**APPENDIX NO. 6 - THE PROPOSAL**

Company Name : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
  
Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Contact person details:

Name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ e-mail:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Phone no.\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

In response to the Request for Proposal No. **03/2023-ABM**:

1. We submit our offer and we declare delivery of the following tasks within the quotes specified in the below table:

|  |  |  |  |
| --- | --- | --- | --- |
| **ID** | **Task** | **Net Value PLN/EUR/GBP/USD\*** | **Gross Value\*\* PLN/EUR//GBP/USD\*** |
| **1.0** | **Study oversight management (including Pass-Through Costs - PTC)** |  |  |
| 1.1  1.2  1.3  1.4  1.5  1.6 | Oversight Management - Startup  Oversight Management - Conduct  Oversight Management - Closeout  Sponsor Teleconferences  Project Manager / Safety Review Committee Meetings  Internal Team Teleconferences | | |
| **2.0** | **Vendor selection, contracting and management during the study (including PTC)** |  |  |
| 2.1  2.2  2.3  2.4  2.5  2.6 | PET-CT Scan Central Reading  Electronic Data Capture (EDC) Vendor  IRT/ IWRS Vendor  Central Laboratory, including Analytical labs  Holter ECG Central Reading  Vendor Management | | |
| **3.0** | **Study Initiation Activities** |  |  |
| 3.1  3.2  3.3  3.4  3.5  3.6  3.7 | Prepare for and Conduct Internal Kickoff Meeting  Prepare for and Conduct Sponsor Kickoff Meeting  Create Core Study Plans, including:  Project Management Plan including Communication Rules, Start-Up Plan, Risk Management Plan & Risk Log, IMP Management and Supply Plan, Protocol Deviations Management Plan, List of SOP Plan, Clinical Monitoring Plan,  Site Initiation Plan, PSV/SIV Slides, Site Pharmacy Manual, Medical Monitoring Plan, Safety Management Plan.  Patient Questionnaire licensing and translations  Prepare Patient Card and Patient Diary  Conduct Team Training Activities- Initial  Conduct Team Training Activities- Ongoing | | |
| **4.0** | **Protocol Amendment Implementation** |  |  |
| 4.1  4.2  4.3  4.4  4.5  4.6 | Manage Protocol Amendment Activities  Amendment - Regulatory Submission (CTA in Europe)  Amendment - IRB/EC Submission  Amendment - Informed Consent Forms update (core, country and site ICFs)  Amendment - Clinical Site Agreements update  Amendment - EDC and Related Tools | | |
| **5.0** | **Trial Master File ("TMF") (including PTC)** |  |  |
| 5.1 | Conduct TMF Maintenance and QC | | |
| **6.0** | **Regulatory and IEC / IRB Applications** |  |  |
| 6.1  6.2  6.3  6.4  6.5  6.6  6.7  6.8  6.9  6.10  6.11  6.12  6.13 | Perform Regulatory Submission and Obtain Clinical Trial Application ("CTA") Decision in Europe  Perform EU-CTR Modification Part 1  Perform EU-CTR Modification Part 2  Perform Regulatory Maintenance Submissions  Perform National Registry Submissions Application  Initial Central EC and IRB Submissions  Initial Local EC and IRB Submissions  Annual EC & IRB Maintenance Submissions  Develop Country Product Labels (for each country)  Regulatory Meetings and Communications  Perform Data Protection Application  Translations  End of Trial Notifications | | |
| **7.0** | **Site Identification and Initiation (including PTC)** |  |  |
| 7.1  7.2  7.3  7.4  7.5  7.6  7.7  7.8  7.9  7.10  7.11 | Perform Country Feasibility and Selection  Perform Site Feasibility and Site Selection for Qualification  Conduct On-Site Qualification Visits / Pre-Study Visits  Develop Contract Strategy & Templates  Site Contract Negotiation  Collect and Approve Site Regulatory Package Documents  Core Informed Consent Form ("ICF")  Country-Specific ICFs  Site-Specific ICFs  Organize, Prepare and Conduct Investigator Meetings  Initiation Visits | | |
| **8.0** | **Clinical Monitoring (100% SDV) and Site Management (including PTC)** |  |  |
