*Our research group is developing a **cost-effective** molecular kit based on the analysis of a **miRNA signature** as non-invasive **blood-biomarker** for early diagnosis of Alzheimer's disease.*

INTRODUCTION

We are neuroscientists and neurologists with strong experience in neurodegenerative diseases from Institute of Neurosciences at Universitat Autònoma de Barcelona (UAB), Memory Unit at Hospital de Sant Pau, Barcelona and the Spanish network biomedical research center in neurodegenerative diseases (CIBERNED).

OUR ASSAY provides a feasible detection technique from obtaining a simple blood sample, miRNA extraction and qPCR using standard methods and equipment with easy results collection and interpretation. All that through non-invasive procedures, suitable for routine screening at a reference laboratory or hospital and with medical cost strongly diminished. Thus, we broad therapeutic window, reduce medical health cost and offer new possibilities for patients and caregivers.

Recently, after years of efforts, a new treatment to fight against Alzheimer's Disease (AD) has appeared, ADUHELM™ (aducanumab-avwa) from Biogen. Despite the generated doubts, it seems to delay AD progression. The current problem is to diagnose early and present biomarkers are expensive, time-consuming and without the capacity to test everyone potentially elegible for aducanumab. An earlier diagnostic tool becomes more necessary.

OUR GOAL is to develop a cost-effective molecular assay based on the analysis of a miRNA signature as non-invasive blood-biomarker for early AD. A simple blood test for molecules that may indicate signs of disease in the brain opening the possibility to offer a potential companion-diagnostic assay.

DIAGNOSTIC PLATFORM

Our miRNA-based platform is designed to quick, specific and direct diagnose of early Alzheimer's disease through a cost-effective protocol/assay for routine screening that could be implemented as a kit ready to be currently used in the analysis laboratories of hospitals worldwide.

The platform relies on the detection and analysis of the three synaptic-related miRNAs (miR-92a-3p, miR-181c-5p, miR-210-3p) in blood sample as a specific biomarker for eAD at early stages that may be also used to predict the progression from MCI to AD. Thus, this signature could not only be a good diagnostic marker but also might be a good prognostic tool.

International priority patent was registered in 2019 (PCT/EP2019/065458) protecting not only the miRNAs from our signature but also all the components needed for their measurement in blood samples and the future molecular kit that will be used for the tests. In 2020 national phases were presented to protect our asset in US and Europe.

Our miRNAs signature has three major advantages:
a) Our molecular signature is targeting synaptic proteins and this is a relevant aspect since it is considered that synaptic dysfunction is an early event in AD development;
b) We can differenciate between MCI subjects that will or will not develop AD, predicting MCI to AD transition and;
c) Our molecular signature discriminate eAD among others forms of dementia.

Our group has amassed a multi-country and multi-center repository of > 600 heterogeneous samples together with a large amount of analytical and clinical data for each patient. Combined with our group active international network of foundations, hospitals and biobanks globally, this sample repository is a key strategic advantage to the research group.

Our experienced scientific group structures, designs and defines all of its R&D activities while working closely with partners at prestigious institutions leveraging their know-how, scale, equipment and facilities. Core partners include Hospital de Sant Pau, Fundación ACE and Fundación Princesa Sofia/Fundación CIEN.

INSTITUTIONS

Websites:
https://inc.uab.cat/en
https://ciberned.es/en/

HQ:
Barcelona (Spain)

DIAGNOSTIC FOCUS

Early Alzheimer's Disease (eAD)

Mild Cognitive Impairment (MCI)

Alzheimer's Disease (AD)

MANAGEMENT TEAM

Alfredo J. Miñano-Molina, PhD.
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UAB Full Professor
AECM Visiting Professor

Alberto Lleó, MD, PhD.
Neurologist
Head of Memory Unit
Hospital Sant Pau, UAB

FINANCIAL NEEDS
(next year)

550,000.00€ - PoC validation
(> 600 new patients samples)

650,000.00€ - LDT/IVD device
(prototype design)

CONTACT DETAILS

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CLINICAL PARTNERS

Sant Pau memory unit

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ace alzheimer center BARCELONA

