**OFFER FORM**

**APPENDIX NO 1 TO RFQ NO 03 07 2024 E**

**Data of the Bidder**:

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| --- | --- |
| 1. **Name:** |  |
| 1. **Registered office address:** |  |
| 1. **EU VAT no.:** |  |
| 1. **Person authorised to contact the Ordering Party:** | |
| Name and surname: |  |
| Telephone numer: |  |
| E-mail adress: |  |

**Part of the order: Part 1**

**CPV name and code: 73110000-6 Research services.**

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|  | **Answer / confirmation of compliance**  \*- delete inappropriate | **Comments, if any** |
| General plan for a single PK study:   |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | | **Group** | **Compound** | **Dose mg/kg** | **Route** | **Sample collection** | **Gender** | **Animals** | **Conditions** | | 1 | tbd | tbd | IV (5min infusion) | pre-dose, in-dose\*\*, 5‘, 15‘, 30‘, 1h, 2h, 4h, 8h, 24h, 48h (plasma)  15’, 1h, 2h (whole blood)  pre-dose, 0-8h, 8-24h, 24h-48h (urine) | male | 2 | Fasted | | 2 | tbd | tbd | PO | pre-dose, 10‘, 20‘, 40‘, 1h, 2h, 4h, 8h, 24h, 48h (plasma)  20’, 1h, 2h (whole blood)  pre-dose, 0-8h, 8-24h, 24h-48h (urine) | male | same as above\* | Fasted |   tbd – to be determined  \* cross-over study design  \*\*just before the end of 5-minute infusion   * 1. **Animals**   Cynomolgus monkeys, naïve or non-naïve, males, age-matched, n=2 animals/species. Timelines should be presented for the study execution.   * 1. **Regimen of diet**   Water *ad libitum* before and during the study execution. Food *ad libitum* during pre-treatment and fasted overnight before treatment; food will be restored 4 hours after dose administration.   * 1. **Administration routes and treatment regimen**   Animals (males) will be administered (single oral and intravenous administration) with the dose selected based on Sponsor’s data (low-dose PK studies).   * 1. **Preparation of test article formulation**   Test compound (small molecule; oncology indication) will be delivered by Sponsor together with the detailed description of formulation. Formulations remaining after dosing should be kept for further analysis.   * 1. **Evaluated parameters**   Individual body weights on day of dosing. Clinical observations post-dose and at the time of sampling.   * 1. **Blood and urine sampling**   Blood samples from each animal will be taken at 10-11 time points, up to 48h post-dosing. Collection of about 0.6 mL of whole blood at each time point, to secure about 100 uL of whole blood in a separate vials at the three preselected timepoints, and to separate plasma from the remaining blood. Collection of about 2 mL of urine at four intervals post dosing. Urine samples should be fortified with formic acid (at a final concentration of 0.2% v/v) before analysis and storage.   * 1. **Sample analysis**   Plasma and urine samples bioanalysis, including LC-MS-MS method development. Secured whole blood ( c.a. 100 uL) as well as all remaining plasma (min. 150 uL) and urine (c.a. 1 mL) samples will be stored at -80°C until shipped to Sponsor. Shipment costs in dry ice must be included.   * 1. **Reporting**   Non-GLP study and report, including PK parameters calculation for plasma, and evaluation of the parental compound concentration in formulations and urine.  **The estimated minimum number of studies to be performed during the contract period is 1.**  **The estimated number of studies to be performed during the contract period is 3.** | **YES/NO\*** |  |
| **NET PRICE**  of performing **one study** including all costs\* | |  |
| **TOTAL NET PRICE**  of performing **3 studies** including all costs\*  (this value is the subject of the offer evaluation and is the maximum contract value) | |  |

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| **Order performance principles:** | **Answer / confirmation of compliance**  \*delete inappropriate | **Comments** |
| **AGREEMENT DATE**  Deadline for performance of the contract: **31st July 2025.**  In the event of prolonging the completion date of the Project stage, the agreement may be extended following changes in the Project co-financing agreement. | **YES/NO\*** |  |
| **ORDER COMPLETION DATE:** The execution of orders under the contract must take place by **31st July 2025**.  **Samples must be delivered to the Sponsor facility within two weeks after study completion.**  The order completion date is an admission condition, tenders indicating a longer deadline for performance will be rejected. Only those offers whose deadline falls within the deadline indicated in this inquiry are admitted to the assessment. Placing an order should be understood as the effective sending by the Ordering Party Purchase Order to the e-mail address indicated by the Contractor. | **YES/NO\*** |  |
| **PAYMENT TERMS**  Payment deadline for invoices of not less than **30 calendar days**. | **YES/NO\*** |  |

I declare that I have familiarized myself with the content of the RFQ and have no objections.

I declare that the offer is valid at least until 31st August 2024; i.e. until ............................

I understand that if I certify any untruths, my bid will be rejected.

I declare that the Bidder meets the following conditions:

* 1. has the right to carry out a specific activity or perform a specific activity, if such right is required by law;
  2. is engaged in activities compliant with the description of the subject matter of the contract;
  3. has the necessary knowledge and experience as well as the technical potential and persons capable of performing the contract.
  4. Is in an economic and financial situation which guarantees the performance of the contract;
  5. is not in liquidation or have not been declared bankrupt;
  6. is not in arrears with payment of public and legal charges, taxes or social or health insurance premiums - the Bidder shall submit a declaration that they are not in arrears with the above-mentioned receivables (public and legal charges, taxes, social or health insurance premiums);
  7. has not been validly convicted of an offence committed in connection with a tender procedure, an offence of bribery, an offence against trading, or another offence committed for financial gain - applies to a partner in a general partnership, a partner or a member of the management board of a partnership, a general partner of a limited partnership or a limited joint-stock partnership; a member of the management body of a legal person.
  8. has no personal or capital relations with the Ordering Party (mutual relations between the Contracting Authority or persons authorized to contract liabilities on behalf of the Ordering Party, or persons carrying out activities related to the execution of the procedure for selecting the Contractor and the Contractor):
* participating in a company as a partner in a civil partnership or a partnership, holding at least 10% of shares (unless a lower threshold is stipulated by law), being a member of a supervisory or managerial body, a proxy, a representative,
* being married, in a relationship of kinship or affinity in a direct line, or in a relationship of kinship or affinity in a collateral line to the second degree, or being in a relationship of adoption, custody or guardianship, or being in a shared life relationship with the economic operator, its legal deputy, or members of the management or supervisory bodies of contractors competing for the contract,
* remaining with the economic operator in such a legal or factual relationship that there is a reasonable doubt as to their impartiality or independence in connection with the contract award procedure.

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Place and date Signature of the authorized person\*

\*Signature of the person or persons listed in the registers to incur obligations on behalf of the Bidder or in the appropriate authorization.