**AGREEMENT BY AND BETWEEN <<sponsor’s name>>AND CORPORACIÓ SANITÀRIA PARC TAULÍ DE SABADELL FOR CONDUCTING THE POST-AUTHORIZATION OBSERVATIONAL STUDY <<** xxxxxxxxxxxxx **>>*,* with sponsor code <<xxxxxxxxx****>>.**

In Sabadell, on

**BY AND BETWEEN**

The party of the first part, Dr. Lluís Blanch Torra with DNI [Spanish National Identity Card] No. \_\_\_\_\_\_\_\_\_ acting in his role as director of research and innovation and as the legal representative of Corporació Sanitària Parc Taulí of Sabadell (hereinafter referred to as“center”), with domicile at Parc Taulí, 1, 08208, Sabadell, and CIF [Business Tax Identification] No. Q-5850005-I.

The party of the second part, xxxxxxxxx, with DNI No. <<investigator’s DNI No.>> of the Digestive department of the Corporació Sanitària Parc Taulí of Sabadell, acting in his/her own behalf(hereinafter referred to as“principal investigator”), with domicile at Parc Taulí, 1, 08208, Sabadell.

And the party of the third part, Mrs. . << xxxxx >>, in his/her role as << xxxxx >> of << xxxxxx >>, with CIF <<xxxxxx >> and domicile at <<xxxxx >> (hereinafter referred to as “Sponsor's name),

The parties acknowledge one another's necessary and sufficient capacity to bind themselves by means of this agreement.

**EXHIBIT**

1. Whereas, the Sponsor is interested in promoting the Study of the product described in the protocol<<xxxxxxxxxxxx >>.
2. Whereas, the principal investigator is interested in performing the study under the terms and conditions that are expressed below.
3. Whereas, the center is aware of the protocol for the study that is the subject matter of this agreement and expresses its agreement for it to be carried out under the terms and conditions that are expressed below.
4. Whereas, the cited study is<<unicenter/multicenter>> and has a (<<Spanish, European, global, etc.>>) geographic scope.
5. The CREC of Corporació Sanitària Parc Taulí has evaluated the protocol of reference during its meeting on <<date>>, with record number <<CREC No.>>, and has issued the pertinent favorable report on the local aspects of the study.
6. The study was classified by the Spanish Agency of Medicines and Medical Devices on <<xxxxxxxxxxxxxx>> as a <<Post-authorization study of observational (abbreviated as xxxxxxxx) study.

By virtue of the foregoing, the parties agree to establish the following:

**CLAUSES**

1. **SUBJECT MATTER OF THE AGREEMENT**

The principal investigator undertakes to carry out the study proposed by Sponsor in accordance with the characteristics described in the protocol referenced above.

The Sponsor and the investigators agree to assume the responsibilities and obligations of the study in compliance with all current applicable regulations in the matter in Spain, and they state that they are aware of the laws in force and their scope and, in particular, Order SAS/3470/2009 of December 16 for the publication of directives concerning post-authorization observational studies of medications for human use and all the regulations cited therein.

In the event biological samples, genetic studies, or invasive procedures are involved, the stipulations of Law 14/2007 of July 3 on Biomedical Research shall be followed.

The principal investigator shall ensure that all the patients who participate in the study meet the requirements imposed by current law and have provided their informed consent.

1. **PLACE OF EXECUTION**

The study covered by this agreement will be executed within the sphere of the <<department>> department of the Corporació Sanitària Parc Taulí of Sabadell, located at Parc Taulí, 1, Sabadell.

The center states that it is fully aware of the study that is the subject matter of this agreement and expresses its agreement for it to be carried out under the terms established in the protocol approved by the CREC and under the responsibility of the principal investigator.

1. **OBLIGATIONS OF THE PRINCIPAL INVESTIGATOR**

The study that is the subject matter of this agreement shall be conducted under the direct and personal responsibility of the principal investigator, who shall ensure that it is conducted in accordance with the requirements and conditions set forth in the pertinent administrative authorization.

