Results Registration Form

Point of Contact

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Certain Agreements

Principal Investigators are NOT employed by the organization sponsoring the study.

There IS an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

None Selected

Participant Flow

Recruitment Details	This study was conducted at a total of 66 study centres in 8 countries: Czech Republic (10 centres), Denmark (8 centres), Hungary (4 centres), Netherlands (6 centres), Poland (8 centres), Slovakia (7 centres), Spain (7 centres), and United States (16 centres). First subject enrolled: 07 July 2021 and Last subject last visit: 15 July 2022.
Pre-assignment Details	

Type of Units Assigned:

Period: Overall Study

	AZD8233 AZD8233 for subcutaneous use.	**Placebo** Matching placebo solution for subcutaneous injection.	**Total** *(=sum per row)*
Started	Participants 206	Participants 205	411 *(calculated)*
Completed	Participants 196	Participants 201	397 *(calculated)*
Not Completed: *(=Started - Completed)*	10 *(calculated)*	4 *(calculated)*	14 *(calculated)*
Reason for Not Completed			
Total: *(=sum per column)*	10 *(calculated)*	4 *(calculated)*	14 *(calculated)*
Withdrawal by Subject	3	2	5 *(calculated)*
Lost to Follow-up	1	2	3 *(calculated)*
Physician Decision	2	0	2 *(calculated)*
Death	3	0	3 *(calculated)*
Other **Reported by investigator as completed but did not fulfil the Completed study definition.**	1	0	1 *(calculated)*

Baseline Characteristics

Overall Number of Baseline Participants			
	AZD8233 AZD8233 for subcutaneous use.	**Placebo** Matching placebo solution for subcutaneous injection.	**Total(=sum across Arm/Groups)**
Overall Number of Baseline Participants	206	205	411 *(calculated)*
Overall Number Of Units Analyzed **Type Of Units Analyzed**:			Unknown *(calculated)*
Baseline Analysis Population Description	Baseline analysis population is based on the Full analysis set (FAS) which includes all subjects who were randomly assigned to study intervention. Subjects were analysed according to their randomised study medication assignment, irrespective of the treatment actually received. Number Started in the Participant Flow is the number of subjects who were randomised.		

Baseline measure title = "Sex: Female, Male"				
Sex: Female, Male *Units:* Participants *Parameter type:* Number *Dispersion type:* Not Applicable				
Row	Category	**AZD8233** AZD8233 for subcutaneous use.	**Placebo** Matching placebo solution for subcutaneous injection.	**Total** *(=sum per row)*
Female	Number Analyzed:	206 Participants	205 Participants	411 *(calculated)* Participants

		101	94	195 *(calculated)*
Male	Number Analyzed:	206 Participants	205 Participants	411 *(calculated)* Participants
		105	111	216 *(calculated)*

Baseline measure title = "Race (NIH/OMB)"

Race (NIH/OMB)
Units: Participants
Parameter type: Number
Dispersion type: Not Applicable

Row	Category	**AZD8233** AZD8233 for subcutaneous use.	**Placebo** Matching placebo solution for subcutaneous injection.	**Total** *(=sum per row)*
American Indian or Alaska Native	Number Analyzed:	206 Participants	205 Participants	411 *(calculated)* Participants
		1	0	1 *(calculated)*
Asian	Number Analyzed:	206 Participants	205 Participants	411 *(calculated)* Participants
		2	2	4 *(calculated)*
Black or African American	Number Analyzed:	206 Participants	205 Participants	411 *(calculated)* Participants
		9	3	12 *(calculated)*
Native Hawaiian or other Pacific Islander	Number Analyzed:	206 Participants	205 Participants	411 *(calculated)* Participants
		0	1	1 *(calculated)*
White	Number Analyzed:	206 Participants	205 Participants	411 *(calculated)* Participants
		194	199	393 *(calculated)*

Baseline measure title = "Region of Enrollment"

