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AB Science and its partners receive €8.6 million as part of a project supported by Bpifrance (ex-OSEO) for the development of a new therapy in Alzheimer's disease

AB Science SA (NYSE Euronext – FR0010557264 – AB), a pharmaceutical company specialized in research, development and marketing of protein kinase inhibitors (PKIs), announces the creation of a partnership in the development of a new targeted therapy in Alzheimer's disease.

The consortium will receive €8.6 million from Bpifrance (the French state innovation agency) within the framework of the Industrial Strategic Innovation (ISI) program, and gathers together **AB Science**, the Brain and Spine Institute (**ICM**), MIRCen from the Atomic Energy Commission (**CEA**), the National Institute of Health and Medical Research (**INSERM**), **Imagine** Foundation and **Skuldtech**, a biotechnology company specialized in the discovery of biomarkers and development of diagnostic and testing tools companions.

AB Science, initiator and leader of this project entitled ROMANE (**Ro**le of **Ma**st Cells in **Ne**urology), will receive a total amount of €5.9 million from Bpifrance in the form of grants and repayable advances.

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The three main objectives of the ROMANE project are to:
- Validate the role of mast cells as a therapeutic target in neurodegenerative diseases, including Alzheimer's disease.
- Develop a targeted therapy, masitinib, in Alzheimer's disease.
- Propose new tools for diagnosis and monitoring of patients with Alzheimer's disease on the basis of blood biomarkers and new imaging techniques.

Mast cells as therapeutic targets in neurodegenerative diseases

Mast cells, which are key immune cells, are present in large quantities in the brain and in the spinal cord, especially around the blood vessels. There is evidence suggesting that mast cells play a major role in the passage of inflammatory cells from the blood into the brain. Since there are many arguments implicating a neuro-inflammatory component in the early stages of Alzheimer's disease, it is possible that mast cells significantly contribute to the development of the neuro-inflammatory process in Alzheimer's disease.

The functional activity, migration and survival of mast cells can be modulated by masitinib, a tyrosine kinase inhibitor, via the inhibition of c-Kit and Lyn, two kinases specifically expressed in mast cells.

INSERM, ICM, MIRCen/CEA and AB SCIENCE will conduct research on preclinical models to assess:
- The role of mast cells in Alzheimer's disease.
- Masitinib's effect on the symptoms of Alzheimer's disease.

These results are anticipated to confirm the clinical benefit of masitinib in Alzheimer's disease, and provide better understanding on the mechanism of action of masitinib in this pathology.

Development of a targeted therapy in Alzheimer's disease

Within the framework of this project, AB SCIENCE will conduct a phase 3 study of masitinib in Alzheimer's disease, which is already currently recruiting patients. In addition to blocking mast cell activity, masitinib may exert an effect on other pathways:

- By modulating the production of β-amyloid peptides at the origin of senile plaques, which are characteristic of Alzheimer's disease. In fact, PDGF-R kinase increases the expression of gamma-secretase, an enzyme involved in the production of β-amyloid peptides. Masitinib, by blocking PDGF-R, could thus regulate amyloid synthesis.

- By modulating the production of hyperphosphorylated tau protein, the major component of neurofibrillary tangles in the brain of patients with Alzheimer's disease. In fact, the tau protein in neurofibrillary tangles is abnormally phosphorylated by the tyrosine kinase Fyn. Masitinib, by blocking Fyn, could then help to inhibit the phosphorylation of tau protein and thus prevent neurofibrillary tangles.

The phase 3 study of masitinib in Alzheimer's disease was initiated based upon promising results obtained from a previous phase 2 study, in which masitinib was administered as an add-on therapy to standard care during 24 weeks. Data indicated that masitinib was capable of retarding the rate of cognitive decline of Alzheimer's disease as compared against placebo, with an acceptable tolerance profile. Improvement in cognitive function and functional capacity was seen in the masitinib treatment group, as evident through the sustained and statistically significant response in ADAS-Cog, as well as the mean change in ADAS-Cog and ADCS-ADL values relative to baseline. The phase 2 results have been published: Alzheimers Res Ther. 2011 Apr 19;3(2):16. doi: 10.1186/alzrt75.

New assessment tools for diagnosis and monitoring of patients

The third part of this project focuses on the development of imaging markers and genetic biomarkers so that simple and objective tools can be used routinely for the diagnosis and monitoring of patients suffering from Alzheimer's disease.

Thus, MIRCen/CEA, IMAGINE and AB SCIENCE aim to explore the correlation between response or non-response to masitinib treatment, assessed via validated cognitive parameters and the following diagnostic measures:

- The cerebral perfusion of patients according to MRI/ASL (Arterial Spin Labeling) and according to another imaging technology based on the administration of a NMR contrast agent (fast stationary method by T1 effect - RSST1);
- The load evolution of amyloid plaque via the "gadolinium staining" imaging technique with contrast agent.

Finally, Skuldtech, a biotechnology company specialized in the discovery of biomarkers and development of diagnostic tools and companion tests, will use the blood samples collected during the clinical phase conducted by AB SCIENCE, to develop predictive companion tests, based on genetic biomarkers that will predict response or non-response to the treatment. Based on additional blood samples, Skuldtech will also develop in this project a diagnostic test for the evaluation and confirmation of Alzheimer's disease development stage.

About Bpifrance's "Industrial Strategic Innovation" Program

The "Industrial Strategic Innovation" program (ISI) encourages the emergence of European champions of innovation. It supports ambitious collaborative innovative projects with an industrial purpose, run by companies of a medium size (fewer than 5,000 employees) or SMEs (fewer than 250). These projects are considered highly promising in the event of success: they aim at marketing the products of breakthrough technologies that could not succeed without public support. The aid is generally of an amount between 3 and 10 million euros in the form of repayable advances and grants.

