Innovation Portfolio
14MBC001

Alzheimer's disease (AD) early detection technology

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HIGHLIGHTS

- ✓ **Optimizing patients' recruitment in clinical trials**
- ✓ **Early AD detection in the clinical practice**
- ✓ **Test based in blood biomarkers**

TECH STATUS

- ✓ **TRL: Clinical Proof-Of-Concept**
- ✓ **IP: N. Phase On Progress (ES, EP, US, CA, AU, JP, BR) EP3124621**

Problem to be solved

Alzheimer Disease (AD) is an unmet medical need. Current pharmacological treatments are symptomatic and low effectives without the existence of a curative therapy. There is not any diagnostic test implemented in the clinical practice yet.

Background

AD is considered a slowly progressive brain disease that begins about 20 years before clinical symptoms emerge. Mild cognitive impairment (MCI) patients are considered a prodrome of AD, and 15% of diagnosed MCI progress to AD per year.

Nonetheless, the main line of detection of dementia symptoms is performed in primary care by non-pharmacological approaches due to the cost and complexity of current medical analysis that requires to be performed in hospital environment.
The early susceptibility detection would optimize patients' recruitment for clinical trials, increasing the probability of new drugs registration.

Technology

Our diagnostic test represents the determination of biomarkers non-related with β-amyloid nor tau. Therefore, our unique value proposition is that our test is based on an epigenetic analysis in blood samples, covering the analysis of a large number of methylcytosines in mtDNA by next generation sequencing. As systemic mitochondrial dysfunction has been proposed just before the appearance of cerebral abnormal protein aggregates, our findings may become a pool of biomarkers very useful for the detection of patients at early stages of AD.

Applications

All clinical trials have failed because patients' recruitment has been performed at advance stages of the disease. Therefore, Pharmaceutical Companies are our potential clients at short-term, in order to optimize patients' recruitment in current clinical trials, as well as, to reanalyze finished clinical trials in order to identify effective drugs that have been discarded.

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IDIBELL Technology Portfolio

As a second step, the technology should be easily introduced in national health systems and private medical insurances.

Technology status

The group has robust data on the target validation obtained in the lab. It also has non-regulatory preclinical studies and first clinical proof-of-concept of target.

IP status: patent ongoing in national phases (Europe, USA, Canada, Brazil, Japan and Australia).

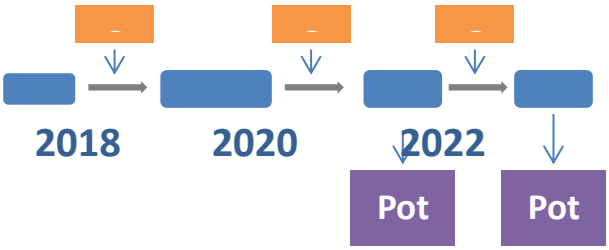
Market Opportunity

AD is an unmet medical need due to impossibility of an early diagnosis and treatment. More than 47 M people are affected worldwide and the incidence will increase in the following years due to the increase in lifespan (130 M patients in 2050 is estimated). There is an AD infra diagnostic in Spain and Europe (above all in mild phase) and it is established with a delay about 12-24 months after the first symptoms. This aspect reduces quality of life in patients and caregivers. Moreover, according to experts, AD market will grow from $5.7 billion to nearly $19 billion by 2022 in nine major pharmaceutical markets (US, UK, France, Germany, Italy, Spain, Japan, China, and Brazil).

Business Opportunity

ADmit Therapeutics is seeking a company partner to further develop the technology through a co-development and/or investment.

The business model of ADmit Therapeutics will be based in an acquisition after obtaining the CE mark of the IVD or after launching the product into the market, achieving the first sales. In this moment, the acquisition can be feasible by a big Medtech or Big Diagnostic company:



Another potential scenario which will be also feasible is based in the out-licensing of the product to those big third parties. The license agreement should include upfront payment, milestones associated to product development (e.g. obtaining of FDA clearance) and royalties on net sales. This should be reinforced by the fact that ADmit Therapeutics wishes to create a portfolio of projects (diagnosis of Parkinson's disease and Dementia with Lewy Bodies). The first one to be out-licensed should be the IVD test for early AD diagnosis.

On top of that, ADmit Therapeutics will provide diagnostic services to pharmaceutical companies aiming to conduct clinical trials enrolling AD patients.

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