Rzeczpospolita Polska

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

**03/2023-ABM**

*Preparation and comprehensive execution of the phase II, Proof-of-Concept, clinical trial in order to assess efficacy, pharmacokinetics, pharmacodynamics and safety of chitinase inhibitor OATD-01 in patients with active pulmonary sarcoidosis.*

we provide answers to questions that have arisen up to 09/02/2023 12:00 PM (CET).

**Questions concerning the object of the tender**

1. Q: Do we need to account for CHIT1 activity in plasma and sputum into the budget, in addition to the sarcoidosis biomarkers listed in the protocol?
   A: Yes, CHIT1 activity in plasma and sputum will be assess in central lab and needs to be added to the budget.
2. Q: Regarding PK services is there an existing PK assay that can be transferred to us? Or does this request require PK method development as well as clinical sample analysis?
   A: We do have PK methods developed, they would only need cross-validation by the bioanalytical lab.
3. Q: As the IMP is neither an AB nor a small molecule can you please also let us know whether you use MS, ELISA or another general method for testing?
   A: The IMP is actually small molecule and the PK assay is LC-MS.

**Questions concerning the formal issues of the tender**

1. Q: The entity/ country for contracting on our side would default to USA due to some larger portion of work done there.
   This then entails a different VAT % compared to having an entity chosen in Europe (like Poland) – does Molecure have any preference for this choice?
   A: since we are buying CRO services, we treat it as an import of service from a VAT point of view, therefore our partner should see it in parallel as an export of service and put no VAT on the invoice.

**The deadline to submit offers remains February 10, 2023 23:59:59 CET**