

EPAD CCSC Preliminary Questionnaire

Note: This questionnaire is a non-binding expression of interest to the EPAD Clinical Candidate Selection Committee (CCSC) and a preliminary presentation of information about a potential candidate compound to facilitate discussion with the CCSC prior to submission of the formal Nomination Form. It has been designed to elicit non-confidential information to expedite the process. If you prefer a signed Confidential Data Agreement (CDA) prior to responding to this questionnaire, please let us know and one of the CCSC members will contact you. Should you choose to proceed to a formal submission of your compound as a candidate, a CDA will be signed at the time of submitting the formal Nomination Form to ensure the confidential handling of the required documentation (e.g., Investigator's Brochure, regulatory correspondence, preclinical and clinical study reports, etc.).

- A. Is there a general interest in studying one of your compounds for the secondary prevention of AD in the EPAD PoC trial? YES/NO
- B. If yes, by when do you anticipate your compound will be ready to enter the EPAD PoC trial from a current perspective (indicate year and quarter, e.g., Q2 2017):

Additional information (as mentioned, this questionnaire has been designed to elicit non-confidential information to expedite the process. If you prefer a signed CDA prior to responding to this questionnaire, please let us know and one of the CCSC members will contact you):

- 1. Presumed target of the compound (e.g., amyloid, tau, inflammation, neurotransmitter, mitochondria, other):
- 2. Is there human evidence for target engagement (yes/no)?
- 3. Nature of intervention (e.g., small molecule, antibody, vaccine, nutraceutical, other, etc.):
- 4. Has suitability for advancement into Phase 2 been discussed with any regulatory authorities (yes/no)? If so, have they concurred with readiness for Phase 2 (yes/no)?
- 5. The EPAD secondary prevention population includes subjects ranging from at-risk of AD with evidence for AD pathology but without clinical symptoms (i.e., "preclinical" AD) through prodromal AD (i.e., mild cognitive impairment due to

AD), but without evidence for dementia. Is the population proposed for study with your compound within this scope and, if so, would it encompass the entire population or a subgroup? If a subgroup, can you provide the nature of the subgroup?

6. Are there available biomarkers for testing target engagement, or for detecting downstream pharmacodynamic effects of the compound (yes/no)?
7. Will any special safety assessments (e.g., imaging other than neuroimaging, invasive procedures, etc.) be required in Phase 2 (Note: it is not necessary to specify the assessment at this time)?
8. Can you confirm that you will be able to provide adequate drug supply and matching placebo?
9. Can you confirm that you are willing to provide funding for your portion of the PoC?

Please list any questions or concerns you might have about nominating your compound or about studying it in the EPAD PoC: