Call for expressions of interest CANCER INNOVA (Business Factory Medicines)

PREAMBLE

After the success of the **I2D2 Program** carried out by the **Galician Innovation Agency**, the **Janssen/ Johnson & Johnson** company and the **Kærtor Foundation** between 2017-2019, they are now joined by the **Scientific Foundation of the Spanish Association Against Cancer (FC AECC)** and **the pharmaceutical company Lilly** to pool efforts, synergies and experiences in favour of a new program in the field of drug discovery focused on oncology, which allows innovative projects to be incubated and advanced up to clinical proof of concept in humans.

The "Cancer Innova Program within the framework of the Business Factory Medicines" "Cancer Innova Program" or "CIP Program", once again focuses on the concept of reverse transference to allow:

- The promotion of scientific research aimed at the discovery of drugs or related techniques, and / or providing benefits in the treatment of cancer.
- The creation of a pole of open innovation applied to drug discovery to treat cancer.
- The generation of socio-economic value.

OBJECT OF THE CALL

The purpose of the call is to add value to biomedical research with an inclusive vision from the Cancer Innova Program within the framework of a Business Factory Medicines.

The partners involved in this project want to contribute in this way to the discovery of drugs for cancer, supporting the best biomedical science on the mechanisms of the disease.

To do this, the Kærtor methodology applies disruptive science to drug discovery, reducing the risk of failure and filling the gap towards its industrial application.

MANNER, PLACE AND DEADLINE OF SUBMISSION OF APPLICATIONS

Those interested in participating in this call must fill in the short **Expression of Interest** form that appears on the website (**www.cancerinnova.com**).

The first selected projects to start the incubation phase will be chosen from the Expressions of Interest (EoI) received until **21st December 2020 at 15:00** (CET) (first evaluation) and **31st January 2021 at 15:00** (CET) (second evaluation), although the call will remain open and projects received after these dates will continue to be considered until the funds reserved for the project are completed.

The information required in this phase is of a general nature and refers to a first, non-confidential approach. After the Selection Phase, the necessary agreements will be signed with the researchers and their institutions.

The information received on both the subject and the origin and authorship of the EoI will be treated by the Kærtor Foundation and FC AECC based on the confidentiality clauses available at the **link**.

BENEFICIARIES

If you are a researcher specialized in cancer mechanisms, belonging to a public entity or a private company, and you want to apply your research towards drug discovery, we would like to collaborate with you.

What we know how to do is accelerate early drug discovery, using the Kærtor methodology, creating a parallel process to that of your research without interfering with it.

This parallel process of drug discovery does not affect the publication in any format of your lines of research, but rather potentiate it by creating synergies with the new tools of the CIP program. In this process, the only confidentiality is inherent to the drug candidate molecules.

In our methodology, a steering committee will be created for each selected project, in which you will be integrated, and a communication channel will be opened in real time that allows the investigations, even being parallel, to be receptive and permeable to the progress of each one.

GRANTS

The call is co-financed by the Kærtor Foundation, the FC AECC, GAIN and the pharmaceutical companies Janssen, of the J&J group, and Lilly. All of them participate in the selection and monitoring of those projects that are within the following **areas of interes**.

IMMUNOTHERAPY

Therapeutic approaches based on the stimulation of the human immune system in order to make it capable of attacking and killing cancer cells.

SYNTHETIC LETHALITY

Use of mechanisms in which defects in the expression of two or more genes cause cell death.

TUMOUR AGNOSTIC THERAPY

Therapeutic mechanisms directed at molecular targets of cancer that may be relevant for the treatment of different types of tumours.

METABOLIC MODULATION

Use of cancer-specific metabolism for the development of new targeted and selective therapies.

INVASIVENESS AND METASTASIS

Blockage of the routes by which metastasis processes occur and elimination of secondary tumours generated by these routes.

EPIGENETICS

Use of regulatory mechanisms based on epigenetic targets for the development of antitumor drugs.

