

In connection with the questions received to the following request for quotation:

No. 20/2020 - SARCO:

Expert advisory services in the field of preclinical studies regarding chronic toxicity studies in rodent (Sprague Dawley rat) and non-rodent (Beagle dog) for OATD-01 chitinase inhibitor,

we provide answers to questions that have arisen up to 11/05/2020 15:00 (CET).

Questions concerning the object of the tender:

1. By chronic toxicity we assume this refers to a 6 month rat study and a 9 month dog study?

Answer: Yes, we are talking about standard chronic studies last 6 months in rodents and 9 months in non-rodents (refer to ICH S4).

2. Is the expectation that Contractor would propose a number of suitable vendors for OncoArendi to select the most appropriate CRO? Or will OncoArendi provide details on the selected CRO based on previous experience with the drug candidate OATD-01?

Answer: All studies for OATD-01 drug candidate are carried out with Charles River Laboratories Inc. (CRL). Chronic studies has already been contracted with CRL and are in progress. Contractor would be involved in the analysis, evaluation, interpretation and positioning of results from both studies and if necessary peer review of histopathological slides. Verification of reports from completed chronic toxicity studies, monitoring on site visit and GLP audit.

3. Given the current climate with COVID-19, many CRO's are delaying commencement of studies. Thus, there is a possibility that the final study reports would not be available by the end of contract on 31 Dec 2021. Is there a possibility to extend contract date, if required?

Answer: The contract will secure the period necessary to finalise the reports.

4. When does OncoArendi anticipate commencement of dosing on both studies?

Answer: Both in vivo studies phase are ongoing.

5. The number of proposed hours to conduct the work is set at 725 h, does this take into account on-site monitoring and travelling time?

Answer: Yes, it takes into account CRL Spencerville Ohio on site monitoring visit and GLP audit towards the end of the dog study: including: 3 days on-site - one toxicology senior expert and one GLP auditor.