

**Table S1 Inclusion and exclusion criteria**

| <b>Inclusion criteria</b>  | <b>Exclusion criteria</b>   |
|--|---|
| <i>Provisional enrollment (at screening)</i>   |   |
| Written informed consent before starting the study   | Stress urinary incontinence   |
| Patient was $\geq 20$ years of age at the time of informed consent. Female patients had to be an outpatient with OAB who had been postmenopausal for $\geq 1$ year. Male patients had to be an outpatient with OAB who did not wish to have children in the future | Transient symptoms suggestive of OAB  |
| Previously treated with MIRA at a stable dose of 50 mg once daily for $\geq 6$ weeks before the start of the screening period  | Urinary tract infection, urinary calculus, or interstitial cystitis, or a history of recurrent urinary tract infection ( $\geq 3$ episodes within 24 weeks before the start of the screening period)  |
| Capable of walking to the bathroom without assistance  | Bladder or prostate tumor or a medical history of these type of tumors  |
| OABSS total score of $\geq 3$ points and an OABSS question 3 score of $\geq 2$ points  | PVR volume of $\geq 100$ mL or had benign prostatic hyperplasia or lower urinary tract obstruction  |
|  | Uncontrolled hypertension (SBP of $\geq 180$ mmHg or DBP of $\geq 110$ mmHg measured in a sitting position)   |
|  | Pulse rate of $\geq 110$ b.p.m. or $< 50$ b.p.m.  |
|  | Contraindication to antimuscarinics   |
|  | Glaucoma, ulcerative colitis, hyperthyroidism, dementia, cognitive dysfunction, parkinsonism symptoms, or a clinically significant cerebrovascular disorder   |
|  | Serious heart disease, liver disease, kidney disease, immunological disease, lung disease, etc., or a previous malignant tumor (except patients who had not received treatment for a malignant tumor for $\geq 5$ years before the start of the screening period and were not considered to be at risk of recurrence) |
|  | Known hypersensitivity to $\beta$ -agonists or antimuscarinics  |
|  | Receiving treatment with flecainide acetate or propafenone hydrochloride  |
|  | Long QT syndrome; vulnerable to an arrhythmia, such as bradycardia or acute myocardial ischemia; hypokalemia; or ischemic heart disease, such as angina pectoris  |
|  | Used any prohibited concomitant medication within 4 weeks before the start of the screening period  |

| Inclusion criteria   | Exclusion criteria   |
|--|--|
|  | <p>Receiving catheterization or intermittent self-catheterization or had pelvic organ prolapse that affected urinary tract function</p> <p>Received radiotherapy that affected urinary tract function</p> <p>Received surgical therapy that may have affected urinary tract functioning within 24 weeks before the start of the screening period</p> <p>Received non-pharmacological therapy for OAB such as electric stimulation therapy, biofeedback therapy, bladder training, or pelvic floor muscle exercise training within 2 weeks before the start of the screening period</p> <p>Diagnosed with a mood disorder, a neurotic disorder, or schizophrenia, or had a history of these diseases</p> <p>Participated in any clinical trial or post-marketing clinical study, involving other ethical drugs or medical equipment, within 12 weeks before the start of the screening period or was currently participating in this type of study</p> <p>Judged to be unsuitable for the study by the investigator</p> |
| <i>Final enrollment (at randomization)</i>   |  |
| <p>OABSS total score of <math>\geq 3</math> points and an OABSS question 3 score of <math>\geq 2</math> points</p> | <p>Polyuria with a mean daily urine volume of <math>&gt;3000</math> mL (confirmed using the micturition diary during the screening period)</p> <p>PVR volume of <math>\geq 100</math> mL or had benign prostatic hyperplasia or lower urinary tract obstruction</p> <p>Uncontrolled hypertension (SBP of <math>\geq 180</math> mmHg or DBP of <math>\geq 110</math> mmHg measured in a sitting position)</p> <p>Pulse rate of <math>\geq 110</math> b.p.m. or <math>&lt;50</math> b.p.m.</p> <p>Any of the following after examination of the screening visit results: an abnormal ECG that precluded participation or a QTcF of <math>\geq 450</math> ms, AST or ALT of <math>\geq 100</math> IU/L, or creatinine of <math>\geq 2.0</math> mg/dL</p> <p>Satisfied any of the screening exclusion criteria</p> <p>Not eligible for the study in the opinion of the investigator</p>  |

ALT, alanine aminotransferase; AST, aspartate aminotransferase; DBP, diastolic blood pressure; ECG, electrocardiogram; MIRA, mirabegron; OAB, overactive bladder; OABSS, overactive bladder symptom score; PVR, post-void residual; QTcF, QT interval corrected for heart rate by Fridericia's formula; SBP, systolic blood pressure.