| 8.1  8.2  8.3  8.4  8.5  8.6  8.7 | Conduct Site Management & Contacts  Conduct On-Site Monitoring Visits - One Day  Conduct On-Site Monitoring Visits - Two Day  Conduct Remote Monitoring Visits  Conduct On-Site Termination Visits  Clinical Meetings and Communications  Investigator Site Files management | | |
| **9.0** | **Investigator Payments (including Inv Grants and patient travel costs)** |  |  |
| 9.1  9.2  9.3 | Administer Investigator Payments  Conduct Transparency Reporting Activities (if applicable)  Patient Travel Costs management | | |
| **10.0** | **Central Lab Setup and Maintenance** |  |  |
| 10.1 | Central Lab Setup, Maintenance and Closure (including PTC) | | |
| **11.0** | **Clinical Data Management (including PTC)** |  |  |
| 11.1  11.2  11.3  11.4  11.5  11.6  11.7  11.8  11.9  11.10  11.11  11.12  11.13 | Develop Data Management Plan and Guidelines  Develop EDC Database & Related Tools  Develop Offline Listings  Conduct Data Cleaning Activities  Validation of Electronic Data  Coding Setup and Maintenance  Perform Final Database Lock Activities  Conduct EDC Archiving Activities  Clinical Data Management Meetings and Communications  Local Lab Data Management  Perform EDC Version Update - if applicable  DSMB Activities  Interim Analysis | | |
| **12.0** | **Biostatistics and Statistical Programming** |  |  |
| 12.1  12.2  12.3  12.4  12.5  12.6  12.7  12.8  12.9 | Develop Statistical Analysis Plan ("SAP")  Program Tables, Listings, & Figures ("TLF")  Program Datasets  Perform Statistical Analysis Dry Run 1  Run Final TLFs  Conduct Stats Archiving Activities  Biostatistics and Statistical Programming Meetings and Communications  In-text TLF Development/Pre-Programming & Program/QC In-Text Table  Interim Analysis | | |
| **13.0** | **Data Surveillance** |  |  |
| 13.1  13.2 | Data Surveillance Plan & System Setup  Conduct Data Surveillance Activities | | |
| **14.0** | **Protocol Deviations** |  |  |
| 14.1  14.2 | Program Protocol Deviation Specification  Conduct Protocol Deviation Review | | |
| **15.0** | **Medical Monitoring** |  |  |
| 15.1  15.2  15.3  15.4  15.5 | Medical Monitoring Set-Up  After-Hours Medical Monitoring  Medical Interaction with Sponsor  Medical Review of Listings  Medical Meetings and Communications | | |
| **16.0** | **Pharmacovigilance ("PV")** |  |  |
| 16.1  16.2  16.3  16.4  16.5  16.6  16.7 | Safety Database Set-Up and Maintenance  Serious Adverse Event ("SAE") Processing  Safety Information System Site Reporting  Set Up and Conduct Reporting Activities  Pharmacovigilance Meetings and Communications  Line Listings  Eudravigilence | | |
| **17.0** | **Clinical Study Report ("CSR") Development** |  |  |
| 17.1  17.2  17.3 | Develop CSR  Develop Subject Narratives for CSR  Develop CSR Appendices | | |
| **18.0** | **Medical Writing** |  |  |
| 18.1 | Drug Safety Update Report (DSUR) | | |
| **19.0** | **Patient Recruitment and Retention ("PRR") (including PTC)** |  |  |
| 19.1  19.2  19.3 | Perform Patient Recruitment and Retention Services  Perform Patient Comms Initial Development and Translation Activities  Patient Concierge | | |
| **20.0** | **Data Transfer Activities** |  |  |
| 20.1  20.2 | Conduct Data Transfer Programming Activities  Transfer Data | | |
| **21.0** | **Quality Assurance (including PTC)** |  |  |
| 21.1 | Quality Assurance | | |
| **22.0** | **IMP Management** |  |  |
| 22.1  22.2  22.3 | Packing and Labeling  Batch Certification & QP Release  Clinical Supply Management (Storage, Distribution, Return, Destruction) | | |
| **23.0** | **Other Charges**  Please take into account all costs for subcontractors related to the conduct of a clinical trial not listed above (e.g., all license fees - if applicable, etc.). All other necessary costs, expenses related to office and administrative activities should also be taken into account. |  |  |
|  | **Project Total** |  |  |

