Supplementary Table 1. Exclusion criteria

1	Patients without established CHD or CHD risk equivalents
2	LDL-C,70 mg/dL at the screening visit in patients with a history of documented CVD
3	LDL-C, 100 mg/dL at the screening visit in patients without history of documented CVD
4	Not on a stable dose of lipid lowering therapy (including statin) for ≥ 4 weeks before the screening visit or between screening and randomization visits
5	Currently taking a statin that is not atorvastatin, rosuvastatin, or simvastatin
6	Atorvastatin, rosuvastatin, or simvastatin is not taken daily or not taken at a registered dose
7	Daily dose above atorvastatin 80 mg, rosuvastatin 20 mg, or simvastatin 40 mg
8	Use of fibrates, other than fenofibrate in the past 4 weeks before screening visit or between screening and randomization visits
9	Use of nutraceutical products or over-the-counter therapies that may affect lipids which have not been at a stable dose/amount for ≥ 4 weeks before the screening visit or between screening and randomization visits
10	Use of red yeast rice products within 4 weeks of the screening visit or between screening and randomization visits
11	Patient who has received plasmapheresis treatment within 2 months before the screening visit or has plans to receive this during the study
12	History of a MI, unstable angina leading to hospitalization, CABG, PCI, uncontrolled cardiac arrhythmia, carotid surgery or stenting, stroke, transient ischemic attack, carotid revascularization, endovascular procedure, or surgical intervention for peripheral vascular disease within 3 months before the screening visit
13	Planned to undergo scheduled PCI or CABG, or carotid or peripheral revascularization, during the study
14	Systolic blood pressure (160 mmHg) or diastolic blood pressure (100 mmHg) at screening visit or randomization visit
15	History of New York Heart Association Class III or IV heart failure within the past 12 months
16	Known history of hemorrhagic stroke
17	Age, 18 years or legal age of majority at the screening visit, whichever is greater
18	Patients not previously instructed on a cholesterol-lowering diet before the screening visit
19	Newly diagnosed (within 3 months before randomization visit) or poorly controlled (HbA1c > 9% at the screening visit) diabetes
20	Presence of any clinically significant uncontrolled endocrine disease known to influence serum lipids or lipoproteins
21	History of bariatric surgery within 12 months before the screening visit
22	Unstable weight defined by a variation > 5 kg within 2 months before the screening visit
23	Known history of homozygous or heterozygous familial hypercholesterolemia
24	Known history of loss of function of PCSK9 (i.e., genetic mutation or sequence variation)
25	Use of systemic corticosteroids, unless used as replacement therapy for pituitary/adrenal disease with a stable regimen for at least 6 weeks before randomization
26	Use of continuous estrogen or testosterone hormone replacement therapy unless the regimen has been stable in the past 6 weeks before the screening visit and no plans to change the regimen during the study
27	History of cancer within the past 5 years, except for adequately treated basal cell skin cancer, squamous cell skin cancer, or *in situ* cervical cancer
28	Known history of a positive HIV test
29	Patient who has taken any investigational drugs other than the alirocumab training placebo kits within 1 month or 5 half-lives, whichever is longer
30	Patient who has been previously treated with at least 1 dose of alirocumab or any other anti-PCSK9 monoclonal antibody in other clinical trials
31	Patient who withdraws consent during the screening period (patient who is not willing to continue or fails to return)

Supplementary Table 1. Continued

32	Conditions/situations such as: Any clinically significant abnormality identified at the time of screening that in the judgment of the investigator or any sub-investigator would preclude safe completion of the study or constrain endpoints assessment such as major systemic diseases or patients with a short life expectancy. Considered by the investigator or any sub-investigator as inappropriate for this study for any reason, e.g., Deemed unable to meet specific protocol requirements, such as scheduled visits Deemed unable to administer or tolerate long-term injections as per the patient or the investigator Investigator or any sub-investigator, pharmacist, study coordinator, other study staff, or relative thereof directly involved in the conduct of the protocol, etc. Presence of any other conditions (e.g., geographic, social), actual or anticipated, that the investigator feels would restrict or limit the patient's participation for the duration of the study
33	Laboratory findings during the screening period: Positive test for hepatitis B surface antigen or hepatitis C antibody (confirmed by reflexive testing) Positive serum β-human chorionic gonadotropin or urine pregnancy test in women of childbearing potential Triglycerides > 400 mg/dL (1 repeat laboratory is allowed) eGFR < 30 mL/min/1.73 m^2 ALT or AST > 3 × ULN (1 repeat laboratory is allowed) CPK > 3 × ULN (1 repeat laboratory is allowed) TSH < lower limit of normal or > ULN (1 repeat laboratory is allowed)
34	All contraindications to the background therapies or warning/precaution of use (when appropriate) as displayed in the respective National Product Labeling
35	Known hypersensitivity to monoclonal antibody or any component of the drug products
36	Pregnant or breastfeeding women
37	Women of childbearing potential not protected by highly effective method(s) of birth control and/or who are unwilling or unable to be tested for pregnancy

CHD, coronary heart disease; LDL-C, low density lipoprotein cholesterol; CVD, cardiovascular disease; MI, myocardial infarction; CABG, coronary artery bypass graft; PCI, percutaneous coronary intervention; HbA1c, glycated hemoglobin; PCSK9, proprotein convertase subtilisin/kexin type 9; HIV, human immunodeficiency virus; eGFR, estimated glomerular filtration rate; ALT, alanine aminotransferase; AST, aspartate transferase; ULN, upper limit of normal; CPK, creatine phosphokinase; TSH, thyroid stimulating hormone.

https://doi.org/10.3904/kjim.2018.133