

Table 1
 Overview of Reported Potential Liver Safety Findings
 <Analysis Set>

	PL	T1	T2	Risk Difference T1-PL (95% CI) (N=1790)	Risk Difference T2-PL (95% CI) (N=1801)	Risk Difference T2-T1 (95% CI) (N=1823)
	n/N(%) (N=884)	n/N(%) (N=906)	n/N(%) (N=917)			
Number of Subjects with Liver Safety Findings(a)						
Any Potential Liver Safety Findings	452/884 (51.1%)	427/906 (47.1%)	435/917 (47.4%)	-4.0 (-8.6 - 0.6)	-3.7 (-8.3 - 0.9)	0.3 (-4.3 - 4.9)
Findings Related to Adverse Events	279/884 (31.6%)	261/906 (28.8%)	288/917 (31.4%)	-2.8 (-7.0 - 1.5)	-0.2 (-4.4 - 4.1)	2.6 (-1.6 - 6.8)
Findings Related to Biochemical Tests	271/884 (30.7%)	264/906 (29.1%)	261/917 (28.5%)	-1.5 (-5.8 - 2.7)	-2.2 (-6.4 - 2.0)	-0.7 (-4.8 - 3.5)
Findings Related to Both Adverse Events and Biochemical Tests	49/884 (5.5%)	49/906 (5.4%)	57/917 (6.2%)	-0.1 (-2.2 - 2.0)	0.7 (-1.5 - 2.8)	0.8 (-1.3 - 3.0)

PL=Placebo, T1=Treatment 1, T2=Treatment 2

Note (a): A potential liver safety finding is defined as meeting any of the laboratory thresholds.

N = number of applicable subjects in treatment arm; n = actual applicable observed number with values.