TUMOUR MICROENVIRONMENT

Therapeutic approaches based on attacking cancer through therapies directed at the microenvironment of cancer cells.

MECHANISMS OF RESISTANCE TO TARGETED THERAPY

Blocking this type of escape route to avoid the appearance of resistance that causes the loss of efficacy of drugs directed at specific molecular targets.

COMPOUNDS WITH MULTIPLE ACTIVITY

Development of new products with anticancer activity that combine centres with affinity for different groups in the same molecular aggregate.

TECHNOLOGIES FOR APPLICATION TO ONCOLOGY

Novel technological approaches leading to significant advances in the development of cancer therapies.

After incubation and maturation of the projects, Janssen will be the first license option.

CIP PROGRAM STAGES

01.
Call & Selection

- Announcement
- Selection
- Communication of inclusion in the Program

02.
Incubation

- Signing of the agreements
- Incubation
- Project evaluation and monitoring

03. y 04.
Acceleration & Consolidation

- Transfer of projects to the market

CRITERIA FOR EVALUATION AND SELECTION OF RESEARCH PROJECTS

The Kærtor Foundation and the FC AECC will jointly carry out governance applying the Kærtor Foundation methodology for the preliminary analysis and prioritized classification of the EoIs received, based on the level of innovation and the degree of progress of the program in the process of discovery of drugs.

A Joint Steering Committee will guide the entire program with the participation of:

- Janssen Spain and two other organizations of the Johnson & Johnson group: Discovery Sciences and Johnson & Johnson Innovation.
- Lilly, S.A.U.
- The scientific Foundation of the Spanish Association Against Cancer
- The Kærtor Foundation

A prioritized EoI pipeline will be created based on the evaluations of three Expert Panels:

- **Scientific**, co-led by the Kærtor foundation and FC AECC.
- **Investor**, led by the Kærtor foundation.
- **Industrial**, led by Janssen / Johnson & Johnson and Lilly that will contribute with their experience in the field of drug development to select the projects with the greatest potential to provide new medicines for patients.

All projects that meet the terms and conditions set forth in these rules will be valued. The selection of projects will be carried out according to the following criteria:

- Compliance with the terms of the call.
- Level of innovation (analysis of transformational pharmacological research with industrial interest).
- Degree of progress of the project in the value chain (analysis of the possibilities of advancing from basic research to applied research in pharmacology).
- Future potential of transfer to industrial partners and reaching patients as new transformational medicines for cancer therapy.

Later, the Joint Steering Committee will decide which projects are selected for incubation.

Some projects may be selected for a reserve list that will only be incubated if the Joint Steering Committee deems it appropriate when any of the first selected projects cannot proceed to the Incubation or Acceleration Phase.

Similarly, Kærtor Foundation and FC AECC may also select for independent incubation other projects that are not part of those chosen by the Program Steering Committee, always with the agreement of the group that originally presented the project.

INCUBATION CRITERIA OF THE PROJECTS. SIGNING OF A RESEARCH AGREEMENT

01. COMMUNICATION OF INCLUSION IN THE CIP PROGRAM

Kærtor Foundation and the FC AECC will inform the researchers and institutions of the selected candidate research projects, their inclusion in the CIP Program, either as first selection projects or as projects included in the reserve list.

The selected projects will be asked for more extensive information on the project, they will be evaluated in more detail and if it is prioritized, the corresponding agreements will be signed.

The definitive inclusion in the CIP Program that will determine its participation in the Incubation Phase will be subject to the express acceptance by the selected candidate, which must be formalized by signing a "Research Agreement" by virtue of which the conditions of participation in the CIP Program, as well as the rights and obligations of the selected candidate will be determined. Said Research Agreement will be signed between the selected candidate, the Kærtor Foundation and the FC AECC, and will regulate, among other aspects, the following:

a) Treatment of Prior Rights: Prior Rights (all non-public data and information including industrial secrets, techniques, processes, experimental protocols, designs, animal models, etc. that are already in the hands of the parties, as well as the intellectual and industrial property rights owned by the parties) contributed to the development of the project, will continue to be owned by each of the parties, without prejudice to the fact that their use will be authorized for the good purpose of the research, as long as they are compatible with the purpose of the CIP Program.

b) The distribution of the ownership of the industrial property rights over the results of the incubation, between Kærtor Foundation, the FC AECC and the selected candidate.

c) A special power of attorney for the Incubation Phase by the selected candidate and the FC AECC in favour of Kærtor Foundation, so that it can sign the appropriate agreements to carry out the incubation of the projects.

