Table 3
Shifts in Liver Biochemical Tests Based on Thresholds
<Analysis Set>

Maximum Post-Baseline Result

Maximum Baseline Value	< 3x ULN	>= 3 to < 5x ULN	>= 5 to < 10x ULN	>= 10 to < 20x ULN	>= 20x ULN	Missing
ALT						
PL (N=355)						
< 3x ULN	0	0	0	10 (0.7%)	6 (1.4%)	0
>= 3 to < 5x ULN	0	0	2 (0.2%)	7 (0.5%)	0	0
>= 5 to < 10x ULN	1 (0.1%)	0	3 (0.3%)	40 (2.6%)	19 (4.3%)	0
>= 10 to < 20x ULN	0	0	11 (1.2%)	116 (7.6%)	70 (15.9%)	0
>= 20x ULN	0	1 (0.2%)	4 (0.5%)	40 (2.6%)	25 (5.7%)	0
Missing	0	0	0	0	0	0
T1 (N=318)						
< 3x ULN	0	1 (0.2%)	1 (0.1%)	5 (0.3%)	7 (1.6%)	0
>= 3 to < 5x ULN	0	0	0	5 (0.3%)	3 (0.7%)	0
>= 5 to < 10x ULN	0	0	3 (0.3%)	32 (2.1%)	18 (4.1%)	0
>= 10 to < 20x ULN	0	0	6 (0.7%)	98 (6.4%)	79 (18.0%)	0
>= 20x ULN	0	1 (0.2%)	3 (0.3%)	36 (2.4%)	20 (4.5%)	0
Missing	0	0	0	0	0	0
T2 (N=326)						
< 3x ULN	0	0	0	9 (0.6%)	2 (0.5%)	0
>= 3 to < 5x ULN	0	0	0	10 (0.7%)	1 (0.2%)	0
>= 5 to < 10x ULN	0	0	3 (0.3%)	30 (2.0%)	17 (3.9%)	0
>= 10 to < 20x ULN	0	1 (0.2%)	10 (1.1%)	118 (7.7%)	61 (13.9%)	0
>= 20x ULN	0	0	2 (0.2%)	36 (2.4%)	26 (5.9%)	0
Missing	0	0	0	0	0	0
AST						
PL (N=355)						
< 3x ULN	0	0	3 (0.3%)	6 (0.4%)	0	0
>= 3 to < 5x ULN	0	0	0	8 (0.5%)	0	0
>= 5 to < 10x ULN	0	0	9 (1.0%)	65 (4.3%)	10 (2.3%)	0
>= 10 to < 20x ULN	0	0	25 (2.8%)	193 (12.7%)	19 (4.3%)	0
>= 20x ULN	0	0	2 (0.2%)	13 (0.9%)	2 (0.5%)	0

PL=Placebo, T1=Treatment 1, T2=Treatment 2, ALT=alanine aminotransferase, AST=aspartate aminotransferase, ALP=alkaline phosphatase;
N=number of applicable subjects in treatment arm; n=actual applicable observed number with values.

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Maximum Baseline Value	< 3x ULN	>= 3 to < 5x ULN	>= 5 to < 10x ULN	>= 10 to < 20x ULN	>= 20x ULN	Missing
AST						
PL (N=355)						
Missing	0	0	0	0	0	0
T1 (N=318)						
< 3x ULN	0	0	0	5 (0.3%)	1 (0.2%)	0
>= 3 to < 5x ULN	0	0	2 (0.2%)	9 (0.6%)	0	0
>= 5 to < 10x ULN	0	0	9 (1.0%)	60 (3.9%)	2 (0.5%)	0
>= 10 to < 20x ULN	0	0	15 (1.7%)	184 (12.1%)	19 (4.3%)	0
>= 20x ULN	0	0	1 (0.1%)	8 (0.5%)	3 (0.7%)	0
Missing	0	0	0	0	0	0
T2 (N=326)						
< 3x ULN	0	0	0	7 (0.5%)	2 (0.5%)	0
>= 3 to < 5x ULN	0	0	0	10 (0.7%)	0	0
>= 5 to < 10x ULN	0	0	10 (1.1%)	62 (4.1%)	9 (2.0%)	0
>= 10 to < 20x ULN	0	1 (0.2%)	21 (2.4%)	172 (11.3%)	15 (3.4%)	0
>= 20x ULN	0	0	0	13 (0.9%)	4 (0.9%)	0
Missing	0	0	0	0	0	0
Total Bilirubin						
PL (N=355)						
< 3x ULN	0	6 (1.3%)	32 (3.6%)	6 (0.4%)	0	0
>= 3 to < 5x ULN	3 (0.4%)	4 (0.9%)	66 (7.5%)	11 (0.7%)	0	0
>= 5 to < 10x ULN	7 (1.0%)	30 (6.7%)	140 (15.9%)	26 (1.7%)	0	0
>= 10 to < 20x ULN	0	2 (0.4%)	20 (2.3%)	2 (0.1%)	0	0
>= 20x ULN	0	0	0	0	0	0
Missing	0	0	0	0	0	0
T1 (N=318)						
< 3x ULN	1 (0.1%)	5 (1.1%)	30 (3.4%)	4 (0.3%)	0	0
>= 3 to < 5x ULN	1 (0.1%)	9 (2.0%)	54 (6.1%)	5 (0.3%)	0	0
>= 5 to < 10x ULN	3 (0.4%)	25 (5.6%)	142 (16.1%)	23 (1.5%)	0	0

