**Kantonsspital St.Gallen**

**Interdisziplinäre Medizinische Dienste**
**Muskelzentrum/ALS clinic**

Direkt 071 494 35 81
muskel-als@kssg.ch

Kantonsspital St.Gallen

CH-9007 St. Gallen
Tel. 071 494 11 11
www.kssg.ch

# Mitsubishi MT 1186 / Site 6001 / PI NB
## Inclusion/ Exclusion Criteria

Datum: _____

Patientenname: _____

Patienten-ID: A02-6001- _____

| | INCLUSION CRITERIA | Yes | No |
|---|---|---|---|
| 1 | Subjects must provide a **signed and dated informed consent** form (ICF). Subjects must be **able** (in the judgment of the Investigator) **to understand** the nature of the study and all risks involved with participation in the study. Subjects must be **willing to cooperate and comply** with all protocol restrictions and requirements. | | |
| 2 | Subjects will be male or female, **≥ 18 to 75 years** of age at the time the ICF is signed. | | |
| 3 | Subjects will be diagnosed with **Definite ALS or Probable ALS** according to the El Escorial revised criteria (Appendix 1) for the diagnosis of ALS. | | |
| 4 | Subjects with a **baseline score ≥ 2 points** on each individual item of the ALSFRS- R at screening and baseline visits (Appendix 2). | | |
| 5 | Subjects have a **screening and baseline %FVC ≥ 70%.** | | |
| 6 | Subjects with **1 to 4 points decline for 8 weeks in ALSFRS-R** total score between screening and baseline visits. | | |
| 7 | Subjects whose **first symptom** of ALS has occurred **within 2 years** of providing written informed consent. | | |

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| | EXCLUSION CRITERIA | Yes | No |
|---|---|---|---|
| 1 | Subjects with a **history of spinal surgery** after the onset of ALS, such as surgery for cervical spondylosis or a herniated disc, or plans for such surgery during the study period. | | |
| 2 | Subjects with the possibility that the current symptoms **may be symptoms of a disease** requiring differential diagnosis, such as cervical spondylosis and multifocal motor neuropathy, cannot be ruled out. | | |
| 3 | Subjects undergoing treatment for a **malignancy**. | | |
| 4 | Subjects with a **complication** that could have a **significant effect on efficacy evaluations**, such as Parkinson's disease or syndrome, schizophrenia, bipolar disorder, and dementia. | | |
| 5 | Subjects who have the **presence or history of any clinically significant (CS) disease** (except ALS) that could interfere with the objectives of the study (the assessment of safety and efficacy) or the safety of the subject, as judged by the Investigator. | | |
| 6 | Subjects who are **female and pregnant** (a positive pregnancy test) **or lactating** at the screening visit (Visit 1). | | |
| 7 | Subjects of **childbearing potential** unwilling to use acceptable method of contraception from the screening visit until 3 months after the last dose of study medication. Subjects who are sexually active who **do not agree** to use contraception during the study period. Refer to Appendix 3 for additional contraceptive information. | | |
| 8 | Subjects who have a significant **risk of suicidality**. Subjects with any suicidal behavior or suicidal ideation of type 4 (active suicidal ideation with some intent to act, without a specific plan) or type 5 (active suicidal ideation with specific plan and intent) based on the C-SSRS within the 3 months before the screening visit. | | |

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| | | | |
|---|---|---|---|
| **9** | Subjects who have **alanine aminotransferase (ALT) or aspartate aminotransferase (AST) elevations greater** than 2 times the upper limit of normal (ULN) at screening. | | |
| **10** | Subjects with a Glomerular Filtration Rate **(GFR) < 30 mL/Min Per 1.73 m2** at screening, using the Larsson Equation. | | |
| **11** | Subjects with history of **hypersensitivity to edaravone**, any of the additives or inactive ingredients of edaravone, or sulfites. | | |
| **12** | Subjects with hereditary problems of **fructose intolerance** (eg, fructose, sucrose, invert sugar, and sorbitol). | | |
| **13** | Subjects who **participated in another study** and were administered an investigational product within 1 month or 5 half-lives of the investigational agent, whichever is longer, before providing informed consent for the present study. | | |
| **14** | Subjects who have received any **previous treatment with edaravone.** | | |
| **15** | Subjects who have **received stem cell therapy**. | | |
| **16** | Subjects who are **unable to take their medications orally** at baseline (Visit 2). | | |

PI / SI signature: _____