Region of Enrollment
Units: Participants
Measure Analysis Population Description: The table contains all subjects randomized (Full analysis set)
Parameter type: Number
Dispersion type: Not Applicable

Row	Category	**AZD8233** AZD8233 for subcutaneous use.	**Placebo** Matching placebo solution for subcutaneous injection.	**Total** *(=sum per row)*
USA	Number Analyzed:	206 Participants	205 Participants	411 *(calculated)* Participants
		48	39	87 *(calculated)*
Czech Republic	Number Analyzed:	206 Participants	205 Participants	411 *(calculated)* Participants
		45	44	89 *(calculated)*
Denmark	Number Analyzed:	206 Participants	205 Participants	411 *(calculated)* Participants
		31	21	52 *(calculated)*
Hungary	Number Analyzed:	206 Participants	205 Participants	411 *(calculated)* Participants
		15	14	29 *(calculated)*
Netherlands	Number Analyzed:	206 Participants	205 Participants	411 *(calculated)* Participants

		12	7	19 *(calculated)*
Poland	Number Analyzed:	206 Participants	205 Participants	411 *(calculated)* Participants
		4	10	14 *(calculated)*
Slovakia	Number Analyzed:	206 Participants	205 Participants	411 *(calculated)* Participants
		35	43	78 *(calculated)*
Spain	Number Analyzed:	206 Participants	205 Participants	411 *(calculated)* Participants
		16	27	43 *(calculated)*

Baseline measure title = "Study Specific Characteristic"

Study Specific Characteristic
LDL-C
Units: mg/dL
Description: Baseline LDL-C
Parameter type: Mean
Dispersion type: Standard Deviation

Row	Category	**AZD8233** AZD8233 for subcutaneous use.	**Placebo** Matching placebo solution for subcutaneous injection.	**Total**
	Number Analyzed:	206 Participants	205 Participants	411 *(calculated)* Participants
		103 (31.8)	107.4 (31.9)	105.2 (31.9)

Baseline measure title = "Age Continuous"

Age Continuous
Units: Years
Parameter type: Mean
Dispersion type: Standard Deviation

Row	Category	**AZD8233** AZD8233 for subcutaneous use.	**Placebo** Matching placebo solution for subcutaneous injection.	**Total**
	Number Analyzed:	206 Participants	205 Participants	411 *(calculated)* Participants
		62.4 (8.1)	62.2 (7.7)	62.3 (7.9)

Outcome Measures

Expand All

ALERT: Outcome measures from protocol are not used when records include results.

1. Primary: Percentage change from baseline on serum LDL-C

Reporting Status:

Description: Percentage change in Low-density Lipoprotein Cholesterol (LDL-C) from baseline to Day 197.

Time Frame: From baseline to Day 197

Safety Issue:

Measure Type: Least Squares Mean

Method of Dispersion: 95% Confidence Interval

Unit of Measure: Relative change from baseline in LDL-C %

Type of Units Analyzed: Continuous

Analysis Population Description: Full analysis set includes all subjects who were randomly assigned to study intervention. Subjects were analysed according to their randomised study medication assignment, irrespective of the treatment actually received.

		AZD8233 AZD8233 for subcutaneous use.		**Placebo** Matching placebo solution for subcutaneous injection.	
	Number of Participants Analyzed:	206		205	
	Number of Continuous Analyzed:	206		205	
Percentage change from baseline on serum LDL-C Units: Relative change from baseline in LDL-C %	Category	Least Squares Mean	95% Confidence Interval	Least Squares Mean	95% Confidence Interval
	Number Analyzed: NOTE: Number Analyzed row will not be displayed in PRS when single Measure Row.	-- Continuous 206 Participants		-- Continuous 205 Participants	
		-56.7	-60.8 to -52.7	5.6	1.5 to 9.6

Statistical Analysis		
Groups	AZD8233, Placebo	
Type of Statistical Test	Superiority	
P Value	<0.001	
Method	ANCOVA	
Mean Difference (Final Values)	-62.3	
95% Confidence Interval 2-Sided	-68 to -56.6	
Other Analysis		

2. Primary: Number of subjects with adverse events (AEs)

Reporting Status:

Description: Please refer to the adverse event module for specifics.

