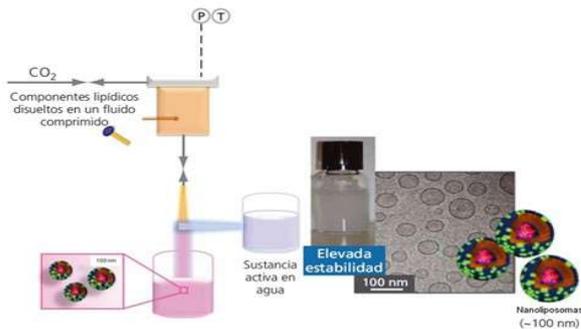


## TERARMET

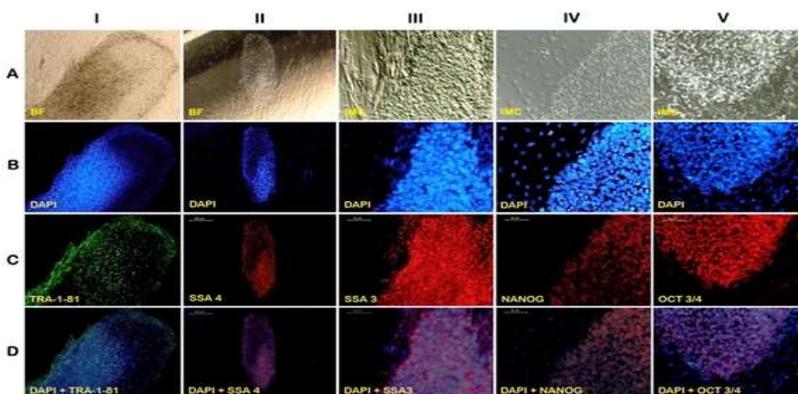
Main objectives of **Teramet** Project are based on the development of new forms of therapy for rare diseases, using cutting edge technologies which may be extrapolated to other diseases with similar causes. So, and in a general way, the objectives of the project can be divided in two big categories:

1. To obtain **new forms of therapy based on the use of nano-technological platforms** (nanoliposomes) functionalized as vehicles for Active Pharmaceutical Ingredients (APIs) from biotechnological origin and also small molecules according to the specific case, to improve efficacy, use of API and to diminish side effects.



2. **To develop new forms of gene therapy**, which may go beyond a chronic treatment for the disease, and advance to a potential curative based on the correction of the genetic inborn errors which cause it.

The project presents a strong innovative profile, as it is based on the use of new generation nano-biotechnological platforms, which possess a high potential for the improvement of the drug based therapies, and, on the other hand, the application of innovative genomic therapies, using vanguard tools which goes beyond conventional gene therapy.



From a socio-economic point of view, Teramet project will mean not only the entry of new drugs in niche markets which are considered as orphan at the current moment, but it also presents the potential to change the life to hundreds of patients and their families which are already affected by this challenge

The TERARMET Project: "Development of Therapies for the Treatment of Rare Congenital Metabolic Diseases", RTC-2014-2207-1 has been funded by the Ministry of Economy and Competitiveness through the Challenges-Collaboration 2014 call of the State Programme for Research, Development and Innovation Oriented to the Challenges of the Society, within the framework of the State Plan of Scientific and Technical Research and Innovation 2013-2016 (BOE of 19 December).

## **IGRALZHEIMER**

### **INVESTIGATION OF THE PHARMACOLOGICAL EFFICACY OF INSATURATED FATTY ACIDS FOR THE TREATMENT OF ALZHEIMER'S DISEASE**

According to the World Health Organization (WHO), a new case of dementia is diagnosed every 7 seconds around the world, having reached 44 million patients in 2013 and it is estimated to reach 50 million in 2020. Alzheimer's disease (AD) is the most common cause of dementia, representing 60-80% of the cases and is the major challenge in our society at the sanitary level. Therefore, finding effective therapies is a priority.

With that purpose in mind, the project IGRALZHEIMER from RETO calling was created with several companies, with the aim to further develop several molecules that have been shown to be effective in mouse models of AD, and now commercialize them as functional-nutraceutical and advance in the development of a future medicine.

To accomplish the proposed activities, this project counts with prominent public and private companies and so, it is expected to surpass with great success the following specific objectives:

- Computational study for the prediction of new crystalline forms of the molecule under study with the purpose of improving its physical, chemical and pharmaceutical properties.
- Develop the synthesis method, scaling and quality control of the molecule under study.
- Improve the knowledge of the action mechanism.
- Develop the nutraceutical product based in the molecule under study.
- Produce development batches of the pharmaceutical product.
- Perform preclinical studies (regulatory and GLP) of bioanalysis, genotoxicity and animal models toxicity.

The project "Investigación de la eficacia farmacológica de ácidos grasos insaturados de diseño para el tratamiento de la enfermedad de Alzheimer (IGRALZHEIMER)", RTC-2015-3542-1, has been financed by the Ministerio de Economía, Industria y Competitividad (Spain), through the Retos-Colaboración 2015 calling of the Programa Estatal de Investigación, Desarrollo e Innovación Orientada a los Retos de la Sociedad from the Plan Estatal de Investigación Científica y Técnica y de Innovación 2013-2016.

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## **ICTUS**

### **PHARMACEUTICAL DEVELOPMENT OF DESIGN LIPIDS FOR THE TREATMENT OF ICTUS AND RELATED PATHOLOGIES**

In our country, millions of people die every year as a consequence of cerebrovascular accident (Stroke), representing one of the leading causes of death in Spain and the rest of industrialized countries. This pathology has devastating aftermath and it is considered the foremost cause of permanent disability and the second cause of dementia. If we add the social cost (specialized caregivers, family dependence), it can be considered that stroke is one of the pathologies with greater impact on quality of life and on public health system.

With the aim to approach the development of new treatments for this disease, the consortium that comprises the project METABOLOPATIAS, of which Praxis Pharmaceutical is a partner, is in the process of being implemented and an attempt will be made to approach the:

- Development and patent of new compounds.
- Biochemical, morphological and physiological assays of those compounds to determine if they show a significant palliative effect in animal models of stroke and metabolic diseases that increase the risk of stroke.
- Development of analytical methods and basic galenic for the potential molecules to be used has drugs for these pathologies.
- Preclinical toxicology and pharmacokinetics assays.
- Development of analytical methods and basic galenic.

The project “Desarrollo farmacéutico de lípidos de diseño para el tratamiento del ICTUS y patologías relacionadas (METABOLOPATÍAS)”, RTC-2015-4094-1, has been financed by the Ministerio de Industria, Economía y Competitividad, through the Retos-Colaboración 2015 calling of the Programa Estatal de Investigación, Desarrollo e Innovación Orientada a los Retos de la Sociedad, from Plan Estatal de Investigación Científica y Técnica y de Innovación 2013-2016.

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## **NANOGROW**

NANOGROW is a project that arises from an in-depth market analysis, following as reference the strategic research lines of Biosciences of the Basque Country and Europe (H2020), mainly focused on products based on cellular therapy, nanotechnologies and advanced materials. In the same way, this proposal looks for generation of well-being and strengthening of leadership of Basque R&D entities in the Biomedic-technological field. In this context, the project NANOGROW is a firm commitment to bring to the market knowledge and cellular therapy products (bioengineered organs) created using the most cutting-edge technologies, such as tissue engineering, nanotechnology and 3D printing or bioprinting. These technologies will surely help strengthen the economy of the knowledge and leadership of the Basque companies in the Biomedic-technological field, aiming to generate the basis of sustainable growth in time.

The previous R&D activities carried out by the Technological Agents of the Basque Network of Science, Technology and Innovation (BNSTI) that participates in the project; such as the University of the Basque country, BIOPRAXIS and CIDETEC, and by the Basque companies involved in the project, such as KARUNA, OSI, AJL, MIZAR, SENDABIO and PRAXIS, will allow merging various technologies to develop and achieve PARTICULAR PRODUCTS, as a result of the public-private collaboration of different entities of the BNSTI and companies of the Basque country.

The project NANOGROW, number file ZE-2017/00014 led by PRAXIS, is subject of aid funded by the expense budget of the Department of Economic Development and Infrastructures of the Basque Country, through the programme to support the R&D of companies, cofounded by the European Regional Development Fund (ERDF).



