December, the 9th, 2017, Lodz,

**EXPLANATION OF REQUEST FOR PROPOSALS ZO-07-2017**

TO ALL INTERESTED PARTIES

By following point 10 of Chapter VI, the ordering party informs that within the request for proposals for supply of FORMULATION DEVELOPMENT OF AN INVESTIGATIVE MEDICINAL PRODUCT INTENDED FOR CLINICAL RESEARCH USE based on the provisions of the Act of April 23, 1964 - the Civil Code (Journal of Laws 2014, item 212, as amended), **questions were received**. Please find the questions and answers are **below**:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Q&A\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Question 1: (...)** Overall pricing of the services and with this pricing per indicated unit is of course binding and will not change unless the project scope changes. However, costs for raw materials, analytical columns etc. cannot be part of the indicated costs since at this point it is not even clear which materials will be used and which amounts subsequently will be needed. The same is e.g. valid for a QP audit to be performed at the API manufacturer.

**Answer**: *The Contracting Party kindly informs, that it expects the Contractor to provide their “best estimate" and include this in their offer. The Contracting Authority realizes that at the time of submitting the offer it is impossible to predict the exact costs of materials, therefore it allows changes to the Contractor's remuneration resulting from these changes (during the execution of the order).*

**Question 2:** Regarding the personnel, we can of course provide you an overview of our team and the related skills but providing a binding scenario who will work at the project to which extent will not be possible as when finally starting the project as a service provider we have to set this in the overall context of all projects we are working on. The overview you are requesting for us is more known to be binding and relevant for partners of the consortium where the project members get paid by the EC but not for third party providers. Therefore, please consider is to be a non-binding information at this stage

**Answer:** *The Contracting party kindly informs that the project that the RFP is being proceeded is* ***not a consortium project.*** *As for the personnel, The Contracting party kindly informs, that at least two people should be described to demonstrate the competencies of Contractor. The project team may be changed during the implementation of the project, however, it should have same competences.*

**Question 3:** As a service provider we will not disclose details on projects we have worked on for other customers as this would not be in accordance with the related signed secrecy agreements. At the stage of final decision we might share this directly with the responsible members of the European commission on the basis of a signed secrecy agreement but hope for your understanding here that this information cannot be disclosed at this point of time and not directly to the project consortium

**Answer:** *The contracting authority kindly informs, that according to RFP provisions,*

*“experience, the contractor must show that within the last three years before the deadline for submission of tenders in the proceedings, and if the period of activity is shorter - during that period the contractor completed at least one service consisting in developing the experimental formulation of the medicinal product.*

*Evaluation of the fulfilment of the above condition will be made on the basis of the list of performed services together with evidence of their proper performance.”*

*In order to participate it is obligatory to present at least one of such services together with confirmation of performing such. The Contracting Authority informs that such information can be presented in a general way and contain confirmation of the service, e.g. by scanning the appropriate statement signed by the recipient of previous service (contact details can be anonymized).*

***If the information in this respect is confidential, the contracting authority allows the conclusion of a confidentiality agreement. This document is attached to this email. The Employer allows sending a completed and signed scan of the subject confidentiality agreement before submitting the offer****.*

**Question 4:** Inspection reports and CAPA plans are also considered to be confidential and will not be shared/disclosed at this stage of discussion. As for the project/customer details we might share this directly with the responsible member of the EC but not with the project consortium directly

**Answer**: *The Contracting party kindly informs that the project that the RFP is being proceeded is* ***not a consortium project. The information submitted will be not revealed to any entity, except of the personnel of contracting party.***

*As for the question regarding submitted recent inspections by regulatory authorities including FDA form 483 and corrective measures or documents alike, the contracting party kindly informs that submitting a synthesis of such documents with the statement confirming authentic of such information is necessary.*

***If the information in this respect is confidential, the contracting authority allows the conclusion of a confidentiality agreement. This contract is attached to this email. The Employer allows sending a completed and signed scan of the subject confidentiality agreement before submitting the offer****.*

BILATERAL NONDISCLOSURE AGREEMENT

This Bilateral Nondisclosure Agreement(“NDA”)**,** is effective as of the \_\_\_\_ day of, \_\_\_\_\_, 20\_\_ (“Effective Date”) by and between **Evestra Onkologia.** (“Evestra”), a corporation registered in Poland, with its principal place of business at ul. Muszynskiego 2 lok. 3.22, 90-151, Lodz, and \_\_\_\_\_\_\_\_\_\_\_\_ (“*Company*”), with its principal place of business at \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, the two entities of which are collectively herein referred to as the “Parties.”

WITNESSETH:

That each of the Parties has requested nonpublic information concerning the business and products of the other for the purposes of exploring a potential business relationship (“Transaction”).