1. The total cost of the Project execution, including all pass-through costs has been calculated as .................................. PLN/EUR/GBP/USD\* Net and ……………………………… PLN/EUR/GBP/USD\* Gross
2. We declare the Project delivery within the following timelines:

|  |  |
| --- | --- |
| **Milestone** | **Timeline** |
| EU CTA Submission |  |
| First EC/IRB submission |  |
| First Patient Enrolled | ……… weeks since the full approval of the study (Regulatory and Ethics) is in place |
| Last Patient Enrolled |  |
| Last Patient Last Visit |  |
| Database Lock |  |
| Study Close Out |  |
| Final Clinical Study Report |  |

1. We **have/have not**\* conducted Pulmonary Sarcoidosis or Idiopathic Pulmonary Fibrosis trial(s) within last 2 years
2. We require our invoices to be paid within …..…. days from the date of receiving correctly issued invoice.
3. We declare that we are acquainted with the contents of the Request for the Offer. We consider ourselves bound with specified requirements and rules of the conduct.
4. We declare to fully accept the presented rules and conditions. We also declare that we were provided with all the necessary information to prepare the offer.
5. We declare that the quote includes all costs related to execution of the order.
6. We declare that we consider ourselves bound by this offer for the time specified in the offer, ie. \_\_\_\_\_ days after the date set for the submission of tenders (minimum 30 days).
7. We declare to conclude an project agreement with the Sponsor, if we are awarded the Project.
8. We declare that the offer **does not contain/contains**\* confidential information within the meaning on counteraction to unfair competition acts. Such information is contained in the following documents: …………………………………\*

*\** *Delete (scratch off) as appropriate.*

*\*\*Please note that a supplier providing services to a VAT registered customer in another Member State without being established there will not charge any VAT on their invoice. The customer will reverse-charge the transaction. Therefore, please provide only Net values in points 1 and 2 of Appendix 6, and short explanation on why Bidder is not obligated to charge VAT on services to businesses in Poland in item 2 of Appendix 6.*

*.............................* ........................................................

*Date* / *legible signature or the signature and stamp   
of the Contractor / person / persons authorized   
to act on behalf of the Contractor\*\*\*/*

*\*\*\*Signature(-s) or the person(-s) authorized to act on behalf of the Contractor. Name stamp is required in the case of an illegible signature.*

**APPENDIX NO. 2 TO REQUEST FOR THE PROPOSAL NO. 03/2023-ABM**

**STATEMENT CONCERNING FULFILLMENT OF THE REQUIREMENTS** **SET OUT IN POINT IV.2 OF THE REQUEST FOR OFFER**

We declare that ………………………………………………………………………………………………………………………. (*company name*)

fulfils the conditions set out in point IV.2 of the Request for proposal No. 03/2023-ABM and that we will deliver the project in accordance with those conditions.

*.............................* ........................................................

*Date* / *legible signature or the signature and stamp   
of the Contractor / person / persons authorized   
to act on behalf of the Contractor\*/*

*\*Signature(-s) or the person(-s) authorized to act on behalf of the Contractor. Name stamp is required in the case of an illegible signature.*

**APPENDIX NO.3 TO REQUEST FOR THE PROPOSAL NO. 03/2023-ABM**

**Statement regarding personal and capital connections   
with the Sponsor**

I, undersigned [\_] acting in the name of the Company under the name [\_], hereby **declare that:**

1. The Bidder **has not** any personal nor equity connections with the Sponsor within the meaning as set out by section 3 downwards.
2. The Bidder **has** a personal or equity connection with the Sponsor or persons authorized to take on commitments on behalf of the Sponsor or persons responsible for the preparation and the execution of the process of selecting the contractor by (please indicate the type of connection referred to in section 3, point 1 to 4)\*\*:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Equity or personal relationship is understood as relations between the Sponsor or individuals authorized to take commitments on behalf of the Sponsor or those acting on behalf of the Sponsor in order to prepare and implement the winning Bidder selection procedure and the Bidder, including in particular:

1) participation in the company, in a civil or limited partnership; holding at least 10% (or less if so prescribed by the respective provisions of applicable law) shares or interests; serving a function of a member of the supervisory organ, a member of the management organ, holder of commercial power of attorney or other proxy;

2) having family ties, such as by marriage, by lineage at first or second degree, by adoption, guardianship or custody, staying in cohabitation with the Bidder, the Bidder’s deputy legal entities or members of management or supervisory bodies of Bidders applying for the contract award;

3) being in such a legal or factual relationship with the Bidder that it may give raise to justified doubts as to the impartiality or independence in connection with the procurement procedure.

