Toxicity of regenerative medicine products are evaluated by a single administration to general or immunodeficient animals. Evaluation items conform to the guideline for repeated dose toxicity studies. The influence on physiology (safety pharmacology core battery) and local irritation are evaluated as necessary.

### Methods

**Animal:** General animal, immunodeficient mouse (nude, NOG, NSG), immunodeficient rat (nude)

**Group composition:**
Control group, test article group (maximum feasible dose or maximum tolerated dose)

**Number of animals:**
10 animals/sex/group, and conduct satellite group as necessary

**Examination items:**
Clinical sign, body weight, food consumption, ophthalmological examination, urinalysis, hematological examination, blood biochemical examination, necropsy, pathological examination, safety pharmacology core battery (cardiovascular, respiratory, and central nervous systems), local irritation (pathological examination of the administration site), etc.

**Test period:** Observation for 14 days after administration

**Accessory study:**
Biodistribution study (PCR for human cell gene, immunostaining, etc.)