

Technology Factsheet

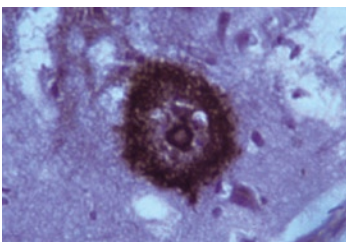
Novel treatments and early stage diagnostics for the prevention and cure of Alzheimer's disease



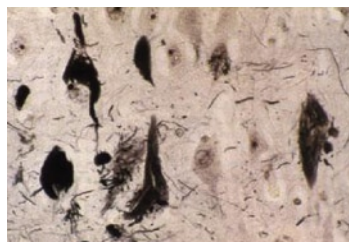
Improved Diagnostics

Despite being the most common form of dementia, there is presently no way to diagnose Alzheimer's disease in its early stages. Early diagnosis would provide the best chance for drug and other interventions to treat or slow the progression of the disease. The development of an effective and improved diagnostic method has the potential to minimise the enormous impact that Alzheimer's disease will have on health, quality of life and healthcare costs in coming years.

- Typical Alzheimer's Disease Pathology



Amyloid plaque



Neurofibrillary Tau Tangles



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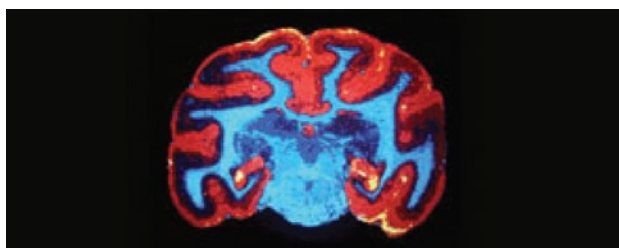
- Diagnostic Imaging Agent

The compounds being developed by Alzhy.me have the potential to be developed as molecular imaging agents for the clinical diagnosis of Alzheimer's disease. To accelerate this program of research, Alzhy.me has established a collaborative research agreement with the Australian Nuclear Science and Technology Organisation (ANSTO), Lucas Heights, NSW, to develop an analogue of ANA-5 as a radiopharmaceutical agent to image amyloid deposits in the brains of living patients.

Because ANA-5 binds to a specific site within the human beta-amyloid protein, with the successful radiolabelling of the compound, the potential exists for the development of an early diagnostic and imaging test for Alzheimer's disease, using either Positron Emission Tomography (PET) or Single Photon Emission Computed Tomography (SPECT) imaging techniques.

The project offers significant commercial potential for the early diagnosis of Alzheimer's disease by allowing:

- More accurate diagnosis of Alzheimer's disease early in the disease course and before significant memory loss occurs.
- Earlier and more appropriate treatment and management of Alzheimer's disease patients.
- Identification of mild cognitive impairment patients likely to progress to Alzheimer's disease.
- Monitoring the response to treatment with new amyloid targeted therapeutics.



PET Image of brain

- Diagnostic Blood Test

The pathological processes of Alzheimer's disease begin years before clinical symptoms are observed. With no marketed definitive diagnostic tests for Alzheimer's disease, clinical diagnosis of Alzheimer's disease is primarily based on subjective methods such as cognitive testing by physicians. There remains a considerable unmet market for a reliable, cost effective and minimally invasive test (e.g. blood test) that would allow early accurate diagnosis of Alzheimer's disease and result in improved patient treatment.

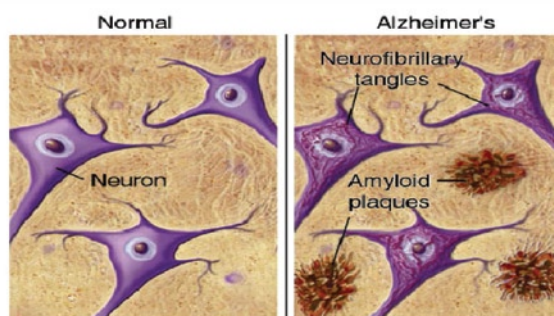
The aim of this project is to develop a minimally-invasive, low cost yet reliable diagnostic kit for the routine detection of disease biomarkers in blood serum.

Analysts predict that a diagnostic blood test for Alzheimer's disease would generate world-wide annual sales of US\$1 billion. Alzhy.me therefore has initiated a program of research based on the Company's proprietary technology to develop a blood test of serum based biomarkers for use in the early diagnosis of Alzheimer's disease. This technology puts Alzhy.me ahead of its competitors as this approach provides greater sensitivity and specificity in the creation of an accurate blood test. Additionally, such a test would improve clinical trials by facilitating better patient recruitment, providing a more accurate diagnosis of the disease and monitoring of drug efficacy.

Disease Modifying Treatments

- Alzheimer's Disease

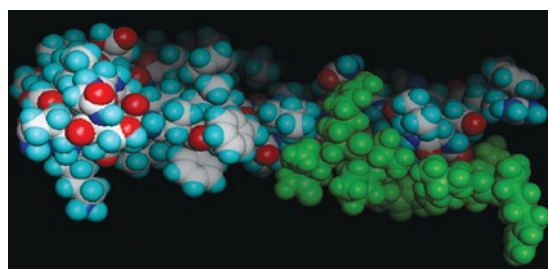
Alzheimer's disease is characterized by the presence of insoluble deposits called senile plaques in regions of the brain that are associated with memory. These plaques are composed of a protein called beta-amyloid, which in high levels is extremely toxic to brain cells. There is now overwhelming evidence that over production and accumulation of beta-amyloid in the brain is central to the pathogenesis of Alzheimer's disease and leads to the destruction of brain cells resulting in a deterioration of mental function. This has been called the "*Amyloid Cascade Hypothesis*".



(Source: <http://www.ahaf.org/alzdis/about/AmyloidPlaques.htm>)

Alzhy.me has used its proprietary intellectual property to generate a selection of potentially therapeutic peptides that specifically neutralise the damaging potential of beta-amyloid. The Company has used innovative screening from focused compound libraries and medicinal chemistry strategies to identify novel peptides that target beta-amyloid. A screening method (involving phage display technology) has identified a family of compounds that specifically bind human, but not rat, beta-amyloid.

Two peptides in particular, ANA-1 and ANA-5, were found to prevent beta-amyloid-induced neurotoxicity. In a rat model of beta-amyloid-induced neurotoxicity treatment with ANA-1 was found to enhance the clearance of beta-amyloid from the brain. In a subsequent proof-of-concept study, treatment with ANA-5 significantly reduced brain beta-amyloid plaque levels by 28% in the PS/APP transgenic mouse model of Alzheimer's disease.



Schematic representations of ANA-1 peptide (shown in green) binding to SOD-like activity site of beta-amyloid.

ANA-5 represents a new and promising therapeutic class of drug in development as a treatment for Alzheimer's disease. The Company is currently developing ANA-5 for the treatment of Alzheimer's disease. Alzhy.me has entered into a research collaboration with the Commonwealth Scientific and Industrial Research Organisation (CSIRO), one of the world's largest scientific research organisations to undertake a lead optimization program to develop an oral available analogue of ANA-5.

- Other Indications

The compounds being developed by Alzhy.me could also potentially target other amyloid related diseases, such as the orphan disease Inclusion Body Myositis, an age-related muscle disease caused by amyloid toxicity in muscle cells.