**PPMI**

1 3 2 **INCLUSION/EXCLUSION - SWEDD (Amend 4)** 8 6

SUBJECT ID | | | | | VISIT NO | | | |

INITIALS | | | | SITE NO | | | | VISIT DATE | | | MM | | DD | | | | | YYYY

SUBJECT INCLUSION CRITERIA (0 = No, 1 = Yes)

1. Subjects must have at least two of the following: resting tremor, bradykinesia, rigidity (must have either resting tremor or bradykinesia); OR either asymmetric resting tremor or asymmetric bradykinesia. 1. ☐

2. A diagnosis of Parkinson disease for 2 years or less at Screening. 2. ☐

3. Hoehn and Yahr Stage I or II at Baseline. 3. ☐

4. Not expected to require PD medication within at least 6 months from Baseline. 4. ☐

5. Male or female age 30 years or older at time of PD diagnosis. 5. ☐

7. Ability to provide written informed consent in accordance with Good Clinical Practice (GCP), International Conference on Harmonization (ICH), and local regulations. 7. ☐

8. Willing and able to comply with scheduled visits, required study procedures and laboratory tests. 8. ☐

9. Women may not be pregnant, lactating or planning pregnancy during the course of the study. 9. ☐

11. Confirmation from imaging core that screening dopamine transporter SPECT scan is consistent with no dopamine transporter deficit (or for sites only conducting PET scan that VMAT-2 PET scan shows no evidence of VMAT deficit). 11. ☐

To be **ELIGIBLE** for study participation **ALL** answers to items 1-5 , 7, 8 and 11 must be **1 = Yes** and item 9 must be **1 = Yes** if female of child bearing potential

SUBJECT EXCLUSION CRITERIA (0 = No, 1 = Yes)

1. Atypical PD syndromes due to either drugs (e.g., metoclopramide, flunarizine, neuroleptics) or metabolic disorders (e.g., Wilson's disease), encephalitis, or degenerative diseases (e.g., progressive supranuclear palsy). 1. ☐

2. Currently taking levodopa, dopamine agonists, MAO-B inhibitors, (e.g. selegiline, rasagiline) amantadine or other PD medication. 2. ☐

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SUBJECT ID [ ][ ][ ][ ] VISIT NO [ ][ ][ ]

SUBJECT EXCLUSION CRITERIA (0 = No, 1 = Yes) Continued

| | | |
|---|---|---|
| 3. | Has taken levodopa, dopamine agonists, MAO-B inhibitors or amantadine within 60 days of Baseline. | 3. [ ] |
| 4. | Has taken levopdopa or dopamine agonists prior to Baseline for more than a total of 60 days. | 4. [ ] |
| 5. | A clinical diagnosis of dementia as determined by the investigator. | 5. [ ] |
| 6. | Received any of the following drugs that might interfere with dopamine transporter SPECT imaging: Neuroleptics, metoclopramide, alpha methyldopa, methylphenidate, reserpine, or amphetamine derivative, within 6 months of Screening. | 6. [ ] |
| 7. | Current treatment with anticoagulants (e.g., coumadin, heparin) that might preclude safe completion of the lumbar puncture. | 7. [ ] |
| 8. | Condition that precludes the safe performance of routine lumbar puncture, such as prohibitive lumbar spinal disease, bleeding diathesis, or clinically significant coagulopathy or thrombocytopenia. | 8. [ ] |
| 9. | Any other medical or psychiatric condition or lab abnormality, which in the opinion of the investigator might preclude participation. | 9. [ ] |
| 10. | Use of investigational drugs or devices within 60 days prior to Baseline (dietary supplements taken outside of a clinical trial are not exclusionary, e.g., coenzyme Q10). | 10. [ ] |
| 11. | Previously obtained MRI scan with evidence of clinically significant neurological disorder (in the opinion of the Investigator). | 11. [ ] |

To be **ELIGIBLE** for study participation **ALL** answers to items 1-11 must be **0 = No**

*To discuss questionable subject eligibility, call the CTCC Project Manager.*

[ ][ ][ ][ ][ ][ ] PROTOCOL DEVIATION CODE