The principal investigator declares before the center and the health authorities that he/she has the training to properly fulfill this agreement, for which purpose he/she has an appropriate team of collaborators consisting of:

Dr. <<collaborator>> (<<department>>department)

The principal investigator and the collaborators assume the obligations stipulated for each one of them in Section 6 of Order SAS/3470/2009 of December 16.

1. **OBLIGATIONS OF THE STUDY SPONSOR**

The Sponsor assumes the obligations established for this role in Section 6 of Order SAS/3470/2009.

However, the following are specifically stipulated as additional obligations of the sponsor:

* To report on the development of the study and the results that are being achieved or about any incidence thereof.
* To submit an annual report and a final report, the latter to be submitted between three to six months after the end of the study to the AEMPS [Spanish Agency of Medicines and Medical Devices] and the competent bodies of the Autonomous Communities where it was conducted.

1. **MONETARY COMPENSATION**

All the financial aspects related to the study are reflected in the financial schedule that accompanies this agreement (Annex I), which includes and specifies the direct and indirect costs.

The Sponsor agrees to pay the total amount of the study reflected in the following amounts, according to what is indicated in Annex I Financial Schedule that accompanies this agreement:

1. CREC rates <<Euros in numbers>> € (<<Euros written out>> Euros).
2. Study costs: <<Euros in numbers>> € (<<Euros written out>> Euros).
3. The invoice for the management of this contract will be request at the beginning of procedure.

The appropriate VAT will be applied to all of these items and they will be paid in accordance with what is established in Clause 6 of this agreement.

This compensation has been approved for a total of <<xxxxxxxx>> patients who all complete the full course of the study in accordance with the protocol thereof. If the number of patients projected is not reached or is surpassed, the monetary amount will be established in proportion to the number of patients actually studied.

In the case of included patients who do not complete the treatment, the amount to be paid will be calculated in proportion to the time of their participation in the study, as specified in the study budget that is attached as an addendum to the agreement.

Any other variation in the budget, both in regard to amounts and items and conditions, shall be approved by mutual agreement among the parties.

1. **FORM OF PAYMENT**

The rates for the evaluation of the project by the CREC, equivalent to 1075 + VAT Euros, will be paid at the time the study is submitted to Fundació Parc Taulí.

The payment of the remuneration per included patient agreed to in the previous point will be made upon submission of an invoice by Fundació Parc Taulí.

All payments will be routed through Fundació Parc Taulí, with NIF G60331238 and corporate domicile at Parc Taulí, 1, 08208 Sabadell. Payments must be made upon submission of invoices, with VAT included, applying the prorated percentage in force on the issue date of each invoice.

Account number 0081-5154-29-0001813582.

Banco de Sabadell, Pl. Sant Roc, 20, 08201 Sabadell.

Swift\_ BSABESBB.

IBAN: ES02 0081 5154 2900 0181 3582.

(To invoice: must include name of sponsor, data, CIF or TAX id.

CRO data. Information on whom to be bill and who will make the payments. Contact person data.

If this information is modified, it must be notified to the email address indicated below).

Invoices must be requested from: facturai3ptauli.cat (contact person: Roser Renom).

The Sponsor shall pay the invoice no later than 30 days from the date of invoice.

Payments will be made every <<payment period>> months, upon the presentation of the pertinent report by the principal investigator, for the cases conducted.

The last payment will be made once the count and control of the supplies utilized have been done and the drugs supplied, but not utilized, have been withdrawn.

1. **DURATION OF THE STUDY**

The study that is the subject matter of this agreement may begin once the pertinent permits and administrative authorizations have been obtained, from the date it is signed, and will have an estimated duration of <<xxxxxx>> months from the start thereof. If recruitment has not been completed within the appropriate time frames, the contracting parties shall adopt, by mutual agreement, such provisions as they may deem appropriate.

The study shall be suspended before its completion, by written notification, if any of the following circumstances should arise:

1. Due to the principal investigator’s noncompliance with the terms of this agreement.
2. If compliance with the protocol is deficient or the data recorded is repeatedly inaccurate or incomplete.
3. By mutual agreement in writing among the contracting parties.
4. If the Sponsor decides to terminate or suspend it for business reasons or for not being able to complete it due to a lack of patients or centers.

The Sponsor shall prepare a report explaining the reasons for suspending the study.

If the study should be suspended, the sponsor shall notify all the appropriate health authorities and the participating centers’ CRECs of the suspension.

**8. INCLUSION OF PATIENTS**

The Sponsor reserves the right to discontinue inclusion of patients in any of the following cases:

1. If the principal investigator does not include the agreed-upon number of patients during the designated time frame.
2. When, in the case of a multicenter study, the total number of patients to be included in the study has already been reached by other investigators.

In either case, the Sponsor agrees to notify the CREC and the principal investigator.

**9. LIFE OF THE AGREEMENT**

This agreement will go into effect at the time it is signed by the parties and will be in effect as long as the study lasts.

The study will be understood to have ended when the principal investigator submits the final report to the Sponsor, who shall notify receipt of the final report to the CREC of reference and to the CREC of the center.

In the event of early termination of the study, the Sponsor shall pay for all the services that have been rendered.

**10. CONFIDENTIALITY AGREEMENT**

In light of the confidential nature of all the documentation belonging to the Sponsor, as well as of the documentation arising from conducting the study, the principal investigator, his/her collaborators, and the center undertake to:

1. Receive and store all information in a confidential manner and use it solely for the purposes and objectives set forth in this agreement.
2. Disclose said information to third parties only when legally required or with prior written consent from the Sponsor, and provided that the third party agrees, in writing, to maintain the confidentiality of the information under the terms set forth herein.

The foregoing shall not apply to any information that:

1. Is or becomes part of the public domain through no fault of the principal investigator.
2. Is lawfully received by third parties without breach of this confidentiality agreement by the principal investigator.
3. Was previously known to the principal investigator.

**11. PROTECTION OF PERSONAL INFORMATION**

The Sponsor and investigators must guarantee the confidentiality of the identity and personal information of the participating subjects and ensure that there is compliance at all times with what is set forth in Organic Law 15/1999, RD 1720/2007, and EU Directive 95/46/EC, on the protection and transmission of personal information.

The reports and records prepared by the principal investigator for the Sponsor, shall not contain the patients’ personal information, and this data shall have been previously subjected to a dissociation process so that said data cannot be associated with the person identified.

In light of the meticulousness of the study and the Sponsor’s obligations, when the personal information of the investigators and/or patients is stored and processed, the appropriate measures shall be taken to protect it and avoid access by unauthorized third parties, under the terms stipulated by Organic Law 15/1999 on the Protection of Personal Information.

The center and the principal investigator also agree to adopt the necessary technical and organizational measures to guarantee the security of personal information and avoid its unauthorized alteration, loss, treatment, or access, taking into account the state of technology, the nature of the data stored, and the risks to which it is exposed, whether due to human action or the physical or natural environment, and especially those risks stipulated as high level risks by Royal Decree 1720/2007 of December 21, approving the Regulations for applying Organic Law 15/1999 of December 13 on the Protection of Personal Information or any laws that may develop or replace them. The center and the investigator also undertake, at the request of the sponsor, to accredit proper compliance with their obligations in regards to the protection of personal information.

The center and the principal investigator shall allow the health authorities to inspect the study records, as well as the data associated with them, when so requested. The research center and the principal investigator shall collaborate with such access and auditing in accordance with the provisions of Organic Law 15/1999.

The study monitor, if any, shall have access to the pertinent clinical documentation for the patients included in the study during each visit he or she may make, in accordance with the stipulations of Organic Law 15/1999.

