**REQUEST FOR PROPOSALS FOR SAFETY PHARMACOLOGY CARDIOVASCULAR SYSTEM STUDY IN DOG FOR EC313 COMPOUND.**

Case ZO-02-2019

Commencing a job within project no, POIR.01.01.01-00-0123/16 entitled ***"Development of Selective Endometriosis Therapy Based on Mesoprogestins"*** we invite to submit a tender for **SAFETY PHARMACOLOGY CARDIOVASCULAR SYSTEM STUDY IN DOG FOR EC313 COMPOUND**.

1. **CONTRACTING ENTITY:**

Evestra Onkologia Sp. z o.o., seated in Łódź at ul. Jana Muszyńskiego 2 lok. 3. 22, 90-151 Łódź, KRS 0000544596, NIP 5311691730, REGON: 360861230, e-mail: [zamowienia@evestraonkologia.pl](mailto:mwierzbicki@evestraonkologia.pl);

1. **PROCEDURE TYPE:**

The procedure is in the form of a request for proposals according to the competitiveness rule, pursuant to art. 70¹ - 705 of the act of 23rd April 1964 – the Civil Code (Journal of Laws of 2018, item 1025, as amended.).

1. **GENERAL INFORMATION:**

The order is co-financed from the Smart Development Operating Programme 2014-2020 within the project no. POIR.01.01.01-00-0123/16 entitled ***"Development of Selective Endometriosis Therapy Based on Mesoprogestins"*** The project key objective is to validate a new active substance on in vitro and in vivo models and to perform clinical trials for further development of a new form of endometriosis therapy.

1. **DESCRIPTION OF THE SUBJECT OF THE PROCUREMENT:**

1. The subject of the procurement includes services of **SAFETY PHARMACOLOGY CARDIOVASCULAR SYSTEM STUDY IN DOG FOR EC313 COMPOUND** which is the subject of the project entitled: "Development of Selective Endometriosis Therapy Based on Mesoprogestins" A detailed scope of the procurement has been included in Attachment no. 4 hereto.

2. The Contractor shall develop a time attachment for tests within each task, which shall in particular include:

1. Conducting the experiment according to schedule provided. The Contractor will develop the schedule of studies including, above all:
2. maximum time to deliver the active substance
3. period for methods' validation (if applicable),
4. experimental part, including *in life*,
5. time necessary for draft report delivery time;

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| NOTE: the time attachment should only include information of use in case of performing a given task within the procured service. **A time attachment template constitutes Attachment no. 5 hereto.** |

1. In case if the tasks are performed, before commencing the task(s), the Contractor shall be obliged to deliver to the Contracting Entity information regarding:

a) a need for certain data (acquired from previous tasks) to be transferred by the Contracting Entity, providing their type and delivery date;

b) a need to perform tests by the Contracting Entity or another entity which are necessary for the performance of the task, providing their type and completion date.

c) the amount of API required with schedule of deliveries

1. The Contractor shall be obliged to allow Contracting Entity's representatives (upon Contracting Entity's request) participation in the tests in the capacity of observers.
2. The Contractor shall deliver full documentation on the tests in a hard copy and in an electronic format (on a medium), sent in an MS Office editable format, in the English language:
3. Interim reports – constituting the summary of in life phase;
4. Final report – giving a detailed description of the results obtained and all the information necessary to submit a dossier for the study in question as an annex to the consent to the Phase I clinical trial (CTA).
5. As of the date of Contracting Entity's approval of each of the Interim Reports and within the fee, the Contractor shall transfer to the Contracting Entity copyright to the pieces (hereinafter referred to as the "Pieces") in the understanding of the Copyright and Related Rights Law (i.e. Off. J. of 2018, item 666, hereinafter referred to as the "Law") created within the procurement by Contractor's employees or subcontractors.
6. The assignment of the copyright and related rights to the Pieces shall be unlimited in time and territory, upon all known fields of exploitation, and in particular shall include the following exploitation fields:
7. recording on any medium, regardless of system and format standards;
8. multiplication by any technique, including for editorial and publishing purposes;
9. making publicly available in Poland and abroad;
10. using, introducing, displaying, transferring and storing in any format, system or standard;
11. entering into computer memory and a multimedia network, including the Internet;
12. placing on digital platforms;
13. making available in such a manner that anyone can access them in a place and time of their choice;
14. dissemination in the form of print, digital recording, multimedia transmission.
15. Procurement Classification according to Common Procurement Vocabulary (CPV): 73.10.00.00 – 3 Research, experiment and development services.
16. **DELIVERY DATE:**

The order shall be completed till 30 of November 2019.

