August, 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 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 blood sampling: Can you advise number of timepoints and over what duration? (eg. 6 timepoints over 24h?)

***Answer***: Yes, 6 timepoints over 24 hour is acceptable

***Question 2***: Tissue sampling and analysis: Can you advise the number of tissues and tissue types?

***Answer***: Uterus should be collected

***Question 3:*** The general guideline says: “The contractor shall prepare a final presentation presenting the course of tests, achieved results and conclusions and shall present the same during a seminar organized in the Contracting Entity’s seat within two weeks from the Contracting Entity’s approval of the final report” Does this mean Contractor shall travel to Poland to present the final results of the completed task? If so, who will cover the travelling expenses?

***Answer***: Yes, the contractor shall travel to Poland to present final results, however the time of such travel may differ from what is stated in guidelines and might be later that two weeks from approval of the final report. The contractor shall cover the costs of travel

***Question 4***: The general guideline IV.3: “The contractor shall develop a time attachment for tests” and a) maximum time to deliver the active substance.”

Does this mean, that the experiments are preferably conducted not in the beginning of the project, but rather towards the end of it (02/2019)?

***Answer***: The Contracting Authority kindly informs, that the aforementioned does not indicate that the studies would be done in the end of said period. The quoted information from guidelines means that the Contractor, in his offer, shall inform how much time, before starting the experimental phase, the API shall be delivered to Contractor's seat.