Table 14.1.3.1.1
Demographics and Baseline Characteristics
(ITT Population)

	Placebo (N=122) n (%)	Treatment (N=127) n (%)	Overall (N=249) n (%)
Age (years)			
n	122	127	249
Mean (SD)	49.3 (7.61)	49.0 (7.40)	49.1 (7.49)
SE	0.69	0.66	0.47
Median (Q1, Q3)	49.5 (45.0, 55.0)	50.0 (43.0, 55.0)	50.0 (44.0, 55.0)
Min, Max	30, 60	29, 60	29, 60
< 65 years	122 (100.0)	127 (100.0)	249 (100.0)
20-29 years	0	2 (1.6)	2 (0.8)
30-39 years	15 (12.3)	14 (11.0)	29 (11.6)
40-49 years	46 (37.7)	43 (33.9)	89 (35.7)
50-59 years	56 (45.9)	64 (50.4)	120 (48.2)
60-69 years	5 (4.1)	4 (3.1)	9 (3.6)
Sex, n (%)			
Male	15 (12.3)	10 (7.9)	25 (10.0)
Female	107 (87.7)	117 (92.1)	224 (90.0)
Child-bearing Potential? [1]			
Yes	40 (32.8)	48 (37.8)	88 (35.3)
No	67 (54.9)	69 (54.3)	136 (54.6)

Abbreviations: IP=investigational product, MELD=Model of End-Stage Liver Disease, ALP=alkaline phosphatase, INR=international normalized ratio, GGT=Gamma Glutamyl Transferase, ULN=upper limit of normal, UDCA=ursodeoxycholic acid, SD=standard deviation, SE=standard error, Min=minimum, Max=maximum, USPI= United States Prescribing Information, IWRS=interactive web response system.
Note: Percentages are based on number of subjects in the ITT Population within each treatment group and overall.
Note: A subject can have multiple races and is summarized as Multiple Races.
[1] Childbearing potential is defined as any woman or adolescent who has begun menstruation and hasn't started menopause.
[2] Baseline Body Mass Index (BMI) is calculated as weight (kg)/ (height (m)) ^2.
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Cross References: Listing 16.2.4.1

Table 14.1.3.1.1
Demographics and Baseline Characteristics
(ITT Population)

	Placebo (N=122) n (%)	Treatment (N=127) n (%)	Overall (N=249) n (%)
Race, n (%)			
White	104 (85.2)	109 (85.8)	213 (85.5)
Black or African American	1 (0.8)	1 (0.8)	2 (0.8)
Asian	7 (5.7)	8 (6.3)	15 (6.0)
American Indian or Alaska Native	1 (0.8)	1 (0.8)	2 (0.8)
Multiple Races	1 (0.8)	4 (3.1)	5 (2.0)
Not reported	8 (6.6)	4 (3.1)	12 (4.8)
Ethnicity, n (%)			
Hispanic or Latino	11 (9.0)	21 (16.5)	32 (12.9)
Not Hispanic or Latino	102 (83.6)	101 (79.5)	203 (81.5)
Not Reported	1 (0.8)	0	1 (0.4)
Unknown	1 (0.8)	0	1 (0.4)
Missing	7 (5.7)	5 (3.9)	12 (4.8)
Baseline Height (cm)			
n	122	127	249
Mean (SD)	164.881 (8.361)	163.624 (8.227)	164.240 (8.300)
SE	0.757	0.730	0.526
Median (Q1, Q3)	165.050 (159.000, 170.500)	163.000 (158.000, 168.000)	164.000 (158.000, 170.000)
Min, Max	145.50, 198.12	148.00, 190.50	145.50, 198.12
Baseline Weight (kg)			
n	122	127	249
Mean (SD)	70.193 (18.097)	69.350 (16.472)	69.763 (17.257)
SE	1.638	1.462	1.094
Median (Q1, Q3)	67.525 (58.500, 78.800)	65.920 (58.500, 76.500)	66.000 (58.500, 77.000)
Min, Max	45.50, 159.50	47.90, 156.65	45.50, 159.50

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Cross References: Listing 16.2.4.1

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Table 14.1.3.1.1
Demographics and Baseline Characteristics
(ITT Population)