Time Frame: On-study period

Safety Issue:

Measure Type: Count of Participants

Method of Dispersion: Not Applicable

Unit of Measure: Participants

Type of Units Analyzed:

Analysis Population Description: The safety analysis set consists of all subjects who have received at least one dose of investigational product. Erroneously treated subjects (e.g., those randomised to treatment A but actually given treatment B) are accounted for in the treatment group of the treatment they actually received.

		AZD8233 AZD8233 for subcutaneous use.	**Placebo** Matching placebo solution for subcutaneous injection.
	Number of Participants Analyzed:	207	203
Number of subjects with adverse events (AEs) Units: Participants	Category	Count of Participants	Count of Participants
	Number Analyzed:	207 Participants	203 Participants
	Any AE	141 (68.12%)	127 (62.56%)

3. Primary: Vital signs - Temperature

Reporting Status:

Description: Mean and standard deviation of Temperature at each scheduled visit by treatment.

Time Frame: Baseline to Day 281

Safety Issue:

Measure Type: Mean

Method of Dispersion: Standard Deviation

Unit of Measure: Celsius

Type of Units Analyzed: Participants with Temperature

Analysis Population Description: Safety analysis set

		AZD8233 AZD8233 for subcutaneous use.		**Placebo** Matching placebo solution for subcutaneous injection.	
	Number of Participants Analyzed:	207		203	
	Number of Participants with Temperature Analyzed:	207		203	
Vital signs - Temperature Units: Celsius	Category	Mean	Standard Deviation	Mean	Standard Deviation
Baseline	Number Analyzed:	207 Participants with Temperature 207 Participants		203 Participants with Temperature 203 Participants	
		36.434	0.437	36.369	0.389
Day 15	Number Analyzed:	201 Participants with Temperature 207 Participants		202 Participants with Temperature 203 Participants	
		36.344	0.404	36.387	0.378

Day 29	Number Analyzed:	201 Participants with Temperature 207 Participants		198 Participants with Temperature 203 Participants	
		36.360	0.422	36.361	0.386
Day 57	Number Analyzed:	199 Participants with Temperature 207 Participants		198 Participants with Temperature 203 Participants	
		36.340	0.420	36.396	0.368
Day 85	Number Analyzed:	195 Participants with Temperature 207 Participants		198 Participants with Temperature 203 Participants	
		36.360	0.416	36.362	0.363
Day 113	Number Analyzed:	195 Participants with Temperature 207 Participants		194 Participants with Temperature 203 Participants	
		36.359	0.391	36.399	0.348
Day 141	Number Analyzed:	189 Participants with Temperature 207 Participants		195 Participants with Temperature 203 Participants	
		36.335	0.398	36.373	0.341
Day 169	Number Analyzed:	194 Participants with Temperature 207 Participants		194 Participants with Temperature 203 Participants	
		36.304	0.454	36.353	0.411
Day 197	Number Analyzed:	191 Participants with Temperature 207 Participants		195 Participants with Temperature 203 Participants	
		36.299	0.477	36.352	0.316
Day 225	Number Analyzed:	190 Participants with Temperature 207 Participants		192 Participants with Temperature 203 Participants	
		36.327	0.472	36.365	0.37
Day 281	Number Analyzed:	186 Participants with Temperature 207 Participants		188 Participants with Temperature 203 Participants	
		36.353	0.396	36.391	0.363

4. Primary: Vital sign - Weight

Reporting Status:

Description: Mean and standard deviation of Weight at each scheduled visit by treatment.

Time Frame: Baseline to Day 281

Safety Issue:

Measure Type: Mean

Method of Dispersion: Standard Deviation

Unit of Measure: kg

Type of Units Analyzed: Participants with Weight

Analysis Population Description: Safety analysis set

		AZD8233 AZD8233 for subcutaneous use.		**Placebo** Matching placebo solution for subcutaneous injection.	
	Number of Participants Analyzed:	207		203	
	Number of Participants with Weight Analyzed:	207		203	
Vital sign - Weight Units: kg	Category	Mean	Standard Deviation	Mean	Standard Deviation
Baseline	Number Analyzed:	207 Participants with Weight 207 Participants		203 Participants with Weight 203 Participants	
		86.642	17.054	88.750	17.566
Day 281	Number Analyzed:	183 Participants with Weight 207 Participants		188 Participants with Weight 203 Participants	
		85.493	16.561	88.759	18.110

5. Primary: Number of Participants With an ECG Determined to be Abnormal and Clinically Significant

Reporting Status:

Description: Number of participants With an ECG Determined to be Abnormal and Clinically Significant at each scheduled visit by treatment

Time Frame: Baseline to Day 281

Safety Issue:

Measure Type: Number

Method of Dispersion: Not Applicable

Unit of Measure: Participants

Type of Units Analyzed: Participants with ECG

Analysis Population Description: Safety analysis set

		AZD8233 AZD8233 for subcutaneous use.	**Placebo** Matching placebo solution for subcutaneous injection.
	Number of Participants Analyzed:	207	203
	Number of Participants with ECG Analyzed:	207	203
Number of Participants With an ECG Determined to be Abnormal and Clinically	Category	Number	Number

Significant Units: Participants			
Baseline	Number Analyzed:	207 Participants with ECG 207 Participants	203 Participants with ECG 203 Participants
		0	0
Day 85	Number Analyzed:	190 Participants with ECG 207 Participants	191 Participants with ECG 203 Participants
		1	1
Day 169	Number Analyzed:	193 Participants with ECG 207 Participants	193 Participants with ECG 203 Participants
		0	0
Day 225	Number Analyzed:	190 Participants with ECG 207 Participants	191 Participants with ECG 203 Participants
		0	0
Day 281	Number Analyzed:	185 Participants with ECG 207 Participants	188 Participants with ECG 203 Participants
		0	0

6. Primary: Vital sign - Systolic Blood Pressure

Reporting Status:

Description: Mean and standard deviation of Systolic Blood Pressure at each scheduled visit by treatment.

Time Frame: Baseline - Day 281

Safety Issue:

Measure Type: Mean

Method of Dispersion: Standard Deviation

Unit of Measure: mmHg

Type of Units Analyzed: Participants with SBP

Analysis Population Description: Safety analysis set

		AZD8233 AZD8233 for subcutaneous use.	**Placebo** Matching placebo solution for subcutaneous injection.
	Number of Participants Analyzed:	207	203
	Number of Participants with SBP	207	203

	Analyzed:				
Vital sign - Systolic Blood Pressure Units: mmHg	Category	Mean	Standard Deviation	Mean	Standard Deviation
Baseline	Number Analyzed:	207 Participants with SBP 207 Participants		203 Participants with SBP 203 Participants	
		130.918	13.284	131.325	11.281
Day 15	Number Analyzed:	201 Participants with SBP 207 Participants		202 Participants with SBP 203 Participants	
		130.438	13.541	131.198	12.711
Day 29	Number Analyzed:	201 Participants with SBP 207 Participants		198 Participants with SBP 203 Participants	
		130.741	13.363	133.152	11.881
Day 57	Number Analyzed:	199 Participants with SBP 207 Participants		198 Participants with SBP 203 Participants	
		130.754	12.536	131.465	14.073
Day 85	Number Analyzed:	195 Participants with SBP 207 Participants		198 Participants with SBP 203 Participants	
		131.913	12.083	132.111	12.238
Day 113	Number Analyzed:	195 Participants with SBP 207 Participants		194 Participants with SBP 203 Participants	
		131.974	12.622	132.493	12.022
Day 141	Number Analyzed:	189 Participants with SBP 207 Participants		195 Participants with SBP 203 Participants	
		131.386	14.246	132.041	14.081
Day 169	Number Analyzed:	194 Participants with SBP 207 Participants		194 Participants with SBP 203 Participants	
		130.959	11.874	132.706	12.481
Day 197	Number Analyzed:	191 Participants with SBP 207 Participants		195 Participants with SBP 203 Participants	
		129.351	14.236	133.149	11.838
Day 225	Number Analyzed:	190 Participants with SBP 207 Participants		192 Participants with SBP 203 Participants	

