

Alzheimer's disease acquires a growing role in Grifols R&D

Grifols has acquired 51% of the capital of Araclon Biotech to ensure the viability of the purchased company projects

- *Araclon Biotech, established in 2004 as a spin-off from the University of Zaragoza, is dedicated to the research and development of therapies and diagnostic methods for Alzheimer's disease (AD)*
- *Grifols has become one of the company's owners through a 51% shareholding owned by Gri-Cel S.A., an investment vehicle created in 2010 to promote the group's participation in research initiatives in new fields of medicine*
- *The biotech company based in Aragon, Spain is validating kits which could help in the early diagnosis of the disease, and is developing a vaccine for Alzheimer's disease*
- *During recent years, Grifols has been at the forefront of some of the most innovative research into the treatment of AD. It is currently performing a new medical trial for the treatment of plasma derivatives*

Barcelona, March 15, 2012: Grifols (MCE:GRF, MCE:GRF.P and NASDAQ:GRFS), the world's third largest plasma product manufacturer and a pioneer in the research and development of therapeutic alternatives designed to contribute to both scientific and social development, has acquired 51% of the equity of Zaragoza-based company Araclon Biotech, ensuring the viability of its projects and the future of the company.

Araclon Biotech was created in 2004 as a spin-off from the University of Zaragoza, and specializes in the research and development of therapies and diagnostic methods for neurodegenerative diseases, although it is currently focusing on Alzheimer's disease (AD), a condition for which there is no cure and of which there are around 350,000 to 380,000 sufferers in Spain¹ and over 25 million in the world².

¹ Prevalence data from the study coordinated by Dr. Jesús de Pedro of the Centro Nacional de Epidemiología.

² Source: Alzheimer's Association and Alzheimer's Disease International.

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Grifols completed the operation by acquiring a stake in the company through Gri-Cel S.A., an investment vehicle created in 2010 to promote the group's participation in fields of medicine which lie outside the scope of its main activities, such as advanced therapies.

Following the purchase, Grifols has become Araclon Biotech's largest shareholder, with a 51% holding, while other founding partners retain 49% of the capital.

The addition of Grifols to the shareholders of Araclon Biotech will guarantee the company's future and enable it to continue to promote its R&D projects, focusing in particular on two research lines:

1. **The diagnosis of AD:** Using a kit patented for the detection of amyloid beta peptides (A β) 40 and 42 in the blood. Araclon Biotech is performing clinical studies with more than 400 individuals, the final results of which it is hoped will contribute to the development of a tool with 3 major applications: The early detection of AD (including in individuals with no symptoms) to monitor patients being treated for Alzheimer's disease and to improve the design of clinical trials on Alzheimer's disease.
2. **Treatments of AD:** Based on immunotherapy. Research focused on developing a series of patented vaccines which have yielded positive results in various animal models and on which clinical trials will start soon.

Araclon Biotech also plans in the future to pursue a number of research initiatives in other neurodegenerative diseases related to illnesses such as vascular dementia, fibromyalgia and multiple sclerosis.

Araclon Biotech does not currently have any products on the market, although its ABtest is available to the scientific community for use in research studies.

The participation of Grifols as a leading shareholder of Araclon Biotech will generate synergies for the group, strengthening the development of some business lines of the Diagnostic division and giving it a presence in the vaccine sector. It also complements other Grifols research projects linked to the search for solutions which promote new diagnostic and therapeutic approaches to Alzheimer's disease including, specifically, a treatment for AD based on plasma derivatives. As a result, the importance of this neurodegenerative disease within the group's overall R&D strategy has grown.

A firm commitment to the search for solutions to Alzheimer's disease: Grifols medical trials

During recent years, Grifols has been at the forefront of some of the most innovative research in the search for solutions for AD.

These include the recent launch of a second medical trial for the treatment of Alzheimer's disease with plasma derivatives. This new approach involves

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combining hemapheresis treatment ³ with the administration of albumin and intravenous immunoglobulin (IVIG), two of the main plasma derivatives, at different intervals and in varying doses. 300 Alzheimer's patients with mild to moderate symptoms, divided into 3 treatment groups, plus a fourth control group. In total, approximately 400 patients from both Spain and the United States.

In addition, in September 2009 Grifols published preliminary results of another trial performed with the participation of three hospitals in Spain and two in the United States with 42 patients with Alzheimer's. These intermediate results, which are being confirmed by the final stages of the study, suggest a tendency to stabilize the illness in patients receiving treatment, and for this reason Grifols decided to extend this research by conducting a clinical trial which got under way recently.

Araclon Biotech and Grifols: Spanish R&D in the fight against Alzheimer's disease

The medical trials promoted by Grifols and its investment in Araclon Biotech reflect the group's commitment to R&D, exploring a range of complementary research which could be translated into treatment for patients with Alzheimer's disease.

Araclon Biotech's experience so far has been positive, both with regard to the development of a useful, effective test which contributes to the early diagnosis of AD, and with regard to efforts to find a vaccine to treat the condition.

- **With respect to the diagnosis of AD, Araclon is working to develop the ABtest40 and ABtest42 kits**

ABtest is based on scientific evidence which supports the existence of a relationship between levels of amyloid beta peptides (Pool A β) in the blood and the development of AD. ABtest 40 and ABtest 42 are kits which enable the detection of amyloid beta peptides A β 40 and A β 42 in the blood using ELISA colorimetric techniques improved by the company. Innovations by Araclon Biotech means that the sensitivity levels, detection rates and reproduction capacity are greater than those of any other product on the market.