**12. OWNERSHIP OF THE RESULTS**

The ownership of the results and the data obtained from the study shall belong exclusively to the Sponsor.

The Sponsor reserves the right to use the results of this study to submit them to the health authorities of any country.

The principal investigator undertakes to provide the Sponsor with the complete test results and all of the data obtained during the study.

The principal investigator agrees to respect the confidential nature of the results and the data obtained during this study.

**13. PUBLICATIONS**

The principal investigator and/or the center undertake not to use or transmit to third parties or disclose and/or publish the results obtained from this study without the prior written consent of the sponsor. In any event, the following conditions shall be respected:

1. The results of this study, if they are part of a multicenter study, may not be published until after publication of the overall results.
2. The study sponsor shall not cite the names of the investigators without their authorization, except in the case of references to already published works.
3. Any publication and/or disclosure, in any form, of the results of medical research conducted with the study sponsor’s products, shall be agreed upon with the study sponsor prior to their publication and/or disclosure. In any event, the legitimate interests of the study sponsor will be protected, such as, for example, achieving optimal patent protection, coordination in submitting documents or other studies underway in the same field to the health authorities, protection of confidential data and information, etc.
4. The Sponsor allows publication of the data obtained from this study in scientific journals of recognized prestige and its disclosure in seminars and conferences within the medical professional sphere under the conditions set forth in Sections 1 and 3 of this agreement
5. Section 3 above is also understood to be applicable to the information obtained in studies not completed or suspended prior to completion.
6. The investigation team shall not disclose the results of the investigation to third parties except under the procedures provided for in this clause.

**14. JURISDICTION**

All legal questions that may arise in relation to (execution and/or interpretation) of this agreement shall be resolved by the courts and tribunals of the city of Sabadell and/or the appropriate higher courts.

And in witness whereof, the parties sign three counterparts of this agreement, one for the principal investigator, another for the center, and a third for the Sponsor, at the place and on the date indicated at the beginning.

Mr./Ms.\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Corporació Sanitària Parc Taulí

Dr. Lluís Blanch Torra

Director of Research and Innovation

Sponsor's representative

Dr. Principal investigator

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| **ADDENDUM I: FINANCIAL SCHEDULE Corporació Sanitària Parc Taulí** | | | | | | |
| Note: VAT not included | | | | | | |
|  | | | | | | |
| **1. CREC rates** | | | | | **0,00 €** | |
|  | | | | | | |
| **2. Study costs ((a)x(b)):** | | | | | **0,00 €** | |
|  | | | | | | |
| **a) Projected TOTAL number of patients ( (CSPT):** | | | | |  | |
|  | | | | | | |
|  | | | | | | |
|  | 2.1 Investigador’s compensation: | | 0,00 € |  | | |
|  |  |  |  | | | |
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|  | 2.2 Other expenses: | | 0,00 € |  | | |
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|  | | | | | | |
| **Cost per evaluable patient**  (Equals 75% of the total cost per evaluable patient) | | | | **0,00 €** | |  |
|  | | | | | | |
| **Institutional Fee**  (Equals 25% of the total cost per evaluable patient) | | | | **0,00 €** | |  |
|  | | | | | | |
| **(b) TOTAL COST per evaluable patient** | | | | | **0,00 €** | |
|  | | | | | | |
| **Total cost of the study** (Except for Extra Costs, if any) | | | | | **0,00 €** | |
|  | | | | | | |
| **FUNDACIÓ PARC TAULÍ Parc Taulí, 1 08208 Sabadell**  **CIF G-60331238** | | | | | | |
|  | | | | | | |
| **Extra Costs** (Costs that do not affect all patients.  Only when appropriate.) | | | | | | |
| Concepts | | | Unitary price | Institucional Fee | **Total cost** | |
| Agreement fees | | |  |  | 500 | |
|  | | | 0,00 | 0,00 | 0,00 | |
|  | | | 0,00 | 0,00 | 0,00 | |