Among other powers, Kærtor will be expressly authorized to sign a license agreement for non-commercial use so that the project can be incubated in the Incubation Phase.

d) A power of attorney in negotiations with Janssen and Lilly, as well as with any other pharmaceutical companies that may be interested, in favour of Kærtor Foundation and the FC AECC, being able by agreement to delegate representation to one or another Foundation depending on the circumstances.

e) The transfer of ownership of the projects in the Acceleration / Consolidation Phase in favour of a company or other corporate vehicle, in exchange for a remuneration previously agreed between the parties.

f) The existence of a right of first negotiation on the projects selected in favour of Janssen.

g) The obligation to transfer a copy of the Research Agreement to pharmaceutical companies.

The subscription of the Research Agreement in the terms described is **essential and is a necessary condition** for the inclusion of a project in the CIP Program.

02. METHODOLOGY IN THE INCUBATION PHASE

The Kærtor Foundation and FC AECC will lead the governance by applying the Kærtor Foundation methodology.

The incubation of the projects will begin according to the order of prioritization and once the corresponding agreements have been signed.

A steering committee will be created for each project, representing the applicant biomedical research team, the translational research team of the Kærtor Foundation, the research team of the AECC Foundation and the Janssen research team.

The Kærtor work methodology will be applied, which includes the evaluation and monitoring of the projects, and its connection with the feasibility analysis for the transition to advanced phases once the incubation is finished.

During this phase, Janssen, along with the other two organizations of the Johnson & Johnson group: Discovery Sciences and Johnson & Johnson Innovation, and Lilly will participate from the Joint Steering Committee, contributing their experience to the development of the selected programs.

The incubation start date of the first selected projects is in the **first quarter of 2021**.

DESCRIPTION OF THE METHODOLOGY AND FINANCING

The fundamental objective of the work that will be carried out within each project is to achieve a validation of the scientific proposal with a view to its possible use within the area of human cancer therapy. The achievement of this objective will imply the accomplishment of a series of tasks, that will be collected in specific roadmaps for each project.

The roadmaps will be prepared by the Kærtor Foundation, FC AECC and the group originating the proposal, and approved by the Joint Steering Committee.

Given the high degree of interdisciplinarity required for the initial phases of the drug discovery process, the roadmap will include experiments in different fields of knowledge, such as Medical Chemistry, in vitro Pharmacology, in vivo Pharmacology or Pharmacokinetics, among others.

It is important to highlight that the funding provided by the Cancer Innova Program will be used to carry out these experiments, which, depending on each specific case, may be outsourced to companies or specialized groups or, if they have the capacities internally, assigned to the originating group of the proposal. The fundamental concept is that the financing is directed to the project, and not to the originating group.

The design of the roadmap will include a series of critical experiments, with clear and measurable objectives, whose purpose is to demonstrate the potential of the proposed biological approach. Success in each of these critical experiments will mean moving to the next phase of the roadmap.

Failure to achieve the objectives in these critical experiments implies the lack of validation of the project's working hypothesis and will lead to its discontinuation and eventually a new project could be incorporated from the reserve list.

The intellectual property of the results of the work carried out during the execution of the Cancer Innova project will be distributed between the originating group and the Kærtor Foundation and the FC AECC, according to the percentages previously agreed between the three parties in the Research Agreement.

Under no circumstances, throughout the execution of the CIP Program, will Janssen, or Lilly, or any other pharmaceutical company, have any intellectual property. Upon successful completion of the Incubation Phase, Janssen will have a First Deal right on the results under fair and market conditions.