		131.188	14.578	133.165	12.746
Day 281	Number Analyzed:	186 Participants with SBP 207 Participants		188 Participants with SBP 203 Participants	
		130.048	13.288	131.043	13.069

7. Primary: Vital sign - Diastolic blood pressure

Reporting Status:

Description: Mean and standard deviation of Diastolic Blood Pressure at each scheduled visit by treatment.

Time Frame: Baseline to Day 281

Safety Issue:

Measure Type: Mean

Method of Dispersion: Standard Deviation

Unit of Measure: mmHg

Type of Units Analyzed: Participants with Blood pressure

Analysis Population Description: Safety analysis set

		AZD8233 AZD8233 for subcutaneous use.		**Placebo** Matching placebo solution for subcutaneous injection.	
	Number of Participants Analyzed:	207		203	
	Number of Participants with Blood pressure Analyzed:	207		203	
Vital sign - Diastolic blood pressure Units: mmHg	Category	Mean	Standard Deviation	Mean	Standard Deviation
Baseline	Number Analyzed:	207 Participants with Blood pressure 207 Participants		203 Participants with Blood pressure 203 Participants	
		78.937	7.608	78.562	6.134
Day 15	Number Analyzed:	201 Participants with Blood pressure 201 Participants		202 Participants with Blood pressure 202 Participants	
		78.318	8.060	78.559	6.946
Day 29	Number Analyzed:	201 Participants with Blood pressure 201 Participants		198 Participants with Blood pressure 198 Participants	
		78.408	8.157	79.611	6.779
Day 57	Number Analyzed:	199 Participants with Blood pressure 199 Participants		198 Participants with Blood pressure 198 Participants	

		78.714	7.799	79.369	7.120
Day 85	Number Analyzed:	195 Participants with Blood pressure 195 Participants		198 Participants with Blood pressure 198 Participants	
		78.867	8.053	79.081	7.575
Day 113	Number Analyzed:	195 Participants with Blood pressure 195 Participants		194 Participants with Blood pressure 194 Participants	
		79.164	8.393	79.584	7.152
Day 141	Number Analyzed:	189 Participants with Blood pressure 189 Participants		195 Participants with Blood pressure 195 Participants	
		78.698	8.505	78.836	7.758
Day 169	Number Analyzed:	194 Participants with Blood pressure 194 Participants		194 Participants with Blood pressure 194 Participants	
		78.139	8.489	78.402	7.359
Day 197	Number Analyzed:	191 Participants with Blood pressure 191 Participants		195 Participants with Blood pressure 195 Participants	
		78.382	7.736	78.615	7.432
Day 225	Number Analyzed:	190 Participants with Blood pressure 190 Participants		192 Participants with Blood pressure 192 Participants	
		78.582	8.313	78.988	7.254
Day 281	Number Analyzed:	186 Participants with Blood pressure 186 Participants		188 Participants with Blood pressure 188 Participants	
		78.812	8.484	78.601	7.249

8. Primary: Vital sign - Pulse rate

Reporting Status:

Description: Mean and standard deviation of Pulse rate at each scheduled visit by treatment.

