Methods

Knight ADRC and ADNI* studies for clinical disease progression in human AD patients

The recruitment, assessment, and exclusion criteria methods for the Knight ADRC study has been published previously\textsuperscript{30,31}. In the case of the ADNI study, further information was previously described\textsuperscript{32}. Knight ADRC individuals were evaluated by Clinical Core personnel at Washington University and in the case of ADNI, each local site was in charge for the evaluation of local participants\textsuperscript{32,33}. Briefly, cases received a clinical diagnosis of AD in accordance with the standard criteria\textsuperscript{34} and presence or absence of dementia. The severity of dementia was staged with the Clinical Dementia Rating (CDR) where 0 indicates cognitive normality, 0.5 is defined as very mild dementia, 1 is mild dementia, 2 is moderate dementia, and 3 is severe dementia\textsuperscript{35}. The scores in each of the six cognitive and functional domains surveyed by the CDR are summed to yield a Sum of Box scores (CDR-SB) ranging from 0 (no impairment) to 18 (maximal impairment)\textsuperscript{36}. Sample selection was done as follow: only participants that had an AD diagnosis at the last visit and had a CSF profile compatible with AD were included in our analyses. Non-AD dementia was excluded, as well as individuals in which the CDR at last assessment was equal to 0. Individuals with diagnoses of neurological diseases other than AD were excluded. Not informative longitudinally measured CDR-SB was removed for each participant. After removing the non-informative data points only individuals with at least 1.5 year of follow-up were included. A total of 592 participants were included in the analyses.

Statistical analysis was carried out using R statistical software and the packages nlme was used for linear mixed model. A linear mixed-model repeated measure framework was used to account for correlation between repeated measures in the same individual. Disease progression was modeled as follows:

\[
Y = \beta_1 [SNP \ast Time] + \beta_2 \ast \text{CDR}_{\text{baseline}} + \beta_3 \text{AGE}_{\text{baseline}} + \beta_4 \text{Gender} + \beta_5 \text{Education} \\
+ \beta_6 \text{SNP} + \beta_7 \text{Time} + \beta_8 \text{PC1} + \beta_9 \text{PC2}
\]

Where: Y was CDR-SB, the change in CDR Sum of Boxes per year baseline CDR, baseline Age, Gender, follow-up time, level of education, and, to avoid the possibility of spurious association due to population substructure, the two first principal components scores were included as covariates.

A portion of the human AD data were obtained from the Alzheimer’s Disease Neuroimaging Initiative database (http://adniloni.usc.edu). The ADNI was launched in 2003 as a public-private partnership, led by Principal Investigator Michael W. Weiner, MD. The primary goal of ADNI has been to test whether serial magnetic resonance imaging (MRI), biological markers, and clinical and neuropsychological assessment can be combined to measure the progression of mild cognitive impairment (MCI) and early AD. For up-to-date information, see www.adni-info.org.

Sample blinding and randomization for animal studies
Randomization

For biochemical assay and histological staining, the "RAND" function in EXCEL was applied to assign each sample a random number and sorted smallest to largest to generate random order. For gene expression assay, equal number of samples from each group were placed on each chip by complete randomization to avoid cross-chip variability.

Blinding

Quantification of brain volume, AT8 staining, p-tau patterns, and fluorescent staining were performed by individuals blinded to samples IDs. Microglial/astrocytic gene expression assays were performed by collaborators who were blinded to sample IDs. Cell culture images were taken and data quantified by individuals blinded to sample IDs.

References


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Lilly and Company; EuroImmun; F. Hoffmann-La Roche Ltd and its affiliated company Genentech, Inc.; Fujirebio; GE Healthcare; IXICO Ltd.; Janssen Alzheimer Immunotherapy Research & Development, LLC.; Johnson & Johnson Pharmaceutical Research & Development LLC.; Lumosity; Lundbeck; Merck & Co., Inc.; Meso Scale Diagnostics, LLC.; NeuroRx Research; Neurotrack Technologies; Novartis Pharmaceuticals Corporation; Pfizer Inc.; Piramal Imaging; Servier; Takeda Pharmaceutical Company; and Transition Therapeutics. The Canadian Institutes of Health Research is providing funds to support ADNI clinical sites in Canada. Private sector contributions are facilitated by the Foundation for the National Institutes of Health (www.fnih.org). The grantee organization is the Northern California Institute for Research and Education, and the study is coordinated by the Alzheimer’s Therapeutic Research Institute at the University of Southern California. ADNI data are disseminated by the Laboratory for Neuro Imaging at the University of Southern California.
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The Data and Publications Committee, in keeping with the publication policies adopted by the ADNI Steering Committee, here provide lists for standardized acknowledgement. The list consists of two parts: I. ADNI Infrastructure Investigators and Site Investigators and II. DOD ADNI Infrastructure Investigators and Site Investigators. Infrastructure Investigators represent the names responsible for leadership and infrastructure. Site Investigators represent the names of individuals at each recruiting site. All papers, including methodological papers, should have an acknowledgement list that consists of Infrastructure Investigators plus the FULL list.

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