

Una manera de hacer Europa



BUENAS PRÁCTICAS

Actuaciones Cofinanciadas

LINE OF "AID TO R & D PROJECTS", CALL 2015.
Sector of BIOMEDICINE.
ANSABERE SURGICAL, SL and PALO BIOPHARMA, SL

Programa Operativo de Navarra

Año 2018

Fondo Europeo de Desarrollo Regional

LINE OF "AID TO R & D PROJECTS", CALL 2015. Sector of BIOMEDICINE. Particularized in the following companies: ANSABERE SURGICAL, SL and PALO BIOPHARMA, SL

Navarra is a benchmark in the research, development and services of biomedicine, as well as in the provision of specialized health services capable of attracting patients and professionals from outside the Autonomous Community, with a young and innovative industry in the manufacture of medicines, medical devices and health technologies.

The R + D Service of the Government of Navarre, with its line of 'Aid for R & D projects', aims to encourage the implementation of research and development projects by companies, with the purpose of promoting a technological improvement in companies, as well as encourage cooperation between companies and the hiring of universities and technology centers for the execution of these projects, all aimed at achieving an increase in the competitiveness of the company by encouraging the investment of own resources in the projects.

Two companies from the biomedicine sector, which have participated in different modalities (individual and carried out in collaboration between several companies), have been chosen as examples of good practices, in projects co-financed with FEDER funds, through this 2015 call for Grants to R & D projects.



ANSABERE SURGICAL, SL it is a reference company in its sector, dedicated to the design, manufacture and commercialization of surgical instruments. His individual R & D project consists on the design and development of a new device that aims to facilitate access and visibility for the surgeon when performing cardiac surgery.



PALO BIOPHARMA, SL it is a biotechnology company, dedicated to the research, manufacture, marketing, distribution and sale of pharmaceutical products. The project in which it has participated in collaboration with IDIFARMA DESARROLLO FARMACÉUTICO, SL, aims to advance the development of an oral medication for glaucoma, alternative to current treatments based on drops that are applied directly to the eyes.

The total cost of ALL the projects CO-FINANCED BY THIS LINE IN THIS SECTOR amounts to 1,336,210 euros and the aid provided by the ERDF amounts to 178,451 euros.

This ERDF contribution has meant that among all funded projects under this call, they have been successfully executed seven R & D projects presented in the field of Biomedicine, representing 12% of the total number of co-financed projects.

We highlight this action as a good practice, according to the following criteria:

1. THE ROLE OF THE ERDF IN THE ACTION HAS BEEN CONVENIENTLY DISSEMINATED BETWEEN POTENTIAL BENEFICIARIES AND THE PUBLIC IN GENERAL.

The call for 2015 for the Aids to R & D projects line was widely publicized by the R & D Service of the Government of Navarre, always highlighting the contribution of the European Regional Development Fund, thus contributing to the publicity and transparency of the action and increasing the awareness of citizens about the added value of European co-financing.

Thus, beyond complying with the requirements that are mandatory in terms of information and communication to receive the European financial contribution, the following communication actions have been carried out:



Website 'www.navarra.es', from where the Government of Navarre provide updated information for citizenship on R + D + i.

And specifically, about the call for aid for R & D projects, which shows that they are co-financed by the ERDF:

http://www.navarra.es/home_es/Temas/Empleo+y+Economia/Innovación/Ayudas+investigacion.htm



News published on 12/17/2014 on the website of the Government of Navarre, aimed at informing all citizens of the imminent call for aid for R & D by 2015.

http://www.navarra.es/home_es/Actualidad/Sala+de+premsa/Noticias/2014/12/17/Ayudas+I+D.htm

Days of diffusion of the call in different centers and points of Navarre, looking for potential beneficiaries:

Aimed to the general public, but with special interest in reaching the potential beneficiaries of the aid. The different scenarios were: the National Center for Technology and Food Safety (CNTA), the Public University of Navarra (UPNA), the National Center for Renewable Energy (CENER) and the ADITECH Technology Corporation. In all of them, the ERDF cofinancing of the line of Aid for R & D projects and the obligation to communicate and publicize the ERDF Funds was expressly addressed.

