.04 (-0.14, 0.07)	
	p-value	0.4893	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
RR, OR and RD estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety

SOC / PT		Seladelpar 10 mg	Placebo
SOC: Musculoskeletal and connective tissue disorders	Number of subjects with events, n/N (%)	31/128 (24.2)	18/ 65 (27.7)
	Analysis Seladelpar 10 mg vs. Placebo		
	Relative Risk (95% CI)	0.87 (0.53, 1.44)	
	p-value	0.5980	
	Odds Ratio (95% CI)	0.83 (0.42, 1.64)	
	p-value	0.6005	
	Peto Odds Ratio (95% CI)	0.83 (0.42, 1.65)	
	p-value	0.6012	
	Risk Difference (95% CI)	-0.03 (-0.17, 0.10)	
	p-value	0.6052	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
RR, OR and RD estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety

SOC / PT		Seladelpar 10 mg	Placebo
SOC: Nervous system disorders	Number of subjects with events, n/N (%)	22/128 (17.2)	9/ 65 (13.8)
	Analysis Seladelpar 10 mg vs. Placebo		
	Relative Risk (95% CI)	1.24 (0.61, 2.54)	
	p-value	0.5539	
	Odds Ratio (95% CI)	1.29 (0.56, 2.99)	
	p-value	0.5509	
	Peto Odds Ratio (95% CI)	1.28 (0.57, 2.88)	
	p-value	0.5512	
	Risk Difference (95% CI)	0.03 (-0.07, 0.14)	
	p-value	0.5382	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
RR, OR and RD estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety

SOC / PT		Seladelpar 10 mg	Placebo
SOC: Nervous system disorders, PT: Headache	Number of subjects with events, n/N (%)	10/128 (7.8)	2/ 65 (3.1)
	Analysis Seladelpar 10 mg vs. Placebo		
	Relative Risk (95% CI)	2.54 (0.57, 11.25)	
	p-value	0.2199	
	Odds Ratio (95% CI)	2.67 (0.57, 12.56)	
	p-value	0.2140	
	Peto Odds Ratio (95% CI)	2.24 (0.65, 7.70)	
	p-value	0.1990	
	Risk Difference (95% CI)	0.05 (-0.02, 0.11)	
	p-value	0.1384	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
RR, OR and RD estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety

SOC / PT		Seladelpar 10 mg	Placebo
SOC: Respiratory, thoracic and mediastinal disorders	Number of subjects with events, n/N (%)	12/128 (9.4)	5/ 65 (7.7)
	Analysis Seladelpar 10 mg vs. Placebo		
	Relative Risk (95% CI)	1.22 (0.45, 3.31)	
	p-value	0.6981	
	Odds Ratio (95% CI)	1.24 (0.42, 3.69)	
	p-value	0.6971	
	Peto Odds Ratio (95% CI)	1.23 (0.43, 3.52)	
	p-value	0.6974	
	Risk Difference (95% CI)	0.02 (-0.07, 0.10)	
	p-value	0.6880	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
RR, OR and RD estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety

SOC / PT		Seladelpar 10 mg	Placebo
SOC: Skin and subcutaneous tissue disorders	Number of subjects with events, n/N (%)	20/128 (15.6)	15/ 65 (23.1)
	Analysis Seladelpar 10 mg vs. Placebo		
	Relative Risk (95% CI)	0.68 (0.37, 1.23)	
	p-value	0.2021	
	Odds Ratio (95% CI)	0.62 (0.29, 1.31)	
	p-value	0.2066	
	Peto Odds Ratio (95% CI)	0.61 (0.28, 1.31)	
	p-value	0.2053	
	Risk Difference (95% CI)	-0.07 (-0.19, 0.05)	
	p-value	0.2243	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
RR, OR and RD estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety

SOC / PT		Seladelpar 10 mg	Placebo
SOC: Skin and subcutaneous tissue disorders, PT: Pruritus	Number of subjects with events, n/N (%)	6/128 (4.7)	10/ 65 (15.4)
	Analysis Seladelpar 10 mg vs. Placebo		
	Relative Risk (95% CI)	0.30 (0.12, 0.80)	
	p-value	0.0160	
	Odds Ratio (95% CI)	0.27 (0.09, 0.78)	
	p-value	0.0157	
	Peto Odds Ratio (95% CI)	0.25 (0.08, 0.73)	
	p-value	0.0111	
	Risk Difference (95% CI)	-0.11 (-0.20, -0.01)	
	p-value	0.0274	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
RR, OR and RD estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety

SOC/PT	Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	OR (95% CI); p-Value	RD (95% CI); p-Value	Interaction p-Value
SOC: Skin and subcutaneous tissue disorders, PT: Pruritus	Age at screening						0.6943
	< 65 years	4/ 99 (4.0)	8/ 53 (15.1)	0.27 (0.08, 0.85); p=0.0251	0.24 (0.07, 0.83); p=0.0241	-0.11 (-0.21, -0.01); p=0.0370	
	>= 65 years	2/ 29 (6.9)	2/ 12 (16.7)	0.41 (0.07, 2.61); p=0.3475	0.37 (0.05, 2.99); p=0.3516	-0.10 (-0.33, 0.13); p=0.4054	
	Age at PBC diagnosis						
	< 50 years	1/ 61 (1.6)	6/ 32 (18.8)				
	>= 50 years	5/ 67 (7.5)	4/ 33 (12.1)				
	Sex						0.9877
	female	6/ 123 (4.9)	9/ 60 (15.0)	0.33 (0.12, 0.87); p=0.0255	0.29 (0.10, 0.86); p=0.0255	-0.10 (-0.20, -0.00); p=0.0430	
	male	0/ 5 (0.0)	1/ 5 (20.0)	0.33 (0.02, 6.65); p=0.4720	0.27 (0.01, 8.46); p=0.4584	-0.20 (-0.55, 0.15); p=0.2636	
	Race						
	white	6/ 114 (5.3)	8/ 56 (14.3)				
	black	0/ 2 (0.0)	1/ 2 (50.0)				
	asian	0/ 7 (0.0)	1/ 4 (25.0)				
	other	0/ 5 (0.0)	0/ 3 (0.0)				
	Region						
	North America	2/ 50 (4.0)	2/ 13 (15.4)				
	Europe	2/ 39 (5.1)	3/ 24 (12.5)				
	Rest-of-World	2/ 39 (5.1)	5/ 28 (17.9)				
	Cirrhosis						0.5345
	yes	2/ 18 (11.1)	2/ 9 (22.2)	0.50 (0.08, 2.99); p=0.4477	0.44 (0.05, 3.76); p=0.4515	-0.11 (-0.42, 0.20); p=0.4795	
	no	4/ 110 (3.6)	8/ 56 (14.3)	0.25 (0.08, 0.81); p=0.0204	0.23 (0.07, 0.79); p=0.0196	-0.11 (-0.20, -0.01); p=0.0334	
	UDCA						NE
	UDCA Use	6/ 120 (5.0)	10/ 62 (16.1)	0.31 (0.12, 0.81); p=0.0173	0.27 (0.09, 0.79); p=0.0170	-0.11 (-0.21, -0.01); p=0.0284	
	UDCA Intolerance	0/ 8 (0.0)	0/ 3 (0.0)	NE	NE	NE	
	Prior Use of OCA and/or Fibrates						0.3684
	yes	2/ 20 (10.0)	2/ 13 (15.4)	0.65 (0.10, 4.06); p=0.6448	0.61 (0.07, 4.98); p=0.6456	-0.05 (-0.29, 0.18); p=0.6549	
	no	4/ 108 (3.7)	8/ 52 (15.4)	0.24 (0.08, 0.76); p=0.0156	0.21 (0.06, 0.74); p=0.0149	-0.12 (-0.22, -0.01); p=0.0282	
	Therapy						0.7083
	Monotherapy (SEL)	0/ 8 (0.0)	1/ 4 (25.0)	0.19 (0.01, 3.75); p=0.2719	0.14 (0.00, 4.26); p=0.2570	-0.25 (-0.67, 0.17); p=0.2482	
	Combinationtherapy (SEL + UDCA)	6/ 120 (5.0)	9/ 61 (14.8)	0.34 (0.13, 0.91); p=0.0315	0.30 (0.10, 0.90); p=0.0313	-0.10 (-0.19, -0.00); p=0.0491	
	Stratification variable: Baseline Pruritus NRS						0.9777
	< 4	4/ 79 (5.1)	7/ 42 (16.7)	0.30 (0.09, 0.98); p=0.0460	0.27 (0.07, 0.97); p=0.0450	-0.12 (-0.24, 0.01); p=0.0637	
	>= 4	2/ 49 (4.1)	3/ 23 (13.0)	0.31 (0.06, 1.75); p=0.1854	0.28 (0.04, 1.83); p=0.1853	-0.09 (-0.24, 0.06); p=0.2365	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on relative risk (alpha=0.05).
RR and OR estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
If overall number of events is less than 1% in either arm and overall Peto Odds Ratio lies within 0.37 - 2.69, p-Value for interaction is calculated from test for heterogeneity of the Peto Odds Ratio in the subgroups using Cochrane`s Q statistic. In all other cases heterogeneity of the Relative Risks is analyzed.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

