August, the 7th, 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 pre-clinical tests (physiochemical, ADME-tox, genotoxicity, safety pharmacology and toxicological tests) necessary to commence 1st phase clinical trials for EC313., conducted in the mode of inquiry based on the provisions of the Act of April 23, 1964 - the Civil Code (Journal of Laws 2014, item 212, as amended), **questions were recieved**. Please find the questions and answers are **below**:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**Q&A**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

***Question 1:*** We are preparing the quotations now and will send these shortly. However, please could you send your Mutual Confidentiality Agreement as we have questions regarding the Test Article. Our main question is knowing if the Test Article is a small molecule or large molecule (biologic, e.g. an antibody). Obviously that impacts which analytical method would be used. Our formulation, analytical, and bioanalytical experts need to understand a little more about the molecule to provide the best advice on the cost and what data gaps there may be such as whether there is an analytical/bioanalytical method available for transfer or one needs to be created.

***Answer:*** The contracting party did not anticipate the signing of confidentiality agreements at the inquiry stage in the tender procedure. At the same time, the contracting authority informs that EC313 is a hormonal steroid and is the same family of small molecular compounds as Ulipristal is.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_***Clarifiactions***\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

The contracting authority does not provide for the possibility of meetings during the the tender procedure. Any question should be asked according to the procedure described in the ZO-07-2017 RFP