## **STOP SIDA**

The Praxis Group has, among its strategic lines, the application of the latest developments in Advanced Therapies for the treatment of AIDS.

HIV continues to be a major global public health issue. In 2015, an estimated 36.7 million people were living with HIV, including 1.8 million children. The vast majority of this number live in low- and middle- income countries. In the same year, 1.1 million people died of AIDS-related illnesses. Since the start of the epidemic, an estimated 78 million people have become infected with HIV and 35 million people have died of AIDS-related illnesses.

HIV infects T lymphocytes through the CCR5 membrane coreceptor. The CCR5D32 is a rare alteration that affects 1% of European population. It is known, that the persons who carry it are naturally resistant to HIV infection. In this project, Praxis Pharmaceutical intends to develop a genic therapy to reproduce the D32 mutation in the cells of persons infected by HIV to, this way, cure the infection. The consortium, led by Praxis Pharmaceutical, is formed also by the Instituto de Investigación del SIDA (IrsiCaixa), el Consejo Superior de Investigaciones Científicas (CSIC) and Karuna Good Cells Technologies, SL.

This project consists of applying the latest advances in genome editing developed and patented (Guraizeak<sup>®</sup>) by some members of the consortium, in order to modify *in vitro* TCD4<sup>+</sup> lymphocytes of persons infected by HIV in order to avoid the expression of the CCR5 protein. During the three years of the duration of the project, it is planned to carry out *in vitro* experiments, as well as with animals, to determine safety and efficacy of the procedure.

The Project *STOP-SIDA, NEW TOOLS OF GENOMIC ENGINEERING FOR THE TREATMENT OF AIDS* is funded by Spanish Ministry of Economy, Industry and Competitiveness, through the National Programme for Research-Social Challenges in the frame of the Scientific and Technical Investigation and Innovation National Plan 2013-2016.



## ***REINDUSTRIALIZATION AID PROGRAM***

### ***PROJECT SUMMARY***

The cyclical investment focuses on the implementation of two new production lines in the plant that Praxis has in Miñano. The first intended for ADVANCED THERAPIES, being the first selected the production of Bioengineered skin from autologous cells applied to the field of Regenerative Medicine. The second oriented the production of innovative nanoformulations applied to any of the Medicine to increase and effectiveness and reduce toxicity of pharmaceutical products.

### ***PROJECT OBJECTIVES***

The set of investments considered priority pers pers pers pers pers pers the creation of new lines that are productive that allow the manufacture of the new aaaa products, as is the case of the Cell Therapy Lines, and also the marketing of innovations that the Praxis Group develops to R&D Projects:

### ***INDUSTRIAL***

- I disarm a new value-added production line that positions Praxis in a reference place in the field of Regenerative Medicine.
- To offer an innovative nanotechnology production platform in order to transfer innovation from research to the market
- Increase business opportunities for the company

### ***ECONOMIC***

- Manufacture and marketing of a new product line within the Regenerative Medicine strategic line with a high profit margin.
- Manufacture, own and for third parties, and marketing of more effective and safe nanopharmaceuticals to any field of medicine.
- to contribute the Spanish industry in the area of biomedicine and nanotechnology, generating employment opportunities.

### ***SAFETY AND PRODUCTIVE EFFICIENCY***

- a Ensure a power supply, avoiding electrical outages that may cause manufacturing batches or affect the product during storage in refrigerators.

### ***ENVIRONMENTAL***

- to treat the environmental impacts associated with the industrial production of skin bioequivalent throughout its life cycle, its production, conditioning and packaging, from the production/production of the raw material to its end of life, always the standards of usefulness, efficacy and safety; using the Life Cycle Analysis (ACV-Sustainable) tool developed by Praxis.
- Creation of efficient production cycles not for the environment, following a policy of reduction, reuse and recycling.

**SOCIAL**

- Give an effective and safe solution to people who undergo wounds, large burns and problems of oral mucosa reconstruction, with an autologous cell therapy that improves their health and quality of life.
- Offer innovative therapeutic options, based on nanotechnologies, more effective and safe to patients.