Time Frame: Baseline to Day 281

Safety Issue:

Measure Type: Mean

Method of Dispersion: Standard Deviation

Unit of Measure: beats/min

Type of Units Analyzed: Participants with pulse rate

Analysis Population Description: Safety analysis set

		AZD8233 AZD8233 for subcutaneous use.		**Placebo** Matching placebo solution for subcutaneous injection.	
	Number of Participants Analyzed:	207		203	
	Number of Participants with pulse rate Analyzed:	207		203	
Vital sign - Pulse rate Units: beats/min	Category	Mean	Standard Deviation	Mean	Standard Deviation
Baseline	Number Analyzed:	207 Participants with pulse rate 207 Participants		203 Participants with pulse rate 203 Participants	
		68.93	11.52	67.88	10.47
Day 15	Number Analyzed:	201 Participants with pulse rate 207 Participants		202 Participants with pulse rate 203 Participants	
		70.63	10.07	69.48	10.42
Day 29	Number Analyzed:	201 Participants with pulse rate 207 Participants		198 Participants with pulse rate 203 Participants	
		68.52	9.91	68.90	10.05
Day 57	Number Analyzed:	199 Participants with pulse rate 207 Participants		198 Participants with pulse rate 203 Participants	
		69.58	10.59	69.90	11.56
Day 85	Number Analyzed:	195 Participants with pulse rate 207 Participants		198 Participants with pulse rate 203 Participants	
		68.90	9.87	69.53	11.10
Day 113	Number Analyzed:	195 Participants with pulse rate 207 Participants		194 Participants with pulse rate 203 Participants	
		70.77	10.58	70.03	10.48
Day 141	Number Analyzed:	189 Participants with pulse rate 207 Participants		194 Participants with pulse rate 203 Participants	
		70.85	11.10	70.00	10.84
Day 169	Number Analyzed:	194 Participants with pulse rate 207 Participants		194 Participants with pulse rate 203 Participants	
		69.35	10.44	68.38	10.31
Day 197	Number Analyzed:	191 Participants with pulse rate 207 Participants		195 Participants with pulse rate 203 Participants	

		70.69	12.26	69.43	8.94
Day 225	Number Analyzed:	190 Participants with pulse rate 207 Participants		192 Participants with pulse rate 203 Participants	
		69.56	10.17	68.79	10.48
Day 281	Number Analyzed:	186 Participants with pulse rate 207 Participants		188 Participants with pulse rate 203 Participants	
		68.39	9.99	69.31	10.90

9. Primary: Treatment emergent platelet count abnormalities

Reporting Status:

Description: Treatment emergent platelet count abnormalities by pre-specified criteria by treatment.

Time Frame: Results at post-dose assessments on date of first dose of IP or at any assessments after the date of first dose of IP.

Safety Issue:

Measure Type: Number

Method of Dispersion: Not Applicable

Unit of Measure: Participant

Type of Units Analyzed:

Analysis Population Description: Safety analysis set

		AZD8233 AZD8233 for subcutaneous use.	**Placebo** Matching placebo solution for subcutaneous injection.
	Number of Participants Analyzed:	207	203
Treatment emergent platelet count abnormalities Units: Participant	Category	Number	Number
Platelet count < LLN	Number Analyzed:	206 Participants	203 Participants
		9	11
Platelet count > ULN	Number Analyzed:	206 Participants	203 Participants
		26	20
Platelet count < 50 x 10^9/L	Number Analyzed:	206 Participants	203 Participants
		0	0
Platelet count < 75 x 10^9/L	Number Analyzed:	206 Participants	203 Participants

		1	1
Platelet count < 100 x 10^9/L	Number Analyzed:	206 Participants	203 Participants
		2	2
Platelet count < 150 x 10^9/L	Number Analyzed:	206 Participants	203 Participants
		19	21
>30% decrease from baseline	Number Analyzed:	206 Participants	203 Participants
		14	14
<150 x 10^9/L or >30% decrease from baseline	Number Analyzed:	206 Participants	203 Participants
		28	26
<150 x 10^9/L and >30% decrease from baseline	Number Analyzed:	206 Participants	203 Participants
		5	9

10. Secondary: Percentage change from baseline on serum PCSK9 Expand

11. Secondary: Plasma concentration of AZD8233 Expand

12. Secondary: Anti-drug antibodies (ADAs) during the treatment period and follow-up period Expand

Limitations and Caveats

Description	

Adverse Events

View Adverse Events