In addition to the presentations that were screened during the different days, an information sheet was prepared with the contacts (telephone and e-mail) of the people managing the grants, who wore the ERDF logo. This contact sheet was distributed both in the conference and later to any interested company.



*Conference at the National Center of Technology and Food Safety (CNTA)
December 11, 2014, 31570 San Adrián 11*

The centers where these conferences took place, made publicity of the same in their respective Web pages, including the FEDER logo. As an example:

<http://aditechcorp.com/ayudas-para-el-fomento-de-la-id-en-2015/>

The selected companies, beneficiaries of the ERDF aid, have also disseminated on their websites, the European funding received:

ANSABERE SURGICAL, SL .

<http://www.ansaberesurgical.com/feder/>

Eskualde Garapeneko Europako Funtsa:
"Europa egiteko modu bat"
Fondo Europeo de Desarrollo Regional:
"Una manera de hacer Europa"

Europar Batasuna
Unión Europea

In the case of PALO BIOPHARMA, in addition to including the EU flag, the name and slogan of the fund on its website, it also indicates through a list, which of its projects are co-financed at a rate of 50% by the ERDF, through the 2014-2020 FEDER PO of Navarra. <https://www.palobiofarma.com/investors/>

Palobiofarma has received a grant co-financed 50% by European Regional Development Fund through the operative Program FEDER 2014-2020 of Navarra to execute the following Projects:

1. Development of new Adenosine A3 receptor antagonists for the Glaucoma treatment.
2. Clinical Development of PBF-1129: An Adenosine A2b receptor antagonist as a new treatment for the idiopathic pulmonary fibrosis.
3. Identification and bioequivalence clinical trial of a pharmaceutically acceptable salt for a new oral treatment of allergic asthma.
4. Clinical Development of PBF-1650: An adenosine A3 receptor antagonist as a new treatment for Psoriasis.

2. THE ACTION INCORPORATES INNOVATIVE ELEMENTS.

Next we will go on to detail the innovative aspects that incorporate the actions developed by the selected companies.

ANSABERE has developed a novel device in the form of a spatula that aims to facilitate the field of work in cardiac surgery ; a field of work for the surgeon never seen before, excellent and new that will allow you to work with a better and more comfortable access and above all with greater amplitude of action and movement capacity allowing to reach the mitral valve inside the heart. With the existing means until now, visibility and access to the heart for cardiovascular surgeons are very limited.

Given the global novelty of this project will proceed to seek protection of their intellectual property through the development of their patent at least European and probably global.

*Below and with the object of a better understanding of the device developed by the company, **figure 1 shows** an image of the new development in comparison with traditional surgery and in **figure 2** an image of the final design of the device in its two different versions, one adapted to conventional surgery and another adapted to minimally invasive mitral surgery (MIS).*

