

Table 4

Summary of Treatment Emergent Adverse Events of Adverse Events Meeting the Liver Safety SMQ (or FMQ)

<Analysis Set>

Preferred Term	T1 n/N (%) (N=356)	PL n/N (%) (N=309)	T2 n/N (%) (N=334)	Risk Difference T1-PL (95% CI) (N=665)	Risk Difference T2-PL (95% CI) (N=643)	Risk Difference T2-T1 (95% CI) (N=690)
Number of patients reporting at least one Narrow or Broad Scope PT	247 (69.4%)	196 (63.4%)	226 (67.7%)	6.0 (-1.2 - 13.1)	4.2 (-3.1 - 11.6)	-1.7 (-8.7 - 5.2)
Narrow Scope PTs						
Hepatic failure, fibrosis, and cirrhosis and other liver damage-related conditions	44 (12.4%)	37 (12.0%)	27 (8.1%)	0.4 (-4.6 - 5.4)	-3.9 (-8.5 - 0.8)	-4.3 (-8.8 - 0.2)
Hepatitis, non-infectious	70 (19.7%)	42 (13.6%)	62 (18.6%)	6.1 (0.4 - 11.7)	5.0 (-0.7 - 10.6)	-1.1 (-7.0 - 4.8)
Liver neoplasms, benign (incl cysts and polyps)	65 (18.3%)	42 (13.6%)	68 (20.4%)	4.7 (-0.9 - 10.2)	6.8 (1.0 - 12.5)	2.1 (-3.8 - 8.0)
Liver neoplasms, malignant and unspecified	85 (23.9%)	75 (24.3%)	103 (30.8%)	-0.4 (-6.9 - 6.1)	6.6 (-0.3 - 13.4)	7.0 (0.3 - 13.6)

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