	Placebo (N=122) n (%)	Treatment (N=127) n (%)	Overall (N=249) n (%)
Baseline BMI (kg/m^2) [2]			
n	122	127	249
Mean (SD)	25.72 (5.894)	25.92 (5.824)	25.82 (5.848)
SE	0.534	0.517	0.371
Median (Q1, Q3)	24.15 (22.00, 28.10)	24.50 (22.10, 28.00)	24.50 (22.10, 28.00)
Min, Max	17.4, 56.5	15.5, 52.5	15.5, 56.5
< 30 kg/m^2	99 (81.1)	103 (81.1)	202 (81.1)
>= 30 kg/m^2	23 (18.9)	24 (18.9)	47 (18.9)
Baseline Rotterdam Criteria			
Early	39 (32.0)	49 (38.6)	88 (35.3)
Moderate	78 (63.9)	72 (56.7)	150 (60.2)
Advanced	5 (4.1)	6 (4.7)	11 (4.4)
Baseline Child-Pugh Score			
n	118	126	244
Mean (SD)	5.6 (0.89)	5.5 (0.76)	5.5 (0.82)
SE	0.08	0.07	0.05
Median (Q1, Q3)	5.0 (5.0, 6.0)	5.0 (5.0, 6.0)	5.0 (5.0, 6.0)
Min, Max	5, 9	5, 8	5, 9
Baseline Child-Pugh Class, n (%)			
A	96 (78.7)	111 (87.4)	207 (83.1)
B	22 (18.0)	15 (11.8)	37 (14.9)
Not Evaluated	1 (0.8)	0	1 (0.4)
Missing	3 (2.5)	1 (0.8)	4 (1.6)

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Cross References: Listing 16.2.4.1

Table 14.1.3.1.1
Demographics and Baseline Characteristics
(ITT Population)

	Placebo (N=122) n (%)	Treatment (N=127) n (%)	Overall (N=249) n (%)
Baseline MELD Score			
n	122	127	249
Mean (SD)	8.64 (1.817)	8.30 (1.750)	8.47 (1.788)
SE	0.165	0.155	0.113
Median (Q1, Q3)	8.40 (6.90, 10.10)	8.10 (6.40, 9.40)	8.20 (6.60, 9.70)
Min, Max	6.4, 12.7	6.4, 13.3	6.4, 13.3
Baseline MELD-Na Score			
n	122	127	249
Mean (SD)	9.15 (2.122)	8.92 (2.389)	9.03 (2.261)
SE	0.192	0.212	0.143
Median (Q1, Q3)	9.00 (7.20, 10.90)	8.70 (6.80, 10.30)	8.80 (7.00, 10.30)
Min, Max	6.4, 13.6	6.4, 17.7	6.4, 17.7
Baseline Alkaline Phosphate (ALP) (U/L)			
n	122	127	249
Mean (SD)	541.8 (293.29)	522.7 (282.55)	532.1 (287.44)
SE	26.55	25.07	18.22
Median (Q1, Q3)	489.0 (300.0, 714.0)	498.0 (314.0, 669.0)	490.0 (307.0, 706.0)
Min, Max	149, 1526	78, 1337	78, 1526
Baseline Creatinine (umol/L)			
n	111	113	224
Mean (SD)	62.089 (13.254)	61.657 (13.004)	61.871 (13.101)
SE	1.258	1.223	0.875
Median (Q1, Q3)	59.000 (52.450, 69.330)	58.050 (53.000, 68.670)	58.670 (52.875, 69.000)
Min, Max	42.33, 115.00	41.33, 114.33	41.33, 115.00

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Table 14.1.3.1.1
Demographics and Baseline Characteristics
(ITT Population)

