

Supplementary Table 1. Inclusion and exclusion criteria

Inclusion criteria	<ol style="list-style-type: none"> 1. 19 years ≤ age 2. Persons with a confirmed HbA1c at visit 1-1 (pre-screening) that is any of the following <ol style="list-style-type: none"> 1) On metformin (≥ 1,000 mg/day) alone immediately prior to visit 1-1 (prescreening): 7.5% ≤ HbA1c ≤ 11% 2) Concomitant use of metformin (≥ 1,000 mg/day) and other oral anti-hyperglycemic agents other than metformin immediately prior to visit 1-1 (pre-screening): 7.0% ≤ HbA1c ≤ 11% 3) Concomitant use of metformin (≥ 1,000 mg/day) and dapagliflozin (10 mg/day) at a constant dose for at least 8 weeks prior to visit 1-1 (pre-test): 7.0% ≤ HbA1c ≤ 11% 3. Central laboratory HbA1c result of 7%–11% at visit 1-2 (screening) 4. BMI ≤ 45 kg/m² at visit 1-1 (pre-screening) and visit 1-2 (screening) 5. Adherence to each of metformin, dapagliflozin, and placebo during the run-in period determined at visit 2 is greater than 70% and less than 120% 6. A person who voluntarily decides to participate and gives written consent after being informed of the purpose, methods, and effects of the study
Exclusion criteria	<p>Exclusion criteria for visit 1-1 (pre-screening) or visit 1-2 (screening)</p> <ol style="list-style-type: none"> 1. History of hypersensitivity to any component of the investigational drug in this study or to drugs in the same class (biguanide, SGLT2 inhibitor, thiazolidinedione) 2. People with major systemic diseases, such as <ol style="list-style-type: none"> 1) Diabetes other than type 2 (such as type 1 diabetes, secondary diabetes, or congenital kidney diabetes) 2) Serious uncontrolled diabetes complications (e.g., proliferative retinopathy not controlled by medication, severe diabetic neuropathy) 3) Acute or chronic metabolic acidosis, including lactic acidosis and diabetic ketoacidosis 4) History of ketoacidosis or diabetic coma and pre-coma 5) Clinically significant hematuria 6) Hypopituitarism or adrenal insufficiency 7) Uncontrolled hyperglycemia (fasting plasma glucose level > 270 mg/dL) 8) Uncontrolled hypertension (systolic blood pressure > 180 mm Hg or diastolic blood pressure > 110 mm Hg) 9) Severe hypertriglyceridemia (triglyceride > 500 mg/dL) 10) Moderate to severe renal dysfunction <ul style="list-style-type: none"> • If people are already taking metformin 1,000 mg: eGFR < 45 mL/min/1.73 m² • If people are already taking metformin > 1,000 mg: eGFR < 60 mL/min/1.73 m² • Renal replacement therapy 11) Hepatic impairment <ul style="list-style-type: none"> • AST or ALT levels ≥ 3 × ULN • Total bilirubin levels ≥ 2 × ULN • Hepatitis, hepatic dysfunction, liver cirrhosis 12) Human immune deficiency virus infection 13) Severe infection (e.g., severe infection requiring ongoing antibiotic or immunotherapy) or severe trauma as determined by the investigator 14) Acute or chronic conditions that can cause tissue hypoxia, such as pulmonary infarction, severe pulmonary dysfunction, respiratory failure, or shock 15) Unstable mental illness whose symptoms are not controlled by medication 16) Patients with gastrointestinal disease and surgery that may affect the absorption, distribution, metabolism, and excretion of investigational medicinal products 17) People with genetic problems such as galactose intolerance, Lapp lactase deficiency, or glucose-galactose malabsorption

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Supplementary Table 1. Continued

3. History of malignancy within the last 5 years
 - 1) History of bladder cancer more than 5 years old is also not eligible
4. History of alcoholism or drug abuse within the past year
5. Cardiovascular disease within the last 6 months (NYHA Class II or greater heart failure, unstable angina, arrhythmia, myocardial infarction, transient ischemic attack, stroke, history of coronary artery bypass grafting or coronary intervention)
 - 1) Excludes heart failure, even if it occurred more than 6 months ago. Otherwise, those who had the condition more than 6 months ago and are currently cured or in stable condition
6. People whose weight has changed by more than 10% in the last 3 months
7. Surgical procedures involving general anesthetics within the last 4 weeks (excluding minor surgery with no food restrictions) or scheduled within 4 weeks of study completion
8. Persons who are expected to require continuous administration of blood glucose-lowering medications other than the investigational drug and conventional medications during this study, or who are expected to require continuous administration of prohibited concomitant medications
9. Pregnant or nursing women or those who do not agree to use adequate contraception for the duration of the study
10. Any other person deemed by the investigator to be unsuitable for participation in this study

HbA1c, glycosylated hemoglobin; BMI, body mass index; SGLT2, sodium glucose cotransporter-2; eGFR, estimated glomerular filtration rate; AST, aspartate aminotransferase; ALT, alanine aminotransferase; ULN, upper limit of normal; NYHA, New York Heart Association.