FUNDACIÓN REINA SOFÍA

cien Fundación Centro de Investigación Enfermedades Neurológicas

EINSTEIN Albert Einstein College of Medicine

Montefiore

NYU Langone Health

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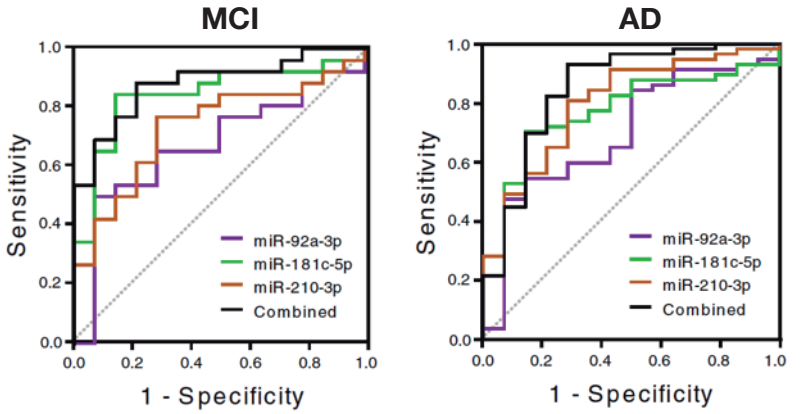
miRNA SIGNATURE SCREENING TEST

We envision to develop a protocol/assay to detect our miRNA signature for routine screening that could be implemented as a kit to diagnose early AD. This devastating disease affects more than 50 million people worldwide and it is expected to reach 152 millions by 2050. Only one disease-modifying therapy exists (ADUHELM™) and a large number of anti-AD drugs failed in clinical trials.

Today, AD can only be clinically diagnosed at late stages when damage has already spread to several brain areas difficulting that therapeutic approaches could be effective. Few biomarkers are used for preclinical AD diagnosis obtained by positron emission tomography (PET) or in cerebrospinal fluid (CSF), but they are not suitable for routine clinical screening because their complexity, economical cost and invasiveness.

Our miRNA signature will offer a tool to solve this problem, allowing an earlier diagnostic of AD at prodromal stages by using a simple blood sample collected as part of a routine check-up, samples can be processed at a reference laboratory or hospital using standard laboratory equipment.

Most recent results of our synaptic-proteins related miRNAs (miR-92a-3p, miR-181c-50 and miR210-3p) presents a sensitive and selective biomarker for early AD stage (eAD) detection and a good predictor of whether MCI is likely to progress to AD.



SENSITIVITY

MCI 84.62%
AD 92.86%

SPECIFICITY

MCI 85.71%
AD 71.43%

miRNA SIGNATURE MARKET AND POSITIONING

Future Alzheimer's diagnostic market consists of ~ 700 million people more than 60 years in the world (near 10%), 20% in the EU and 16,5% in the US. Population is aging and future medicare annual wellness check should include a cognitive evaluation and exploring diagnosis years before symptoms appear. This translates into a growing adressable annual market of ~ $9,9 Bn at a 5.4% CAGR (2021-2028).

To make miRNA signature widely available, we intends to validate and develop it as a LDT/IVD assay. It will be suitable for clinical use that would complement other systems under development.

We will focus on differenciated segments: biopharmaceutical companies, physicians and other healthcare providers, hospitals and health systems and independent clinical laboratories and insurance companies.

ACTION PLAN

Our team has clearly defined priorities going forward:

1 - We are going through the process of creating the Startup ***Sigearly Diagnostics*** where we will develop our portfolio products to early diagnose neurodegenerative diseases based on miRNAs-containing molecular signatures.

2 - We are developing a market research studying competitors, price structure and planning stakeholder's interviews to carry out a business plan.

3 - We are performing a regulatory roadmap to validate our diagnostic assay with the requeriments of regulatory authorities (EMA, FDA).

4 - We are conducting a deep research of partners and commercialization activities in order to find new possible investors.

FINANCIAL HIGHLIGHTS

Since 2017, research group has received funding (~750M€) to investigate the role of miRNAs in AD and others neurodegenerative diseases.