In accordance with the foregoing, once the incubation is finished, a final report will be prepared in which (i) the results will be presented, (ii) it will be proposed to end the incubation to continue with the Acceleration Phase and (iii) the "New Roadmap" for the Acceleration Phase.

ACCELERATION/CONSOLIDATION PHASE. RIGHT OF FIRST NEGOTIATION

Within a period of six months from the issuance of the aforementioned final report, Janssen may exercise its Right of First Negotiation, understood as a pre-emptive right for investment in incubated projects, whatever the financing formula and / or of the vehicle used for this purpose.

Should Janssen waive its Right to First Negotiation, the Kærtor Foundation and FC AECC may freely negotiate with other potential investors interested in the incubated projects. Likewise, if after the anticipated six months of negotiation, an agreement has not been reached, the Kærtor Foundation and FC AECC may initiate negotiations with any third party for the continuation of the incubated projects.

Once the period of exercise of the Right of First Negotiation has elapsed, Janssen will have a right of first refusal under which the Kærtor Foundation and FC AECC must notify Janssen of the conditions offered to any third party, and Janssen will have a right of first refusal that may exercise within thirty (30) calendar days following receipt of said notification.

However, Janssen will only be able to exercise the Right of Refusal if it has previously submitted a binding offer on any of the incubated projects, within the period provided for the exercise of its Right of First Negotiation, and provided that said offer has been rejected by the Kærtor Foundation and the FC AECC.

INCOMPATIBILITIES

There is no incompatibility with other calls for projects funded by the Kærtor Foundation or FC AECC.

However, researchers must declare in the EoI if they are receiving funding from other entities for the same activity, as well as if they have signed other agreements that may generate intellectual / industrial property based on the project.

DURATION

The selected projects will be incubated by a milestone procedure with key experiments and decision-making regarding continuation based on these milestones.

Projects that pass this procedure will be incubated for a maximum of 24 months.

From then on, they will be candidates to continue their development until Proof of Concept in humans.

PARTICIPATION OF OTHER PHARMACEUTICAL COMPANIES

Candidates or beneficiaries of the CIP Program accept and acknowledge the possibility of joining as partners of the "Cancer Innova Program within the framework of the Business Factory Medicines" new pharmaceutical companies in the future, whose rights and duties would be previously communicated to all participants of the Program. The incorporation of new pharmaceutical companies would in no way imply a reduction in the rights of the applicant biomedical research team established in these bases.

LEGAL ASPECTS

01. Acceptance of the terms and conditions
Participation in the call implies acceptance of these terms and conditions, without qualifications or conditions, as well as any resolution that may occur.

If during the development of the CIP Program some of the project owners or the projects themselves do not meet the required requirements, the Joint Steering Committee reserves the right to demand compliance with these, otherwise, the candidature will be excluded.

Likewise, the Joint Steering Committee reserves the right to cancel, modify or suspend any aspect or criterion of the call and selection process.

The commitment assumed by the acceptance of these terms and conditions will take effect from the acceptance of these and will remain in force until two (2) years after the end of the call they hace been accepted, without prejudice to the obligations that they could assume the candidates selected within the framework of the CIP Program and whise term and duration will be the result from the commitments acquired.

02. Responsability
Applicants will be responsible for all damages, direct or indirect, that are caused or may be caused by the violation of these bases, exonerating those responsible or partners of the Program from any liability in this regard, without any exception.

En estos términos, los solicitantes serán responsables de la infracción de derechos de terceros durante su participación en el Programa de esta convocatoria y deberán indemnizar a las terceras partes afectadas y, en su caso, a los responsables del Programa por cualquier daño o perjuicio causado y reclamado judicial o extrajudicialmente, incluyendo expresamente los honorarios de los profesionales intervinientes en los procedimientos, por el incumplimiento de las obligaciones descritas en estas bases.