To date, Araclon Biotech has performed 2 studies on 40 and 128 patients, with the aim of obtaining preliminary data on the diagnostic capacity of the ABtests and their predictive efficacy in different population groups, and is completing a third study with 255 individuals to validate the earlier results in a larger population sample. The aim of this study is to determine the risk of progression towards AD among patients with mild cognitive impairment (MCI).

³ Apheresis is a technique by which blood is separated out into its different components such as plasma, red blood cells, platelets and other cells. In this case, a quantity of plasma similar to that obtained by plasmapheresis is collected, with the difference that the plasma obtained is replaced with albumin. The cells are injected straight back into the patient, enabling rapid recovery.

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- **Development of vaccines as treatment for AD: ABvac**

Araclon Biotech has also developed and patented a treatment based on an innovative active immunotherapy (vaccine) for amyloid beta peptides 40 and 42. So far the group has tested formulations of its vaccines in animal models and is awaiting approval to start clinical trials.

In general terms, the trials performed so far have produced promising results in terms both of efficacy and of safety. No toxicity has been observed, and there has been a correct immune system response, with the production of anti-A β antibodies and evidence of active immunization.

About Alzheimer's disease

Alzheimer's disease is viewed as an epidemic of the 21st century affecting the elderly population in the developed world. According to the *Alzheimer's Association*, the disease affects 10% of those aged over 65, and up to 25% of people aged over 85, although only between 2% and 7% of cases are diagnosed at the early stages.

In the United States there are about 4.5 million patients, and it is estimated that by 2050 there could be some 15 million. At the same time, the direct and indirect health costs associated with caring for patients amounts to 85,000 million euros per year in the United States alone⁴.

In Spain, the situation is similar to that of other developed countries. The prevalence of the disease in Spain is currently estimated at between 350,000 and 380,000 cases, according to the team led by Dr. Jesús de Pedro of Spain's National Epidemiology Center. Expenditure linked to dementias, including AD, totaled approximately 14,000 million euros per year in 2010 (18,000 million dollars)¹

However, taking into account the fact that Alzheimer's disease primarily strikes people aged 65 years or older and that the proportion of sufferers rises with age, the phenomenon of aging populations tends to lead to a gradual increase in the total number of patients. Indeed, medium and long-term forecasts estimate that in 25 years time the population with Alzheimer's disease could grow by around 75% if current trends continue.

About Grifols and Gri-Cel

Grifols is a Spanish group, specializing in the hospital-pharmaceutical sector, and with a presence in over 100 countries. Since 2006, Grifols ordinary (Class A) shares have been listed on the Spanish Continuous Market and it has been included in the Ibex-35 (GRF) since 2008. Since 2011, non-voting Grifols shares (Class B) have also been listed on the Spanish Continuous Market (GRF.P) and on the NASDAQ (GRFS) via ADRs (American Depositary Receipts).

Grifols today is the world's third largest producer of plasma derivatives by capacity and is the sector's largest European company, with a balanced and diverse range of products.

⁴ Data from the study "Alzheimer's & Dementia 6 (2010) 98-103" conducted by the Karolinska Institutet-Alzheimer's Disease Research Center and i3 Innovus (Sweden)

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The group will strengthen its position within the industry as a vertically integrated company, on the basis of its completed and additional planned investments. In terms of raw material, Grifols is the leading plasma collection company, with supplies assured via its network of 147 plasmapheresis centers in the United States, while its production plants in Spain and the United States ensure that it has the fractionation capacity to satisfy rising demand.

Geographic diversification is one of the key elements of the group's strategy for growth, and it has a major presence in the United States, Canada and Europe, together with a strong commitment to R&D, to which it allocates approximate 5% of sales revenue. Grifols holds a large number of patents and has a range of research projects under way, of which more than a dozen have passed the preclinical development stage.

Gri-Cel S.A. is the company through which Grifols participates in joint R&D projects and companies, in areas of medicine other than plasma derivatives, such as advanced therapies. As a Grifols investment vehicle it currently has shares on Nanotherapix (60% equity share) and Araclon Biotech (51% equity share).

About Araclon Biotech

Founded in 2004, the company was created to develop a large-scale research project into the diagnosis and treatment of Alzheimer's disease. The project, which arose at the University of Zaragoza, has been led from the start by Professor Manuel Sarasa, current Scientific Director of Araclon Biotech.

Araclon is a company dedicated to the research and development of therapies and methods for the diagnosis of degenerative diseases. It currently has four projects under way: One in the diagnosis of Alzheimer's disease (where it has already patented a kit for the detection of blood levels of amyloid beta 40 and 42), another for the treatment of Alzheimer's disease (based on immunotherapy), an emerging project which seeks to address the challenge of predicting Alzheimer's disease in asymptomatic individuals.

Araclon holds a number of patents, including a European patent for the treatment of Alzheimer's disease and another for its diagnosis.

www.araclon.com – www.grifols.com

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Royal Decree-Law 5/2005, of March 11, and/or Royal Decree 1310/2005, of November 4, and its implementing regulations.