

Questions to the Request for Offers No. 42/2020 – ARG:

- 1. Can you please let me know if an electronic version is sufficient or do you need the original documents (until August 10th)?**

According to the RFQ (point VII.5), offers shall be issued only via email to: malgorzata.borkowska@oncoarendi.com, so please send us an electronic version with your electronic signature or a scan of documents with a handwritten signature.

- 2. As stated in previous tenders, gross contract value is not applicable in our case (we are a Swiss company and do not charge any EU client VAT), so we will only provide net contract value and state “not applicable” for gross contract value. Please confirm that this is acceptable.**

Please enter the same value in the net and gross amount.

- 3. With respect to experience in modelling and simulation activities to provide human PK and dose predictions, we do not offer the use of programs such as WinNonlin or similar programs which are in use for clinical PK/PD modelling and dose predictions to plan clinical studies. Our experience in modelling and simulation activities to provide human PK and dose predictions applies to the preclinical context. We understand that this is requested and therefore our experience is in full compliance with the subject of this Request. Please advise should that not be the case.**

OATD-02 is developed as immunooncology agent and, for that reason, FiH clinical trial will be done in advanced cancer patients. From ethical perspective, the anticipated dose should be safe but also exert pharmacological effect. Therefore, it is assumed that dose prediction might require some advanced PK/PD modelling. We do not require the use of specific software (e.g, WinNonlin) for this purpose but we cannot preclude that such capabilities might be needed. It should be noted that the dose prediction should be based on comprehensive understanding of the expected compound's PK characteristic in humans which may go beyond simple allometric scaling. Based on our experience and activities undertaken so far, OATD-02 compound demonstrates complex pharmacological characteristics.