SOC/PT	Subgroup Level	Seladelpar 10 mg (N=128) n/ N (%)	Placebo (N=65) n/ N (%)	Seladelpar 10 mg vs. Placebo RR (95% CI); p-Value	Seladelpar 10 mg vs. Placebo OR (95% CI); p-Value	Seladelpar 10 mg vs. Placebo RD (95% CI); p-Value	Interaction p-Value
SOC: Skin and subcutaneous tissue disorders, PT: Pruritus	Stratification variable:						
	Baseline ALP Level						0.1954
	< 350 U/L	3/ 93 (3.2)	8/ 47 (17.0)	0.19 (0.05, 0.68); p=0.0109	0.16 (0.04, 0.65); p=0.0098	-0.14 (-0.25, -0.02); p=0.0170	
	>= 350 U/L	3/ 35 (8.6)	2/ 18 (11.1)	0.77 (0.14, 4.21); p=0.7643	0.75 (0.11, 4.95); p=0.7651	-0.03 (-0.20, 0.15); p=0.7726	
	Gamma-GT (GGT)						0.4221
	<= 3 x ULN	1/ 33 (3.0)	3/ 14 (21.4)	0.14 (0.02, 1.24); p=0.0780	0.11 (0.01, 1.22); p=0.0725	-0.18 (-0.41, 0.04); p=0.1055	
	> 3 x ULN	5/ 95 (5.3)	7/ 51 (13.7)	0.38 (0.13, 1.15); p=0.0865	0.35 (0.10, 1.16); p=0.0865	-0.08 (-0.19, 0.02); p=0.1127	
	Total Bilirubin I						NE
	<= 1 x ULN	6/ 108 (5.6)	10/ 60 (16.7)	0.33 (0.13, 0.87); p=0.0252	0.29 (0.10, 0.86); p=0.0246	-0.11 (-0.21, -0.01); p=0.0358	
	> 1 x ULN	0/ 20 (0.0)	0/ 5 (0.0)	NE	NE	NE	
	Total Bilirubin II						
	< 0.6 x ULN	3/ 59 (5.1)	5/ 32 (15.6)				
	>= 0.6 x ULN	3/ 69 (4.3)	5/ 33 (15.2)				

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n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; RR=Relative Risk; OR=Odds Ratio; RD=Risk Difference; NE=Not estimable.

----- NO OBSERVATIONS FOR THIS REPORT -----

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
RR, OR and RD estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
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Gilead Sciences, Inc.
Seladelpar - Study RESPONSE - Last patient last visit: 11Aug2023
RESPONSE - Seladelpar 10 mg vs Placebo
Incidence of Adverse Events leading to discontinuation of study drugs by SOC and PT
Safety

SOC / PT	Seladelpar 10 mg (N=128)	Placebo (N=65)
SOC: Blood and lymphatic system disorders	1/128 (0.8)	0/ 65 (0.0)
SOC: Blood and lymphatic system disorders, PT: Coagulopathy	1/128 (0.8)	0/ 65 (0.0)
SOC: General disorders and administration site conditions	1/128 (0.8)	0/ 65 (0.0)
SOC: General disorders and administration site conditions, PT: Disease progression	1/128 (0.8)	0/ 65 (0.0)
SOC: Hepatobiliary disorders	0/128 (0.0)	1/ 65 (1.5)
SOC: Hepatobiliary disorders, PT: Hyperbilirubinaemia	0/128 (0.0)	1/ 65 (1.5)
SOC: Immune system disorders	0/128 (0.0)	1/ 65 (1.5)
SOC: Immune system disorders, PT: Overlap syndrome	0/128 (0.0)	1/ 65 (1.5)
SOC: Investigations	1/128 (0.8)	0/ 65 (0.0)
SOC: Investigations, PT: Liver function test increased	1/128 (0.8)	0/ 65 (0.0)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1/128 (0.8)	0/ 65 (0.0)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), PT: Papillary thyroid cancer	1/128 (0.8)	0/ 65 (0.0)
SOC: Psychiatric disorders	0/128 (0.0)	1/ 65 (1.5)
SOC: Psychiatric disorders, PT: Suicide attempt	0/128 (0.0)	1/ 65 (1.5)

Analysis based on Treatment-Emergent Adverse Events (TEAEs).