

## Appendix 1. Inclusion and exclusion criteria of the study

### Inclusion criteria

- (1) Aged between 40 and 75 at the time of consent
- (2) Subjects with an estimated 10-year atherosclerotic cardiovascular disease risk of 7.5% or higher with type 2 diabetes mellitus according to the criteria of the American Diabetes Association at the time of screening
- (3) Subjects with glycosylated hemoglobin (HbA1c) of 6% or more and less than 10% at the time of screening
- (4) Subjects with a body mass index of 35 kg/m<sup>2</sup> or less at the time of screening
- (5) Women of childbearing potential must be negative in the pregnancy test result at the time of screening, and those who have agreed to implement effective contraceptive methods (including medically impossible to conceive) during the clinical trial period
- (6) A person who understands the purpose and contents of the clinical trial, the characteristics and risks of the test drug, and gave written consent after receiving a sufficient explanation

### Exclusion criteria

- (1) Type 1 diabetes mellitus
- (2) Subjects with chronic hepatitis B or C, severe liver dysfunction (aspartate transaminase, alanine transaminase, ALP, or creatine phosphokinase three times or more of the upper limit of normal [ULN]) at the time of screening
- (3) Those who drink more than 210 g per week at the time of screening
- (4) Subjects whose estimated glomerular filtration rate using the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) formula at the time of screening is less than 30 mL/min/1.73 m<sup>2</sup>
- (5) Those undergoing renal replacement therapy at the time of screening (hemodialysis or peritoneal dialysis)
- (6) Those who have used other statin drugs (3-hydroxy-3-methylglutaryl coenzyme A converting enzyme inhibitors) or fibrate drugs other than rosuvastatin within the last 3 months at the time of screening
- (7) Those taking any drug that affects low-density lipoprotein (e.g., fenofibrate, omega-3 fatty acid, etc.)
  - \*Registration available after 4 weeks wash-out
  - \*You can register if you have taken omega-3 fatty acid for 2 weeks before participating in the clinical trial and have taken it at the same dose during the clinical trial
- (8) Those who have used thiazolidinedione drugs within the last 3 months prior to screening
- (9) Patients receiving cyclosporine concomitantly
- (10) Persons who are human immunodeficiency virus-positive at the time of screening
- (11) Pregnant women, women who are lactating, or women of childbearing potential who are not likely to use appropriate contraceptive methods as judged by the investigator
- (12) Those with a history of muscle disease or rhabdomyolysis due to statin use
- (13) Those hypersensitive to statin and ezetimibe
- (14) Subjects with endocrine or metabolic diseases known to affect serum lipids or lipoproteins
  - \*Uncontrolled diabetes (HbA1c  $\geq$  10%)
  - \*Uncontrolled thyroid dysfunction (thyroid stimulating hormone  $\geq$  3 times the ULN)
- (15) Those with a history of acute arterial disease such as unstable angina, myocardial infarction, transient ischemic attack, cerebrovascular disease, coronary artery bypass grafting or coronary intervention within 6 months prior to screening
- (16) Those who have had gastrointestinal surgery or have drug absorption disorders due to gastrointestinal disorders
- (17) Those who have taken other clinical trial drugs within 30 days before the screening visit
- (18) During the study period, those who cannot discontinue concomitantly contraindicated drugs that may affect the treatment effect of all diabetes and/or hypercholesterolemia other than this clinical trial drug
- (19) A person with a serious or unstable medical or psychological condition judged by the tester to reduce safety or successful participation in the test
- (20) In addition to the above, those judged by the investigator to be unsuitable for participation in this clinical trial