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TRANSLATIONAL

GEDUCATION

O CLINICAL

O INFRASTRUCTURE

GWG Review of Clinical Program Applications

0 DISCOVERY

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Clinical Stage Programs

CLINICAL STAGE





Scoring System for 2.0 Applications

Score of "1"

Exceptional merit and warrants funding.

Score of "2"

Needs improvement and does not warrant funding at this time but could be resubmitted to address areas for improvement.

Score of "3"

Sufficiently flawed that it does not warrant funding and the same project should not be resubmitted.

Applications are scored by all scientific members of the GWG with no conflict.



CLIN1-08295: IND Enabling Studies of a Cell Therapy for Parkinson's Disease

Therapy: Dopaminergic neurons derived from human embryonic stem cells for treatment of Parkinson's disease.

Indication: Patients with Parkinson's disease who are not adequately treated with conventional therapy.

Goal: Complete IND-enabling activities to submit a well-supported IND for a future clinical trial.

Major Proposed Activities:

- Manufacture GMP cell product.
- Complete preclinical safety and efficacy studies.
- Design a Phase I clinical trial and submit a well-supported IND.

Funds Requested: \$6.8M



CLIN1-08295: IND Enabling Studies of a Cell Therapy for Parkinson's Disease

Budget Review: Pass

GWG Score: 3 do not fund, do not resubmit

- Votes for score of 1: 0
- Votes for score of 2: 0
- Votes for score of 3: 12

CIRM Team Recommendation: Do not fund and do not allow reapplication (concur with GWG recommendation)