***Please delete (scratch off) as appropriate either section 1 if the personal or equity connections are not applicable, or section 2 if personal or equity connections are applicable.***

|  |  |
| --- | --- |
| *\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*  *Date* | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  */legible signature or the signature and stamp of the Contractor / person / persons authorized to act on behalf of the Contractor\*\*\*/* |

*\*\* Fill in only if personal or capital connections are applicable.*

*\*\*\* Signature(-s) or the person(-s) authorized to act on behalf of the Contractor. Name stamp is required in the case of an illegible signature.*

.**APPENDIX NO. 7 TO REQUEST FOR THE PROPOSAL NO. 03/2023-ABM**

DECLARATION OF COMPLIANCE WITH THE INFORMATION OBLIGATIONS PROVIDED FOR IN ARTICLE 13 OR ARTICLE 14 OF THE GDPR

**I hereby declare that I have complied with the information obligations provided for in Article 13 or Article 14 of the GDPR1) towards natural persons from whom I have obtained, directly or indirectly, personal data in order to compete for the award of a public contract in this procedure.2**

.....................................................

*signature(-s) or the person(-s) authorised*

*to act on behalf of the Contractor*

*and a name stamp/name stamps\**

*\*name stamp in the case of an illegible signature*

1) Regulation (EU) 2016/679 of the European Parliament and of The Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (O.J. EU L 119 of 04.05.2016, p. 1).

2) If the contractor does not provide personal data other than data directly related to the contractor or if the application of the information obligation is excluded pursuant to Article 13(4) or Article 14(5) of the GDPR, the contractor shall not make the declaration (delete the declaration wording by, for instance, crossing it out).

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

INFORMATION CLAUSE

Pursuant to [Article 13(1) and (2)](https://sip.legalis.pl/document-view.seam?documentId=mfrxilrtgm2tsnrrguytsltqmfyc4mzuhaztimztgq) of Regulation (EU) [2016/679](https://sip.legalis.pl/document-view.seam?documentId=mfrxilrtgm2tsnrrguyts) of the European Parliament and of The Council [of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive](https://sip.legalis.pl/document-view.seam?documentId=mfrxilrvgaytgnbsge4a) 95/46/EC (“**GDPR**”), we hereby inform that:

* Your personal data is controlled by OncoArendi Therapeutics spółka akcyjna (joint-stock company) with its registered office in Warsaw, address: Żwirki i Wigury 101, 02-089 Warsaw, entered in the register of entrepreneurs of the National Court Register, kept by the District Court for the capital city of Warsaw, 12th Commercial Division of the National Court Register, under KRS Number 0000657123, e-mail address: contact@oncoarendi.com, tel. 22 552 67 24 (“**Controller**” or „**Company**”). In matters relating to personal data protection, please contact Marta Borkowska, e-mail: m.borkowska@oncoarendi.com, tel. 22 552 67 24.
* Your personal data will be processed on the basis of Article 6(1)(c) of the GDPR for the purpose of the tendering procedure conducted on a competitive basis, under which you have responded to the request for quotation.
* Your personal data will be stored for a period of 5 years from the end of the year when the performance of the agreement with you is complete. If your bid is not selected, your personal data will be stored for a period of 5 years from the end of the year when the tender procedure you submit your bid for has ended.
* Your provision of personal data is voluntary, yet necessary to participate in the tender procedure conducted by the Company on a competitive basis.
* Your personal data will not be subject to automated decision-making pursuant to Article 22 of the GDPR;
* you have the right:
* of access your personal data;
* to rectification of your personal data;
* to request from the controller restriction of processing of personal data, subject to the cases referred to in Article 18(2) of the GDPR;
* to file a complaint with the President of the Personal Data Protection Office, if you believe that the processing of your personal data violates the GDPR provisions;
* to erasure of personal data, except the cases referred to in Article 17(3) (b), (d) or (e) of the GDPR;
* to data portability referred to in Article 20 of the GDPR, except and subject to the cases indicated there
* you do not have the right to object to the processing of personal data on the basis of Article 21 of the GDPR, since the legal grounds for the processing of your personal data is Article 6(1)(c) of the GDPR.
* Your personal data may be transferred outside the European Economic Area. However, if in the course of business it becomes necessary that your personal data be transferred outside the European Economic Area on account of your obligations, we will make every effort and ensure that the receiving entities observe the principles set forth in the GDPR, int. al. that they meet the requirements of the Privacy Shield framework.
* Your provision of data is voluntary.