1. **PROCEDURAL INFORMATION:**
2. Contractors who meet the following criteria can apply:
3. in respect of competencies or authorisations to perform specific activities, the Contracting Entity has set no specific conditions.

This condition shall be assessed based on a submitted declaration on meeting the criteria for participation in the proceedings.

1. in respect of technical capacity, the Contracting Entity has set the following minimum criteria:
2. in respect of available resources necessary for the due performance of the procurement, the Contractor shall be obliged to show it has a dedicated laboratory with equipment which allows for the performance of the tests;

This condition shall be assessed based on a submitted declaration on having a dedicated laboratory.

1. in respect of professional capacity, the Contracting Entity has set the following minimum criteria:
2. in respect of staff capable of performing the task, the Contractor shall show that it can delegate at least two individuals to work on the procurement who have higher education, experience and qualification necessary to perform the experiments included in the submitted tender.

This condition shall be assessed based on a submitted list of individuals delegated by the Contractor to perform the order, including information on their qualifications.

1. in respect of economic or financial situation necessary for the due performance of the procurement, the Contracting Entity has set no special condition.

This condition shall be assessed based on a submitted declaration on meeting the criteria for participation in the proceedings.

1. the following shall not cause exclusion from the procedure:
2. circumstances listed in Guidelines Chapter 6 sect. 6.5.1 item 8;
3. liquidation or no bankruptcy declared, excluding contractors who after being declared bankrupt executed a composition agreement approved by a legally valid court decision, if the agreement does not provide for satisfaction of creditors by liquidation of the bankrupt's assets.

This condition shall be assessed based on documents listed in item 2 point 1).

1. Apart from the declaration on meeting the criteria to participate in the proceedings which constitutes Attachment no. 3 hereto, the Contractor shall submit:
2. In order to confirm no grounds to exclude from the proceedings due to a conflict of interests, the Contractor shall submit:
3. a declaration according to a specimen which constitutes Attachment no. 2 hereto – regardless of its organisational and legal status;
4. Contractors who are subject to compulsory registration in a separate register shall include a current copy from the register appropriate for them due to their organisational and legal status;
5. In order to confirm the fulfilment of the obligation laid down in item 1 point 2, the Contractor shall submit a declaration on availability of resources necessary to complete the order. A list template constitutes Attachment no. 3 hereto.
6. In order to confirm the fulfilment of the obligation laid down in item 1 point 3, the Contractor shall submit a list of individuals delegated to work on the order, including information on their education, qualifications, experience needed for the due performance of the order and the scope of delegated works together with basis for such individuals to be at the Contractor's disposal.
7. The Contractor can only place one offer for the entire subject of the procurement within a given task. The Contracting Entity has not set a maximum number of tasks a Contractor may apply for. The Contracting Entity has not set any restrictions on the number of tasks which can be granted to one contractor.

The offer should be made in the Polish or English language, in a permanent way which guarantees that the content can be read.

1. The Contracting Entity recommends the tender to be prepared using forms which constitute attachments hereto or exactly according to the Offer Form which constitutes Attachment no. 1 hereto.
2. The Contracting Entity recommends numbering all the pages.
3. The Contractor shall place the offer by sending an email to [zamowienia@eevestraonkologia.pl](mailto:zamowienia@eevestraonkologia.pl) entitled:

***"Offer for* SAFETY PHARMACOLOGY CARDIOVASCULAR SYSTEM STUDY IN DOG FOR EC313 COMPOUND*.***

***Do not open before 17th of May 2019"***

1. **The Contracting Entity allows Contractors to submit motions and enquire about the contents hereof until 6th of May 2019** To this end, the Contracting Entity has established the following forms of communication with Contractors: electronic, to the address: zamowienia@evestraonkologia.pl. A written form shall always be acceptable.
2. Any information regarding the proceedings shall be published by the Contracting Entity on its own website and in the competitiveness base under the address: bazakonkurencyjności.funduszeeuropejskie.gov.pl
3. Individuals authorised to contact Contractors:
4. for substantive issues:

- dr Hans Joachim Zentel

e-mail: [hjzentel@evestraonkologia.pl](mailto:hjzentel@evestraonkologia.pl)

* dr Ewelina Mnich
* emial: [emnich@evestraonkologia.pl](mailto:emnich@evestraonkologia.pl)

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b) for formal issues:

- dr Maciej Wierzbicki,

e-mail: [mwierzbicki@evestraonkologia.pl](mailto:mwierzbicki@evestraonkologia.pl) ;

- Robert Kochański, MA

e-mail: [rkochanski@evestraonkologia.pl](mailto:robertkochanski@evestraonkologia.pl) ;

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| **All electronic correspondence should be addressed CC: zamowienia@evestraonkologia.pl** |

1. The Contracting Entity may introduce changes in the terms and conditions of the proceedings. Provisions of point 12 shall apply respectively.
2. The Contracting Entity shall correct the offer in respect of obvious spelling errors, calculation mistakes considering calculation consequences resulting from the changes and other mistakes which make the offer incompliant with the request, provided this does not introduce essential changes in the offer.
3. The Contracting Entity shall request the contractor to remedy any deficiencies in the offer, and in particular the documents named in item 2.
4. The Contracting Entity can invalidate the proceedings without providing any reason or terminate the proceedings without an outcome during each phase.
5. **The agreement will be concluded subject to the approval of the National Centre for Research and Development and it's approval of further research.**
6. **PRINCIPLES OF PERSONAL DATA PROCESSING:**
7. In accordance with Article 13(1) and (2) of Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of individuals 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) (OJ L 119, 04.05.2016, p. 1), hereinafter referred to as "the GDPR", I hereby inform you that:

1) the administrator of your personal data is Evestra Onkologia Sp. z o.o., with its registered office in Łódź at ul. Jana Muszyńskiego 2 lok. 3.22, post office 90-151 Łódź, KRS 0000544596, NIP 5311691730, REGON: 360861230,

2) Your personal data will be processed on the basis of Article 6(1)(c) of the GDPR for the purpose of this procurement procedure,

3) the recipients of your personal data will be persons or entities to whom the documentation of conduct in accordance with the requirements of the horizontal guidelines will be made available,

4) Your personal data will be stored. for a period of 4 years from the date of completion of the contract award procedure, and if the duration of the contract exceeds 4 years, the storage period covers the entire duration of the contract,

5) your obligation to provide personal data directly to you is a statutory requirement in connection with your participation in a public procurement procedure; the consequences of not providing certain data result from the PUBLIC TENDER Act,

6). in relation to your personal data, decisions will not be taken by automated means, applying to Article 22 of the GDPR,

7) You have:

(a) the right of access to your personal data pursuant to Article 15 of the GDPR;

(b) The right to rectify your personal data pursuant to Article 16 of the GDPR;

(c) the right under Article 18 of the OROD to require the controller to restrict the processing of personal data, except in the cases referred to in Article 18(2) of the GDPR;

(d) the right to lodge a complaint with the President of the Office for the Protection of Personal Data if you consider that the processing of your personal data concerning you is in breach of the provisions of the GDPR.

8) You are not entitled to it:

(a) In conjunction with Article 17(3)(b), (d) or (e), the right to erasure of personal data;

(b) the right to transfer personal data as referred to in Article 20 of the GDPR,

1. The right to object to the processing of personal data pursuant to Article 21 of the GDPR as the legal basis for the processing of your personal data is Article 6(1)(c) of the GDPR.
2. **OFFER VALIDITY TERM:**

The Contractor shall be bound by the submitted tender for a period of 90 days. The 90-day period shall commence on the elapse of the deadline for tender submission.