About Alzheimer's disease

Alzheimer's disease is the most frequent neuro-degenerative disease in the world, affecting approximately 6% of people aged over 65 years, i.e. 850,000 people in France. The disease represents an important medical need. In fact, Alzheimer's disease is associated with an elevated risk of death. In the United States, Alzheimer's disease is the sixth-leading cause of death across all ages. Regardless of the cause of death, 61% of people diagnosed with Alzheimer's disease at age 70 are expected to die before age 80 compared with 30% of people at age 70 without Alzheimer's disease. In particular, the inability in late-stage Alzheimer's disease to move around can make a person more vulnerable to infections, including pneumonia which can be fatal.

Alzheimer's disease is characterized by the appearance of lesions that gradually invade and destroy brain neurons, resulting in progressive cognitive decline and memory. The two types of lesions are the amyloid deposits in the brain parenchyma (amyloid plaques) or blood vessels (amyloid angiopathy), and neurofibrillary tangles. Besides these lesions, inflammation contributes to alter neurons. No treatment which stops or reverses the disease process is available so far.

About masitinib

Masitinib is a new orally administered tyrosine kinase inhibitor that targets mast cells, important cells for immunity, as well as a limited number of kinases that play key roles in various cancers. Owing to its novel mechanism of action, masitinib can be developed in a large number of conditions in oncology, in inflammatory diseases, and in certain diseases of the central nervous system. Through its activity of inhibiting certain kinases that are essential in some oncogenic processes, masitinib may have an effect on tumor regression, alone or in combination with chemotherapy. Through its activity on the mast cell and certain kinases essential to the activation of the inflammatory cells and fibrosing tissue remodeling, masitinib can have an effect on the symptoms associated with some inflammatory and central nervous system diseases.

About AB Science

Founded in 2001, AB Science is a pharmaceutical company specializing in the research, development and commercialization of protein kinase inhibitors (PKIs), a new class of targeted molecules whose action is to modify signaling pathways within cells. Through these PKIs, the Company targets diseases with high unmet medical needs (cancer, inflammatory diseases, and central nervous system diseases), in both human and veterinary medicines.

AB Science has developed a proprietary portfolio of molecules and the Company's lead compound, masitinib, has already been registered for veterinary medicine in Europe and in the USA, and is pursuing nine on-going phase 3 studies in human medicine in GIST in 1st and 2nd line of treatment, metastatic melanoma expressing JM mutation of c-Kit, multiple myeloma, mastocytosis, severe persistent asthma, rheumatoid arthritis, Alzheimer disease and progressive multiple sclerosis. The company is headquartered in Paris, France, and listed on Euronext Paris (ticker: AB).

For more information: www.ab-science.com.

About Skuldtech

Founded in 1999, Skuldtech is a biotechnology company specialized in the discovery of new biomarkers and the development of new diagnostic and companion tests. Biomarkers identified and selected by the company's research team are derived from its technology platform, which combines high throughput sequencing, quantitative RT-PCR, and proprietary bioinformatics and biostatistics programs, representing 13 years of development and technical expertise in the analysis of gene expression. Thanks to its unique scientific expertise in the analysis of gene expression of blood cells and "total" blood, Skuldtech is positioned in the field of personalized medicine and of the development of companion tests and of patient stratification tests, to meet the growing need for new treatments best suited to patient profiles.

For more information: www.skuldtech.com

About MIRCen/CEA
MIRCen-Molecular Imaging Research Center is a service of preclinical research at CEA created to develop and evaluate innovative therapies (gene and cell therapy and medication) for neurodegenerative diseases in particular. These research programs are based on expertise in the fields of animal models engineering, in vivo and in vitro imaging and translational research. MIRCen is open to academic and industrial collaboration platform. Finally, the unit coordinates the infrastructure for translational research biotherapy called NeurATRIS, which is the French contribution to the European translational research infrastructure EATRIS.
For more information: www-dsv.cea.fr/dsv

About ICM
Established in Paris at the initiative of Professors Gerard Saillant, Yves Agid and Olivier Lyon-Caen, the Institute for Brain and Spinal Cord is the realization of a new model for research in neuroscience. Installed at the Pitie-Salpetriere hospital, this international research institute of 22,000 m2 is unique in the heart of the nursing process. Governments, businesses and donors join hands together to allow patients, physicians and the most prominent researchers from around the world to work together to find new treatments for diseases of the nervous system.
For more information: www.icm-institute.org

About INSERM
The U1068 is part of the Center for Cancer Research Marseille (CRCM) of INSERM, located within the campus of the Institut Paoli-Calmettes, the anti-cancer Marseille regional center. The CRCM has more than 160 people, researchers (INSERM and CNRS), ITA INSERM, PH (doctors and pharmacists) and hospital technical staff (CPI) as MCU and PU-PH, doctoral and post-doctoral students. As critical mass is reached, interactions and complementarities between the teams have shown a strong ambition to cancer research, contributing to knowledge in basic research in selected areas, but also to the transfer and applications of these results to the patient, and in return, to clinicians questioning.
For more information: crcm.marseille.inserm.fr

About Imagine Foundation
Imagine is a unique place on the cutting edge of technology with the aim to better understand the genetic diseases and to provide faster diagnostic and therapeutic solutions as expected by patients and their families. The Imagine Foundation aims to lead a project to medical and scientific excellence in organizing, structuring and developing the site of the Necker Hospital for Sick Children in Paris, the research, care and education on genetic diseases of child and adult.
For more information: www.institutimagine.org

This document contains prospective information. No guarantee can be given as for the realization of these forecasts, which are subject to those risks described in documents deposited by the Company to the Authority of the financial markets, including trends of the economic conjuncture, the financial markets and the markets on which AB Science is present.

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