**Table 1** Inclusion and Exclusion Criteria

Inclusion criteria

Patients will be eligible for the study if they meet all of the following criteria:

1. Japanese male or female patients 20 years of age or older;
2. Clinical diagnosis of cerebral cortical ischemic stroke;
3. Occurrence of an ischemic stroke with clear motor or speech deficit documented by National Institutes of Health Stroke Scale (NIHSS) score of 8 to 20 (at the baseline assessment) that did not change by ≥4 points from the screening to the baseline assessment;
4. Onset of ischemic stroke must have occurred within 18 to 36 hours prior to the start of administration of the investigational product;
5. Confirmation of hemispheric cortical infarct with brain magnetic resonance imaging (MRI) including diffusion-weighted imaging with b-value of 1,000 demonstrating an acute lesion measuring ≥ 2.0 cm of longest diameter;
6. A modified Rankin Scale (mRS) of 0 or 1, by either self-report or family report, prior to the onset of ischemic stroke;
7. Female patients who meet either:
   1. Not pregnant, not breastfeeding, and not planning on becoming pregnant during the trial.
   2. Not of childbearing potential, defined as one who has been postmenopausal for at least 1 year, or has been surgically sterilized, or has had a hysterectomy at least 3 months prior to the start of this trial.
   3. If of childbearing potential, one who has agreed to use an effective contraceptive method up to the end of the trial. Effective contraceptive methods include contraceptive methods used consistently and correctly (oral contraceptives, intrauterine devices, diaphragm, or male or female condoms), abstinence, and a sterile sexual partner;
8. Male patients with female partners of childbearing potential must agree to use adequate contraceptive methods (a combination of a condom and another form of contraception) up to the end of the trial if engaging in sexual intercourse;
9. Patients or legal representatives must freely sign the informed consent form after the nature of the trial and the disclosure of his/her data have been explained;
10. Willing and able to comply with all aspects of the treatment and testing schedule; and
11. Willing and able to return to the trial site for the post-treatment evaluations.

Exclusion criteria

Patients will not be eligible for the study if they meet any of the following:

1. Presence of a lacunar, a lesion of ≤ 2.0 cm of longest diameter, or a brainstem infarct on MRI as the etiology of symptoms of ischemic stroke;
2. Reduced level of consciousness (score of 3 for item 1a of NIHSS);
3. Occurrence of a hemorrhagic transformation as evidenced by computerized tomography (CT) or brain MRI scan that is clinically significant in the opinion of the investigator;
4. Ipsilateral focal neurological deficits from prior lesions in the brain that would complicate evaluation;
5. Experienced seizures since the onset of ischemic stroke;
6. History of a neurological event such as stroke or clinically significant head trauma within 6 months prior to the start of screening;
7. Patients who both received tPA treatment and underwent mechanical reperfusion (patients are eligible for the trial if they had only one of them, tPA treatment or mechanical reperfusion);
8. Uncontrolled hypertension, defined as persistent systolic blood pressure >220 mmHg or diastolic blood pressure >120 mmHg, despite antihypertensive therapy;
9. Blood glucose level <50 mg/dL or >350 mg/dL at baseline;
10. Patients who have a significant comorbid medical condition(s), including, but not limited to:
    1. Severe kidney disease requiring hemodialysis or peritoneal dialysis;
    2. Advanced liver disease such as hepatitis or liver cirrhosis;
    3. Severe congestive heart failure or history of ejection fraction <30%;
    4. Severe lung disease requiring home oxygen; or
    5. Active unstable angina requiring daily treatment with nitrates or other medications;
11. Known human immunodeficiency virus infection, ongoing systemic infection, severe local infection or who are immunocompromised;
12. Alzheimer’s disease or other dementias, Parkinson’s disease, or any other neurological disorder that in the opinion of the trial doctor would affect their ability to participate in the trial or confound study assessments;
13. History of malignant tumor(s) within 2 years of the onset of ischemic stroke, with the exception of adequately treated basal or squamous cell carcinoma of the skin;
14. Contraindication for MRI such as implanted pacemakers or other metallic prosthesis incompatible with MRI, body weight, or claustrophobia;
15. Thrombocytopenia (platelet count <100,000/mm3) or heparin-induced thrombocytopenia;
16. Known allergy to human tissue or bovine or porcine products, or religious objections to biological products;
17. Prior participation in another clinical trial involving investigational pharmacological agents or devices within 30 days prior to providing consent to receive the investigational product, or participation in investigational rehabilitation stroke recovery program is planned;
18. Other serious medical or psychiatric illness that is not adequately controlled and, in the investigator’s opinion, would not permit the subject to be managed according to the protocol;
19. Previous surgical removal of the spleen;
20. Major fluctuation in neurological status since the onset of ischemic stroke indicating progression or expansion of ischemic stroke, or possible transient ischemic attack; or
21. Plan to have a neurovascular procedure (e.g., carotid endarterectomy, stent placement, etc.) within the first year following ischemic stroke.