

Table 2  
Elevations in Liver Biochemical Tests Based on Thresholds  
<Analysis Set>

	PL n/N (%) (N=355)	T1 n/N (%) (N=318)	T2 n/N (%) (N=326)	Risk Difference T1-PL (95% CI) (N=673)	Risk Difference T2-PL (95% CI) (N=681)	Risk Difference T2-T1 (95% CI) (N=644)
ALT						
> 3x ULN	9/355 (2.5%)	8/318 (2.5%)	11/326 (3.4%)	-0.0 (-2.4 - 2.4)	0.8 (-1.7 - 3.4)	0.9 (-1.8 - 3.5)
> 5x ULN	63/355 (17.7%)	53/318 (16.7%)	50/326 (15.3%)	-1.1 (-6.8 - 4.6)	-2.4 (-8.0 - 3.2)	-1.3 (-7.0 - 4.3)
> 10x ULN	197/355 (55.5%)	183/318 (57.5%)	190/326 (58.3%)	2.1 (-5.4 - 9.6)	2.8 (-4.7 - 10.2)	0.7 (-6.9 - 8.4)
> 20x ULN	70/355 (19.7%)	60/318 (18.9%)	64/326 (19.6%)	-0.9 (-6.8 - 5.1)	-0.1 (-6.1 - 5.9)	0.8 (-5.3 - 6.9)
AST						
> 3x ULN	12/355 (3.4%)	11/318 (3.5%)	16/326 (4.9%)	0.1 (-2.7 - 2.8)	1.5 (-1.5 - 4.5)	1.4 (-1.6 - 4.5)
> 5x ULN	93/355 (26.2%)	78/318 (24.5%)	89/326 (27.3%)	-1.7 (-8.2 - 4.9)	1.1 (-5.6 - 7.8)	2.8 (-4.0 - 9.5)
> 10x ULN	236/355 (66.5%)	210/318 (66%)	208/326 (63.8%)	-0.4 (-7.6 - 6.7)	-2.7 (-9.8 - 4.5)	-2.2 (-9.6 - 5.1)
> 20x ULN	10/355 (2.8%)	15/318 (4.7%)	9/326 (2.8%)	1.9 (-1.0 - 4.8)	-0.1 (-2.5 - 2.4)	-2.0 (-4.9 - 1.0)
Total Bilirubin						
> 2x ULN	117/355 (33%)	81/318 (25.5%)	92/326 (28.2%)	-7.5 (-14.3 - -0.6)	-4.7 (-11.6 - 2.2)	2.7 (-4.1 - 9.6)
> 5x ULN	150/355 (42.3%)	154/318 (48.4%)	141/326 (43.3%)	6.2 (-1.3 - 13.7)	1.0 (-6.4 - 8.4)	-5.2 (-12.9 - 2.5)
> 8x ULN	63/355 (17.7%)	63/318 (19.8%)	71/326 (21.8%)	2.1 (-3.9 - 8.0)	4.0 (-2.0 - 10.0)	2.0 (-4.3 - 8.2)
ALP						
> 2x ULN	123/355 (34.6%)	120/318 (37.7%)	125/326 (38.3%)	3.1 (-4.2 - 10.4)	3.7 (-3.5 - 10.9)	0.6 (-6.9 - 8.1)
> 3x ULN	63/355 (17.7%)	57/318 (17.9%)	47/326 (14.4%)	0.2 (-5.6 - 6.0)	-3.3 (-8.8 - 2.2)	-3.5 (-9.2 - 2.2)
ALT or AST and Total Bilirubin						
ALT > 3x ULN and Total Bilirubin > 2x ULN	314/355 (88.5%)	285/318 (89.6%)	293/326 (89.9%)	1.2 (-3.5 - 5.9)	1.4 (-3.2 - 6.1)	0.3 (-4.4 - 4.9)
AST > 3x ULN and Total Bilirubin > 2x ULN	326/355 (91.8%)	294/318 (92.5%)	301/326 (92.3%)	0.6 (-3.4 - 4.7)	0.5 (-3.6 - 4.6)	-0.1 (-4.2 - 4.0)
ALT or AST > 3x ULN and Total Bilirubin > 2x ULN	330/355 (93%)	298/318 (93.7%)	304/326 (93.3%)	0.8 (-3.0 - 4.5)	0.3 (-3.5 - 4.1)	-0.5 (-4.3 - 3.4)

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.