

CATARACT

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Repatha (evolocumab)

Table 94: Adverse Events by Achieved LDL-C Subgroup in One-Year Extension Trials

	LDL-C < 25 mg/dL	LDL-C <40 mg/dL	LDL C ≥ 40 mg/dL			
Year 1 SoC-controlled Period						
N	EvoMab+ SoC: N=666	SoC alone: N=4	EvoMab +SoC: N=1369	SoC alone: N=12	EvoMab +SoC: N=1427	SoC alone: N=1380
Median exposure, months	8.3		8.2		7.2	7.4
All AEs	394 (59.2%)	0%	814 (59.5%)	4 (33.3%)	882 (61.8%)	774 (56.1%)
SAEs	34 (5.1%)	0 (0%)	68 (5.0%)	0 (0%)	85 (6.0%)	80 (5.8%)
Most common AEs (EvoMab+SoC and SoC alone)						
nasopharyngitis	10.2%	0%	9.2%	8.3%	8.1%	8.0%
upper respiratory tract infection	4.4%	0%	3.9%	0%	4.6%	4.1%
back pain	4.2%	0%	3.7%	0%	2.7%	2.5%
arthralgia	3.8%	0%	4.2%	0%	2.7%	2.6%
hypertension	3.5%	0%	3.7%	0%	2.7%	2.8%
diarrhoea	3.3%	0%	2.6%	0%	2.0%	1.5%
cough	3.3%	0%	2.5%	0%	2.5%	2.8%
influenza	2.0%	0%	2.2%	0%	3.8%	2.7%
headache	2.7%	0%	2.7%	0%	3.2%	1.7%
Other AEs of interest (EvoMab+SoC and SoC alone)						
Diabetes	11, 1.7%	0%	20, 1.5%	0%	9, 0.6%	5, 0.4%
Type 2 DM	4, 0.6%	0%	5, 0.4%	0%	8, 0.6%	5, 0.4%
Hyperglycaemia	4, 0.6%	0%	6, 0.4%	0%	1, 0.1%	3, 0.2%
Eye Disorders SOC	15, 2.3%	0%	42, 3.1%	0%	35, 2.5%	28, 2.0%
Cataract	4, 0.6%	0%	11, 0.8%	0%	11, 0.8%	11, 0.8%
Dry Eye	3, 0.5%	0%	8, 0.6%	0%	3, 0.2%	0%
Conjunctivitis allergic	1, 0.2%	0%	4, 0.3%	0%	2, 0.1%	0%
Asthenopia	1, 0.2%	0%	1, 0.1	0%	0%	0%
Select Nervous System Disorders AEs						
amnesia	1, 0.2%	0, 0%	2, 0.1%	0, 0%	0, 0%	1, 0.1%
memory impairment	0	0	4, 0.3%	0	0	0
mental impairment	0	0	1, 0.1%	0	1, 0.1%	0
Select Psychiatric Disorders AEs						
disorientation	0	0	1, 0.1%	0	0	0

Source: Summary of Clinical Safety, Appendix Table 7, ISS Tables 14-6.3.113, 14-6.3.119 and 14-6.3.125