Helping to accelerate AD therapy development with a **Proprietary Blood Test** for Alzheimer’s Disease (AD)

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www.nanosomix.com
**Mission:**
- Commercialize a blood test for identification and monitoring of AD and other neurologic disorders

**Technology:**
- Enrich and analyze brain derived biomarkers contained in Neural Derived Exosomes (NDE’s)

**Goal:**
- Provide investigators and therapy developers with a simple blood test to assess and monitor AD and other neurodegenerative diseases to speed development of effective therapies
Business Overview

Company Formation:
- Founded in 2014 based on work by Dr. Ed Goetzl

Business Model:
- Service Lab

Intellectual Property:
- 4 patents pending

Funding:
- Angel Funding to date
- Series A planned for late 2017/early 2018
Current Neurodegenerative Disease Diagnostics

Biopsy: \textit{Not Possible}

CT

MRI

PET

Image analysis: \textit{Too Expensive! ($5K+)}

Cerebrospinal fluid: \textit{Too Invasive! ($2K+)}

\textbf{Current diagnostic techniques aren’t practical \textit{for routine testing}}
NanoSomiX’ technology selectively enriches blood NDE’s using proprietary L1-Cam immunoaffinity technology and measures inclusive pathogenic AD proteins and biomarkers “Window to the Brain”

Exosomes:
Micro vesicles containing numerous biomarkers

**WHY VALUABLE?**

- Neural Derived Exosomes (NDE’s) cross blood brain barrier into blood
- Contents protected from degradation in blood by membrane

AD and MCI Patient NDEs Following Enrichment

- NDEs average ~ 7 to $10 \times 10^{11}$ particles per ml in patients
- AD & MCI NDEs average $89.75 \pm 2.15$ & $94.5 \pm 4.48$ nm in size

NDE P-T181 and P-S396 Tau Following MCI Conversion to AD

CNC= Controls (MMSE 27-30; CSF Aβ1 >190mg/ml)
MCI= Minimal Cognitive Impairment (MMSE >24, intact ADL)
ADC= MCI transitioned to AD over 36 months
AD= Alzheimer’s Disease (MMSE<20, Aβ1 <190mg/ml)

• Elevated NDE P-T181-tau & P-S396-tau correlate with advancing disease*
• Elevated blood NDE pTau levels observed up to 10 yrs prior to clinical AD**

**Fiandaca et. al. Alzheimer’s & Dementia 2014
Blood NDE Assay Applicable to Multiple Biomarkers

**PLATFORM POTENTIAL:**

Additional NDE markers further differentiate AD from Control:

- Drop in Synaptic proteins
- Uptick in Cathepsin D
- Drop in Insulin resistance
- Drop in GAP43 (growth assoc. protein 43)
- Uptick in Ubiquitin
- Uptick in LAMP1 (lysosome Assoc. membrane protein 1)

NRGN= Neurogranin (post synaptic nerve transmission)

REST= Repressor Element Silencing Transcription Factor (neuron Survival)

Winston, et.al., Alzheimer’s & Dementia, 2016
Goetzel et al. FASEB, 2016
Kapogiannis et al, FASEB 2015
Example of NSX Testing of AD & Control Plasma

Potential Clinical Application:

- Testing with well defined AD & Control plasma at NSX parallels published data
- NSX NDE assay measures 4 key pathologic biomarkers in plasma: P-T181-tau, T-S396-tau, Aβ1-42, & Tau

AD:
- MMSE < 28 (range 22-28), abnormal CSF Aβ1-42 levels
- Ages 67-82; half male-half female

Controls:
- Age and gender matched
- MMSE normal 3 to 5 years prior

EQ1:
- Normal plasma process control
NSX Direct™ Product Status

- Finalizing RUO certification in CLIA Lab
- Current tests: NDE content of Aβ1-42, Tau, p-tau T181 and p-tau S396
- Expansion of RUO NDE biomarkers in progress
- Working with several companies to test potential disease and treatment applications

Going Forward:

- Expand control and AD patient database to establish biomarker range and applicability
- Seeking partners to explore multiple neurologic disease applications
- Transition to LDT to support identification and monitoring of AD and other neurologic disorders
Thank You

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