PL=Placebo, T1=Treatment 1, T2=Treatment 2, ALT=alanine aminotransferase, AST=aspartate aminotransferase, ALP=alkaline phosphatase;
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Maximum Post-Baseline Result

Maximum Baseline Value	< 3x ULN	>= 3 to < 5x ULN	>= 5 to < 10x ULN	>= 10 to < 20x ULN	>= 20x ULN	Missing
Total Bilirubin						
T1 (N=318)						
>= 10 to < 20x ULN	0	2 (0.4%)	13 (1.5%)	1 (0.1%)	0	0
>= 20x ULN	0	0	0	0	0	0
Missing	0	0	0	0	0	0
T2 (N=326)						
< 3x ULN	0	6 (1.3%)	28 (3.2%)	8 (0.5%)	0	0
>= 3 to < 5x ULN	2 (0.3%)	5 (1.1%)	64 (7.2%)	8 (0.5%)	0	0
>= 5 to < 10x ULN	2 (0.3%)	30 (6.7%)	138 (15.6%)	23 (1.5%)	0	0
>= 10 to < 20x ULN	0	3 (0.7%)	8 (0.9%)	1 (0.1%)	0	0
>= 20x ULN	0	0	0	0	0	0
Missing	0	0	0	0	0	0
ALP						
PL (N=355)						
< 3x ULN	187 (26.6%)	99 (22.2%)	2 (0.2%)	0	0	0
>= 3 to < 5x ULN	45 (6.4%)	22 (4.9%)	0	0	0	0
>= 5 to < 10x ULN	0	0	0	0	0	0
>= 10 to < 20x ULN	0	0	0	0	0	0
>= 20x ULN	0	0	0	0	0	0
Missing	0	0	0	0	0	0
T1 (N=318)						
< 3x ULN	178 (25.3%)	87 (19.6%)	0	0	0	0
>= 3 to < 5x ULN	33 (4.7%)	19 (4.3%)	0	0	0	0
>= 5 to < 10x ULN	1 (0.1%)	0	0	0	0	0
>= 10 to < 20x ULN	0	0	0	0	0	0
>= 20x ULN	0	0	0	0	0	0
Missing	0	0	0	0	0	0
T2 (N=326)						
< 3x ULN	193 (27.5%)	71 (16.0%)	1 (0.1%)	0	0	0

PL=Placebo, T1=Treatment 1, T2=Treatment 2, ALT=alanine aminotransferase, AST=aspartate aminotransferase, ALP=alkaline phosphatase;
N=number of applicable subjects in treatment arm; n=actual applicable observed number with values.

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Maximum Baseline Value	< 3x ULN	>= 3 to < 5x ULN	>= 5 to < 10x ULN	>= 10 to < 20x ULN	>= 20x ULN	Missing
ALP						
T2 (N=326)						
>= 3 to < 5x ULN	46 (6.5%)	15 (3.4%)	0	0	0	0
>= 5 to < 10x ULN	0	0	0	0	0	0
>= 10 to < 20x ULN	0	0	0	0	0	0
>= 20x ULN	0	0	0	0	0	0
Missing	0	0	0	0	0	0

PL=Placebo, T1=Treatment 1, T2=Treatment 2, ALT=alanine aminotransferase, AST=aspartate aminotransferase, ALP=alkaline phosphatase;
N=number of applicable subjects in treatment arm; n=actual applicable observed number with values.