Objective: To assess the safety of alirocumab versus control (placebo/ezetimibe) in people with hypercholesterolemia with Type 1 or Type 2 diabetes mellitus (DM) versus those without DM

14 Phase 2 and Phase 3 trials of treatment duration ranging 8–104 weeks

Four Phase 2 studies (n=260)
DFI11565, DFI11566, CL-1003, and DFI12361

10 Phase 3 ODYSSEY studies (n=4974)

LONG TERM

HIGH FH

FH I
FH II
COMBO I
COMBO II
OPTIONS I
OPTIONS II
MONO
ALTERNATIVE

ALIROCUMAB

150 mg Q2W

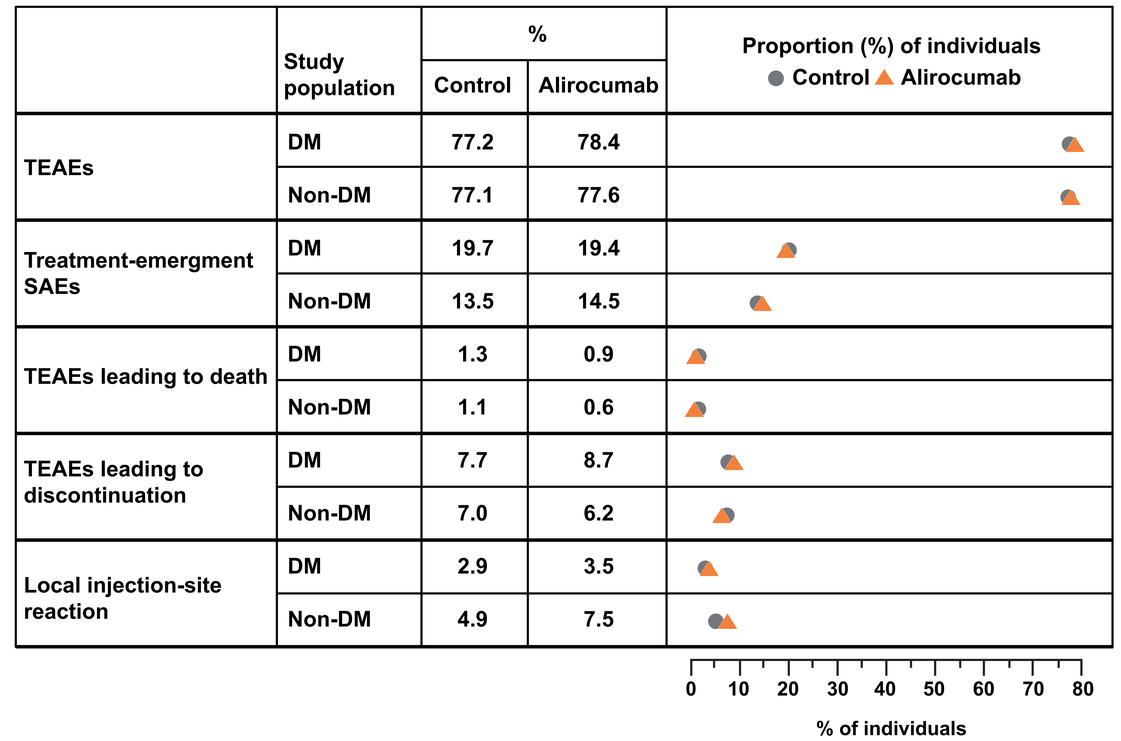
OR

75 mg Q2W

150 mg Q2W

Dose adjustment per study protocol

	Study population	%	
		Control	Alirocumab
TEAEs	DM	77.2	78.4
	Non-DM	77.1	77.6
Treatment-emergment SAEs	DM	19.7	19.4
	Non-DM	13.5	14.5
TEAEs leading to death	DM	1.3	0.9
	Non-DM	1.1	0.6
TEAEs leading to discontinuation	DM	7.7	8.7
	Non-DM	7.0	6.2
Local injection-site reaction	DM	2.9	3.5
	Non-DM	4.9	7.5



Safety of alirocumab was comparable with control, except for a higher frequency of local injection-site reactions observed with alirocumab versus control, regardless of DM status. No clinically significant changes in glycemic parameters were observed

People with DM reported fewer local injection-site reactions than those without. The majority of local injection-site reactions were mild in nature in people with and without DM

These safety results are consistent with prior findings in the overall ODYSSEY study population

5234 people with hypercholesterolemia ▶ **1554** people with DM ▶ **1524** people with Type 2 DM and **28** people with Type 1 DM (two people with unknown DM status)