NOW THEREFORE, in consideration of their respective disclosure(s) of proprietary information, theParties agree as follows:

1. For a period of five (5) years from the above effective date of this NDA, the receiving party ("Recipient") shall not disclose to any party (other than those parties described in this Section 1) any information it receives from the disclosing party ("Owner") that is marked “Proprietary”, “Confidential”, or with comparable legend(hereinafter referred to as "Proprietary Information") and shall not use the Proprietary Information for any purpose other than as permitted under this NDA.

Recipient shall use the same degree of care to avoid disclosure or use of the Proprietary Information as Recipient employs with respect to its own proprietary information of like importance, and never less than reasonable care. Disclosure shall be limited to Recipient's officers, directors, employees, affiliates, advisors, and agents (“Representatives”) who need to know the Proprietary Information for the purpose of evaluating any possible Transaction between the Parties (it being agreed that such Representatives shall be informed of the confidential nature of such information and shall be directed to treat such information confidentially).

In accordance with this NDA, Recipient shall immediately notify Owner in writing upon discovery of any loss or unauthorized disclosure of the Proprietary Information by Recipient by verifiable means of communication.

2. In the event Owner orally discloses its Proprietary Information to Recipient, Owner shall notify Recipient in writing of the oral disclosure within thirty (30) days following the disclosure, identifying the place of oral disclosure and the names of Recipient's employees to whom the disclosure was made and describing the information disclosed.

3. The term Proprietary Information does not include information which:

(i) is previously known to Recipient prior to disclosure hereunder without violation of confidence, or without breach of this NDA; or

(ii) is or becomes generally available to the public other than as a result of a disclosure of Recipient; or

(iii) is received from a third party without obligation of confidence and without breach of this NDA; or

(iv) is independently developed by Recipient without violating its obligations hereunder; or

(v) is approved for release by written authorization of Owner.

4.                 Notwithstanding anything herein to the contrary, Recipient may disclose the Proprietary Information received hereunder in response to a request for disclosure by a court or another governmental authority, including a subpoena, court order, or audit-related request by a taxing authority, provided that Recipient:

(i) promptly notifies Owner of the terms and the circumstances of such request so that Owner may seek, at its sole expense, an appropriate protective order; and,

(ii) furnishes only information that, according to written advice of its legal counsel, Recipient is legally compelled to disclose.

It is agreed that, if in the absence of a protective order Recipient is nonetheless required to disclose any Proprietary Information, Recipient may disclose such information without any liability hereunder.

5. Upon written notice to Owner, Recipient may designate an individual as its coordinator for the receipt, on its behalf, of all Proprietary Information pursuant to this NDA. Recipient may change its designated coordinator upon written notice to Owner.

6. All written and/or electronic data delivered by Owner to Recipient pursuant to this NDA shall be and remain the property of Owner,and the written/electronic data, and any copies thereof, shall, upon Recipient’s receipt of written request from Owner, be promptly returned to Owner, or destroyed at Owner’s option, with immediate written certification of such destruction delivered to Owner by Recipient.

In addition, all documents, memoranda, notes, and other writings whatsoever prepared by Recipient or its Representatives based on the Proprietary Information shall be delivered to Owner or be destroyed.

7. Owner understands that Recipient may currently or in the future be developing information internally, or receiving information from other parties that may be similar to Owner's information.

Accordingly, nothing in this NDA shall be construed as a representation or inference that Recipient will not independently develop products, for itself or for others, which compete with the products or systems contemplated by Owner’s information; provided that Recipient does not breach its obligations pursuant to this NDA in connection with such development.

8. In addition, Recipient and its Representatives will not, without the prior written consent of Owner, disclose to any person, either the fact that discussions or negotiations are taking place, or any of the terms, conditions, or other facts regarding same, including the status thereof.

9. Recipient agrees that, in the event Owner is required to bring an action to enforce the provisions of this NDA, the damages to Owner for improper disclosure of the Proprietary Information are irreparable, and upon meeting its burden of persuasion to establish such improper disclosure, Owner is entitled to equitable relief, including an injunction and a preliminary injunction.

10. Neither party makes any representations or warranties about the accuracy, completeness or correctness of the Proprietary Information, nor will such representation or warranty be implied.

11. This NDA may be modified only by a written instrument duly signed by authorized representatives of the Parties.

12. This NDA or any section thereof shall not be construed against any party due to the fact that said NDA or any section thereof was drafted by said party.

13. This NDA is non-assignable, is binding upon all parties and their Representatives and shall be governed and construed in accordance with the laws of Poland.

CONFIRMED AND AGREED: CONFIRMED AND AGREED:

## Evestra Onkologia

### BY: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ BY: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Print: Ze’ev Shaked, PhD.Print:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Title: Prezes ZarzaduTitle: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_