Figure 1: New Development versus traditional surgery

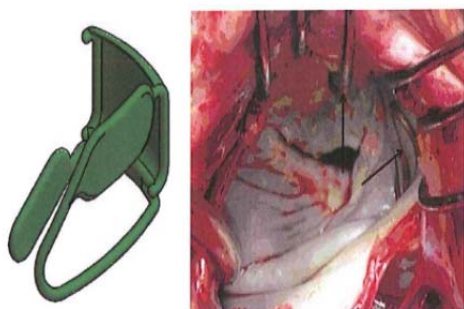


Figure 2: Final design of the device

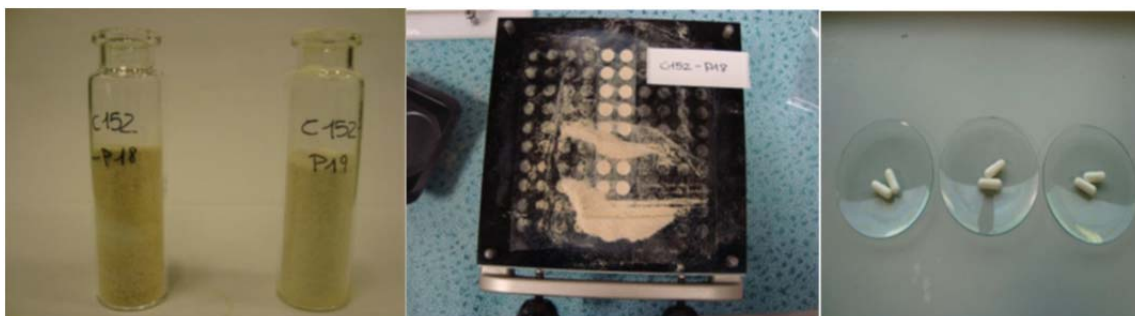


PALO BIOPHARMA SL has developed an oral medication for glaucoma as an alternative to current treatments; Research in considered a completely new therapy in relation to existing ones.

Currently therapy for glaucoma is based on the use of drugs (mostly eye drops) to decrease the amount of fluid (aqueous humor) in the eye or improve its flow outward . The use of these eye drops can cause side effects such as reactions related to their active ingredient or irritation of the surface of the eye.

The project proposes the development of an oral medication that by its composition acts directly on the cause of the disease and stops its progress. In addition, as it is a medicine for oral administration, the adherence of the patient with the treatment will be greatly improved and, therefore, the results after it will be optimized.

The following illustrations reflect part of the encapsulation process during the clinical trials of the drug



3. ADEQUACY OF THE RESULTS OBTAINED FROM THE ESTABLISHED OBJECTIVES

This line of aid from the Government of Navarre with FEDER co-financing has fulfilled its main objective of promoting the development of projects that incorporate technological innovations. Next, it is presented the adequacy of the results obtained by the selected companies regarding their initial objectives.

ANSABERE SURGICAL, SL, has developed a device that represents an authentic novelty worldwide in the field of cardiac surgery, providing the surgeon with both visibility and access to the heart. The results obtained with this device have been as expected; the company directed its efforts towards the creation of an innovative product that would make it possible to perform cardiovascular surgery in a much simpler way than the current one. The potential market for the product has great potential worldwide.

PALO BIOPHARMA S.L., completes project for the development of the first drug for the oral treatment of glaucoma; This drug aims to reduce the pressure of the eye, thus protecting the optic nerve but at the same time avoiding the side effects caused by the use of eye drops. The different phases of clinical trials have been completed in patients demonstrating that the administration of the drug is safe and tolerable.

4. CONTRIBUTION TO THE RESOLUTION OF A PROBLEM OR DEBILITY DETECTED IN THE FIELD OF EXECUTION

One of the effects of the economic crisis was the drop in business spending in R & D. Recovering investment in business R & D is essential to increase the competitiveness in the medium and long term of companies in the region.

The results achieved with the projects financed by the ERDF selected, have improved the competitiveness of the companies that have developed them and contribute to solving the problems detected in their respective fields.

ANSABERE SURGICAL, SL in the development of its device, took into consideration the need to respond to a weakness detected in the field of cardiac surgery.

The performance of cardiovascular surgeries is one of the most developed and habitual medical specialties in our country (around 15,000 surgeries are performed per year in Spain). Almost all these interventions are performed by conventional surgery, to repair or replace the mitral or aortic

valves. In many cases, the cardiac surgeon encounters difficulties of access and visibility of the organ.

The development of this device yields very positive results facilitating the work of the surgeons; since, access to the mitral valve is improved and greater visibility of the work field is provided. As a result, a less traumatic surgery is also achieved for patients, the days of admission are reduced and the recovery process is shortened.

PALO BIOPHARMA, S.L., for the development of its novel drug, considers that glaucoma is a common disease that presents unmet therapeutic needs. Current medications mitigate symptoms but do not treat the causes and therefore the disease progresses slowly to cause loss of vision. In addition, current medications are administered topically, which is an added problem for the elderly.

The capsules for oral use act on the causes of the disease, stopping the progress of the same. At the same time, when administered via capsules, treatment for the elderly is facilitated.

5. HIGH DEGREE OF COVERAGE ON THE POPULATION TO WHICH IT IS TARGETED

In the specific case of the actions carried out by the selected companies, taking into account that they belong to the field of Biomedicine, the medium and long-term coverage of this type of project is very high over the population worldwide.

