August, the 30th, 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:*** serial sampling - is it a collection of tissues or blood for further investigation?

***Answer 1:*** The contracting party presumes that the question is about pharmacokinetic studies. Serial sampling involves blood samples. We also recommend reading the file "ZO-07-2017\_Answers to questions\_4". At the same time the Ordering Party accepts offers with sampling of more than 3 time points

***Question 2:*** Are 3 time points only related to the final tissue collection or serial and final samples collection?

***Answer 2:*** This information refers to the preferred pattern of serial blood collection. Tissue samples should be taken once. At the same time the Ordering Party accepts offers with sampling more than 3 times

***Question 3:*** If time points are related to organ resection, should the test groups be increased by an additional number of individuals?

**Answer 3:** As above

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**Clarification 1:** The contracting authority permits the change of the blood sampling scheme in the PK