1. **DEADLINE FOR THE SUBMISSION OF TENDERS:**
2. Tenders shall be submitted till **17th of May 2019 12:00 hrs** – date and hour of reception by the Contracting Entity shall be binding.
3. The tenders shall be sent in an electronic format to the following address:[zamowienia@evestraonkologia.pl](mailto:zamowienia@evestraonkologia.pl). If the tender is sent in an electronic form, the Contractor shall safeguard the tender so that its content cannot become acquainted with before the elapse of the deadline for tender submission. Provisions of point 9 Chapter VI shall apply
4. The Contracting Entity does not provide for a public opening of tenders. According to the transparency rule of the proceedings, the Contracting Entity, upon a request from the Contractor, shall make the minutes from tenders' opening available.
5. **ASSESSMENT CRITERIA:**
6. The Contracting Entity shall evaluate the tenders according to the following tender assessment criterion:
7. Financial criterion (price) – weight 100 %;

The Contracting Entity shall score by dividing the value of the cheapest tender by the analysed offer value and then multiplying the outcome by the weight, according to the following formula: **WP= (WONC /WOB) x weight,** where WP – score value in the financial criterion, WONC – value of the cheapest tender, WOB – value of the analysed tender.

**NOTE:**

**Should the contractor provide prices in currencies other than PLN, the Contracting Entity shall use an NBP exchange rate of the date of publication of the request for proposal in the Competitiveness Base of the Ministry of Development. Exchange rate tables are available at:**  [**http://www.nbp.pl/home.aspx?f=/Kursy/kursy.htm**](http://www.nbp.pl/home.aspx?f=/Kursy/kursy.htm) **;**

**Should a tender be submitted which generates a tax obligation on the part of the Contracting Entity, according to the regulations on tax on goods and services, in order to evaluate such an offer, the Contracting Entity shall add the value added tax to the price provided therein which must be accounted for according to the said regulations. When submitting the tender, the Contractor shall advise the Contracting Entity whether its offer shall generate a tax obligation on the part of the Contracting Entity providing the name (type) of goods or services whose supply shall involve the tax and their net value. Should a tender be submitted which generates a tax obligation on the part of the Contracting Entity, according to the regulations on tax on goods and services, the price of the best or cheapest price shall be increased by the value added tax to the price provided therein which must be accounted for by the Contracting Entity according to the said regulations. Therefore, in such an instance, the price provided in the tender by such a contractor as "gross price" must not include VAT which the Contracting Entity shall be obliged to account for.**

the sum of all points scored for all the tests in a given task shall constitute the basis for assessment, based on the following formula: WP = (WTBO/WMAX) x weight, where: WP – point score for reports delivery criterion, WTBO – number of points scored for the proposed reports' delivery date. WMAX – maximum number of points within the completion date criterion.

1. **AMENDMENT OF THE CONTRACT:**

The Contracting Entity may amend the contract between the Contracting Entity and a Contractor, in case of:

1. changes which result from updating commonly applicable law;
2. reducing the fee amount due to limitation or exclusion of a part of the procurement by the Contracting Entity;
3. extension of the price of the contract, if additional experiments are required to ensure the results credibility;
4. change of the Contract term, in case the Project deadline varies;
5. extension of the Contract term due to organisational issues on the part of the Contracting Entity or technical issues;
6. changes of the price of the contract due to changes to the number of animals subject to tests provided for in the Contract;
7. changes in individuals in charge of contacts and supervision over the contract.
8. occurrence of any events as a result of force majeure;
9. changes in a co-financing contract the Contracting Entity shall execute with an Intermediate Body;
10. **FINAL PROVISIONS:**

The procedure shall be governed by the Polish law. In any matters not stipulated herein, provisions of the act of 23rd April 1964 – the Civil Code (i.e. Off. J. of 2018, item 1025, as amended) and provisions of current Guidelines on Eligibility of Expenses within the European Regional Development Fund, European Social Fund and Cohesion Fund for the years 2014-2020.

Attachment no. 1 to the Request for proposal

Case ZO-02-2019

**Contracting Entity:**

**Evestra Onkologia Sp. z o.o.**

**ul. Jana Muszyńskiego 2 lok. 3.22**

**90-151 Łódź**

**TENDER FORM\***

**(copy for each task)**

Acting for and on behalf of the Contractor:

…............................................................................................................................................................

(CONTRACTOR'S NAME AND SURNAME/FULL NAME)

seated in / residence address \*\*…........................................................................................................

(RESIDENCE ADDRESS / SEAT ADDRESS)

…............................................................................................................................................................

(PHONE, FAX, E-MAIL)

in response to the request for proposal published on ………………………. 2017 at bazakonkurencyjności.funduszeeuropejskie.gov.pl and on the Contracting Entity's website, I am submitting a tender within the proceedings for **SAFETY PHARMACOLOGY CARDIOVASCULAR SYSTEM STUDY IN DOG FOR EC313 COMPOUND.**

, run in the form of a request for proposal.