In the case of the device designed by ANSABERE SURGICAL SL, the potential beneficiary population is the one that suffering from some type of cardiac pathology is going to be operated.. As previously mentioned, given the novelty of this project worldwide, the company has sought its intellectual protection by developing its patent at least European and probably worldwide. That is, the coverage that the company expects this action to achieve is very broad.

ANSABERE SURGICAL SL has as main clients at a national level hospitals and distributors; among them stand out the University Hospital of Navarra, Hospital Vall d'Hebron de Barcelona and General Hospital Gregorio Marañón; At the same time, it is committed to the international arena through partnerships with consolidated companies for the development of instruments for the operating room.

The oral medication obtained by PALO BIOPHARMA SL for the treatment of glaucoma, will benefit all those who suffer from this pathology, alleviating the symptoms and preventing the worsening of the disease. The drug developed is totally new worldwide. The company intends to market it within and outside of Spain, so the degree of coverage of the action is expected to be very high.

6. CONSIDERATION OF THE HORIZONTAL CRITERIA OF EQUAL OPPORTUNITIES AND NON-DISCRIMINATION, AS WELL AS SOCIAL RESPONSIBILITY AND ENVIRONMENTAL SUSTAINABILITY.

The gender approach is present in the actions co-financed by the ERDF, both the calls for subsidies and the contracts include gender clauses. Those companies that meet requirements in relation to equality between men and women and non-discrimination obtain a higher score in the evaluation of the projects submitted to the Government of Navarra. These companies are therefore more likely to be beneficiaries of these aids. On the other hand, it should be noted that in all the calls for aid for R & D projects, a higher score is also awarded to projects framed in the strategic sectors of S3 Navarra that aim to achieve sustainable development in the region. One of the axes of this Strategy is: "Sustainable Navarre, environmentally responsible and efficient in the use of resources".

With regard to the selected companies:

ANSABERE SURGICAL, SL obtained the maximum score in the evaluation criterion that measures the equity between men and women in the company: "Female participation in the research team" when it presented its project for its evaluation by the R + D + i Government of Navarre; Female participation in the research team is valued considering the percentage of hours of women participating in the project with respect to the total hours. In relation to the criterion of environmental sustainability, the use in the manufacturing process of the cardiac device of technical plastics of biomaterials is noteworthy. Mention also that the company is a pioneer in quality certification, Safety and Health ISO 13485: 2003.

PALO BIOPHARMA, SL also obtained the maximum score in relation to the evaluation criterion that measures female participation, in terms of hours of work in the project, in the research team. In relation to the criterion of environmental sustainability, the company carries out an adequate treatment of the residues of chemical origin that are generated during the process of making the capsules.

7. SYNERGIES WITH OTHER POLICIES OR PUBLIC INTERVENTION INSTRUMENTS

The Government of Navarre in session held on February 1, 2017 approved the Smart Specialization Strategy 2016-2030 of Navarra (S3). This strategy identifies six priority economic areas, one of which is health, which should contribute to achieving the strategic vision for the future of Navarra being a benchmark in research, development and biomedical services in 2030. The process of implementing the strategy led to the definition of 24 challenges for the period 2017-2020, of which 2 challenges were addressed to the bio sanitary field.

Likewise, the Science, Technology and Innovation Plan, approved by the Government of Navarra on July 19, 2017, devotes a section to the actions that it is proposed to promote in the health sector, as one of the strategic areas in which in which R + D + i activities should be directed to solve the problems and challenges of society.

On the other hand, the Department of Health defines health research as a "strategic instrument" within the framework of the Navarre Health Plan 2014-2020 and constitutes the basis of the Strategic Map by contributing decisively to the process of evaluation and continuous improvement of the essential process in a results-oriented strategy.

Consequently, it can be concluded that, on the one hand, the Government of Navarre is firmly committed to the promotion of health research to make Navarra a specific weight in this area due to the special conditions of the Autonomous Community (Public and private tissue of health care, universities and health research) and that, on the other hand, health research has a public utility and a social interest beyond any doubt.

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