	Placebo (N=122) n (%)	Treatment (N=127) n (%)	Overall (N=249) n (%)
Baseline Creatinine (mg/dL)			
n	111	113	224
Mean (SD)	0.703 (0.150)	0.698 (0.147)	0.700 (0.148)
SE	0.014	0.014	0.010
Median (Q1, Q3)	0.670 (0.590, 0.780)	0.660 (0.600, 0.780)	0.660 (0.600, 0.780)
Min, Max	0.48, 1.30	0.47, 1.29	0.47, 1.30
Baseline INR (RATIO)			
n	122	127	249
Mean (SD)	0.98 (0.116)	0.97 (0.116)	0.98 (0.116)
SE	0.011	0.010	0.007
Median (Q1, Q3)	1.00 (0.90, 1.00)	0.90 (0.90, 1.00)	0.90 (0.90, 1.00)
Min, Max	0.8, 1.4	0.8, 1.7	0.8, 1.7
Baseline Platelets (10^9/L)			
n	119	127	246
Mean (SD)	209.3 (98.57)	221.5 (97.57)	215.6 (98.05)
SE	9.04	8.66	6.25
Median (Q1, Q3)	201.0 (142.0, 267.0)	219.0 (149.0, 291.0)	212.0 (142.0, 282.0)
Min, Max	31, 581	43, 537	31, 581
Baseline Albumin (g/L)			
n	122	127	249
Mean (SD)	40.32 (3.777)	40.45 (3.799)	40.39 (3.781)
SE	0.342	0.337	0.240
Median (Q1, Q3)	40.90 (38.30, 43.00)	40.70 (38.70, 43.00)	40.80 (38.70, 43.00)
Min, Max	27.3, 46.0	26.7, 49.3	26.7, 49.3

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Demographics and Baseline Characteristics
(ITT Population)

	Placebo (N=122) n (%)	Treatment (N=127) n (%)	Overall (N=249) n (%)
Baseline GGT (U/L)			
n	122	127	249
Mean (SD)	469.3 (392.49)	458.5 (388.68)	463.8 (389.80)
SE	35.53	34.49	24.70
Median (Q1, Q3)	375.0 (210.0, 596.0)	341.0 (212.0, 570.0)	373.0 (212.0, 580.0)
Min, Max	35, 2622	25, 2413	25, 2622
Baseline Total Bilirubin (umol/L)			
n	122	127	249
Mean (SD)	28.63 (14.141)	25.93 (13.235)	27.25 (13.726)
SE	1.280	1.174	0.870
Median (Q1, Q3)	26.30 (18.30, 37.00)	25.00 (14.00, 35.00)	25.70 (15.70, 35.30)
Min, Max	3.7, 61.5	6.3, 68.8	3.7, 68.8
Baseline Total Bilirubin (mg/dL)			
n	122	127	249
Mean (SD)	1.67 (0.828)	1.52 (0.780)	1.60 (0.806)
SE	0.075	0.069	0.051
Median (Q1, Q3)	1.50 (1.10, 2.20)	1.50 (0.80, 2.10)	1.50 (0.90, 2.10)
Min, Max	0.2, 3.6	0.4, 4.1	0.2, 4.1
> ULN	85 (69.7)	81 (63.8)	166 (66.7)
<= ULN	37 (30.3)	46 (36.2)	83 (33.3)
Use of UDCA, n (%)			
Current or Previous	121 (99.2)	124 (97.6)	245 (98.4)
Never	1 (0.8)	3 (2.4)	4 (1.6)

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Demographics and Baseline Characteristics
(ITT Population)

	Placebo (N=122) n (%)	Treatment (N=127) n (%)	Overall (N=249) n (%)
Randomization Strata Factor as entered in the IWRS, n (%)			
UDCA use, bilirubin <= ULN	33 (27.0)	38 (29.9)	71 (28.5)
UDCA use, bilirubin > ULN	78 (63.9)	76 (59.8)	154 (61.8)
No UDCA use, bilirubin <= ULN	4 (3.3)	8 (6.3)	12 (4.8)
No UDCA use, bilirubin > ULN	7 (5.7)	5 (3.9)	12 (4.8)
Baseline Disease Stage 1, n (%) [3]			
On-label per USPI	54 (44.3)	68 (53.5)	122 (49.0)
Contraindicated per USPI	68 (55.7)	59 (46.5)	127 (51.0)
Baseline Disease Stage 2, n (%) [4]			
Compensated	97 (79.5)	107 (84.3)	204 (81.9)
Decompensated	25 (20.5)	20 (15.7)	45 (18.1)

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