I am offering the performance of the order within task no. …. for the price of: PLN ……………………………………………… gross (say: …………………………………………………........................................................................................)

The tender value includes all and any costs related to the performance of the order.

I declare that the order shall be completed till .............. (i.e. within ......... weeks from actual commencement).

I declare that I have experience needed for the due performance of the order.

I declare that I have infrastructure needed for the performance of the order.

I declare that I have qualified staff experienced in running tests on animals.

I declare that I shall complete the order without / with subcontractors\* (if yes, provide the scope of the order which shall be subcontracted).

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I declare that I have obtained all and any information needed for the due performance of the order.

I shall be bound by this offer for a period of 90 days from the deadline for tenders' submission.

The tender together with attachments counts ……… pages.

\* - submit a separate form for each task for which the tender is submitted

\*\* - delete not applicable

…......................................... ………………………………………………………………………

Place, date: signature and personal stamp of the authorised signatory

Attachment no. 2 to the Request for proposal

Case ZO-02-2019

**DECLARATION ON MEETING PARTICIPATION CRITERIA**

**FOR THE PROCEEDINGS AND NO GROUNDS FOR EXCLUSION**

**DUE TO A CONFLICT OF INTEREST**

On submission of the tender for **SAFETY PHARMACOLOGY CARDIOVASCULAR SYSTEM STUDY IN DOG FOR EC313 COMPOUND**, I declare that the Contractor:

…............................................................................................................................................................

(CONTRACTOR'S NAME AND SURNAME/FULL NAME)

seated in / residence address \*\*…........................................................................................................

(RESIDENCE ADDRESS / SEAT ADDRESS)

…............................................................................................................................................................

(PHONE, FAX, E-MAIL)

**meets** the conditions for participation in respect of knowledge and experience, financial status, and technical and human potential;

**is not affiliated** to the Contracting Entity, personally or in terms of equity, by mutual relations between the beneficiary and individuals authorised to bind the beneficiary or individuals performing on behalf of the beneficiary actions related to preparation and running the proceedings for choosing a contractor and the contractor, which in particular includes:

1. being a partner to a civil partnership or another partnership
2. holding at least 10% of shares,
3. acting as member of a supervisory or management board, proxy, attorney
4. being married, in consanguinity or affinity in a straight line, in second degree of kinship or affinity of the second degree in collateral line or by adoption, guardianship or custody

….....................................................................................

signature and personal stamp of the authorised signatory

Attachment no. 3 to the Request for proposal

Case ZO-02-2019

**LIST OF INDIVIDUALS DELEGATED TO WORK ON THE ORDER**

On submission of the tender for **SAFETY PHARMACOLOGY CARDIOVASCULAR SYSTEM STUDY IN DOG FOR EC313 COMPOUND**, I declare that the Contractor:

…............................................................................................................................................................

(CONTRACTOR'S NAME AND SURNAME/FULL NAME)

seated in / residence address \*\*…........................................................................................................

(RESIDENCE ADDRESS / SEAT ADDRESS)

…............................................................................................................................................................

(PHONE, FAX, E-MAIL)

shall delegate the following individuals to work on the order:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **No.** | **Name and surname** | **EDUCATION / EXPERIENCE / QUALIFICATIONS** | **SCOPE OF DELEGATED WORKS** | **LEGAL BASIS FOR DELEGATION** |
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signature of the authorised person

Attachment no. 4 to the Request for proposal

Case ZO-02-2019

**PRICE CALCULATION / SCOPE OF THE ORDER**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Study | Requirements (including standard) | Time of draft report preparation | VAT (if applicable) | Gross price (total) |
| Safety pharmacology: CV study in female dogs | - GLP-compliant  - Based on ICH S7A guideline for safety pharmacology studies for human pharmaceuticals  Test system:  - Species: Beagle dog  - Sex: female  -Rout administration:: oral  - Number of dose groups: 4 (3 treated and 1 control)  - 4 animals to be exposed with each dose  The price should include any other mandatory costs required to perform the study (if not indicated otherwise in the description)  • The price should include any additional costs required to obtain the data required by the market regulator in Europe and obtain approval for Phase I clinical trials; but nothing else |  |  |  |
| TOTAL | | | |  |

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

siganture of authorised person