03. Intellectual property
It is essential that the candidates for the Program are owners of the intellectual and / or industrial property rights over the EoIs or the projects, or hace the corresponding permissions on them with sufficient scope in order to be able to participate in the CIP Program.

Each applicant guarantees that the content of their project is their property and does not infringe any rights, including the intellectual property rights of third parties and that the content is not illegal nor was it created in breach of any obligation with a third party.

The information providede by the apllicant must be correct, truthful, and complete, with the apllicant assuming full responsibility for any inaccuracies. Otherwise, the Joint Steering Committee will hace the right to withdraw, reject or suspend the rights granted to the applicant in these bases, without prejudice to being able to demand, if it were appropiate, compensation for the demages caused, whatever outside his nature.

The applicant accepts that those responsible for the Program make the decisions regarding the call, as well as the final selection of projects. The applicants acknowledges that, even if his project is selected, those responsible for the program are not obliged to fully develp the Program

The candidates acknowledge and assume that the signing of the Research Agreement with the Kærtor Foundation and the FC AECC is essential in order to be able to access the Incubation Phase of the Program, resulting in the negotiation and agreement of the distribution of ownership over the results incubation an essential element in this agreement.

04. Disclosure of information

The participants consent the use of the basic data of the project during the evaluation processes contemplated in the bases, by accepting the confidentiality policy regulated in this **link**.

El contenido de todas las ideas y proyectos presentados a esta convocatoria, y todos los datos e informaciones de cualquier tipo proporcionada por el solicitante, serán tratadas como confidenciales. No obstante, los candidatos que resulten seleccionados se obligan a firmar los acuerdos de confidencialidad con los promotores del Programa PCI a fin de poder compartir con los mismos los datos esenciales que resulten necesarios para la correcta ejecución de cada una de las fases.

05. Communications

All notifications regarding the development of the Cancer Innova Program will be published on the website **www.cancerinnova.com**. Any other individual notification will be communicated through the email or telephone number indicated in the registration of the project on the web, or in the one that is subsequently provided by the main promoters of the project for that purpose.

06. Claims

For the interpretation and fulfilment of these bases, the Joint Steering Committee and the participants will submit to the application of Spanish laws.

Any controversy derived from the interpretation or execution of this document, will be resolved directly by the parties, for which purpose they undertake to make, in good faith, their best efforts for the consensual solution of their controversies, attending to the common intention expressed in the same, within a maximum period of fifteen (15) business days from the date on which either party gives written notice to the other regarding any claim, without the lack of response from the other party suspends the limit set.

Any litigation, controversy or claim resulting from this document or its interpretation that has not been able to be resolved in accordance with the provisions of the preceding section, as well as that relating to non-compliance, resolution or nullity, will be submitted to the jurisdiction of the courts of the city of Madrid, renouncing any other jurisdiction.

07. Data protection and cookie policy

For these purposes, we refer to the information contained in the following link:

- **Confidentiality Policy**
- **Cookies Policy**

08. Miscellaneous

The Joint Steering Committee does not guarantee the availability and continuity of the operation of the platform or the services hosted on it, as it may suffer interruptions or defects in its operation.

Those responsible for the CIP Program do not assume any responsibility for any damage or loss suffered by the participant due to non-operation or the inability to use the information or services provided through the enabled platform. And they will not be responsible for any damage or loss that may be caused by interference, omissions, interruptions, computer viruses or disconnections in the portal and services for any reason.

The applicant will not use the platform to send content that may violate current law or public morals or any other harmful, abusive, disrespectful, defamatory, vulgar, obscene, racist content or in any other way; perform any illegal or fraudulent act; or send any type of documentation or material not related to the purposes of the call.

Those responsible for the CIP Program reserve the right to remove any content that violates these rules.

Participants in the Program assume the obligation to provide additional documentation that may be required by those responsible for the Program to comply with information obligations that may derive from regulations currently in force or that may come into force during the duration of the Program. Failure to supply this information within the given period may lead to the suspension and

/ or resolution of the Program with respect to the offenders.