

Warsaw,10 February 2023

**REQUEST FOR QUOTATION No. 008/2023**

**Service of performing in vitro ADME studies for the drug candidate PKL-021,**

**a small molecule chemical compound**

for the Marceli Nencki Institute of Experimental Biology

 Polish Academy of Sciences

**Ordering Party:** M. Nencki Institute of Experimental Biology PAS,

with registered office at 3 Pasteura Street, Warsaw (02-093), NIP:525-000-92-69, REGON 000325825

Procurement contact person: Barbara Pijet- Binkiewicz

e-mail: b.pijet@nencki.edu.pl

Deadline for submission of bids: **no later than 21 February 2023, 12:00 p.m.**

**I. Description of the subject matter of the contract:**

The subject matter of the contract is: Service of performing in vitro ADME studies for the drug candidate
PKL-021, a small molecule chemical compound, in particular studies including:

1. **MDCK-MDR1 assay**
* assessing transport in both directions (A-B, B-A)
* at least 1 test concentration of a test article
* at least 2 replicates
* incubation time at least 60 min max 150 min
* Data delivery: report in English including P app, efflux ratio, % recovery
1. **CYP induction**
* test system – pooled cryopreserved human hepatocytes (at least 3 donors)
* CYP isoforms tested: CYP1A2, CYP2B6, CYP3A4
* at least 5 test article concentrations, 3 replicates
* experiment time – till at least 48h
* Data delivery: report in English including enzymatic activity and mRNA levels, % of positive control and mean fold induction relative to vehicle control, concentration of metabolite of probe substrate, E max, EC50
1. **Plasma protein binding**
* species: CD-1 mouse, Wistar/ Spraque Dawley rat, Beagle dog, Gottingen/BAMA minipig, White New Zealand rabbit, Cynomolgus monkey and human
* method: equilibrium dialysis
* 1 concentration of a test article, 3 replicates
* data delivery: report in English including fraction unbound (fu) and recovery
1. **Microsomal protein binding**
* species: CD-1 mouse, Wistar/ Spraque Dawley rat, Beagle dog, Gottingen/BAMA minipig, White New Zealand rabbit, Cynomolgus monkey and human
* method: equilibrium dialysis
* 1 concentration of a test article, 3 replicates
* data delivery: report in English including fraction unbound (fu) and recovery
1. **Blood-to-plasma ratio and ery binding**
* species: CD-1 mouse, Wistar/ Spraque Dawley rat, Beagle dog, Gottingen/BAMA minipig, White New Zealand rabbit, Cynomolgus monkey and human
* incubation time at least 60 min, 3 replicates
* data delivery: report in English including mean blood to plasma ratio

**The ordering party will provide:**

* tested item (PKL-021)
* internal standard (PKL-023)
* the analytical procedure for the determination of the test item in rat/dog plasma by LC-MS/MS

At the end of each study the study report should be provided, including the parameters specified above in the study description Taking into account what the Ordering party provides, the Contractor will provide all materials, reagents and equipment necessary for performing the services. All data generated through the service should be available for the Ordering Party or sent to Ordering Party upon request. until 31 December 2023.

**Deadline for delivering the procurement order:**

* Planned date of signing the contract March 2023
* Planned date of shipping the research materials: March 2023
* The Ordering Party requires completion of all studies and submission of all study reports no later than 45 days from providing all required materials to the Contractor.
* The term of the contract: to 31.12.2023

73111000-3 – research laboratory services

Under this Request for proposal, the Ordering Party does not allow the submission of partial bids.

**II Bids evaluation criteria**

In the selection process, the Contracting Authority will be guided by the following criterion applied to the bids fulfilling the conditions for participation in the procedure (Description of the subject matter of the contract - point I).

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| --- | --- | --- |
| Lp. | Description | Criterion  |
| 1. | Price (C) | 90 |
| 2. | Order completion date (D) | 10 |
| 3. | Total | 100 |

1. The number of points (Lp.) awarded to each of the evaluated tenders will be calculated according to the formula: Lp. = C+D:

Lp - total number of points awarded in the offer,

C – the number of points awarded based on the criterion - price,

D - the number of points awarded based on the criterion – payment deadline.

1. Number of points of the examined offer:
2. In the “Price” (C) criterion, points shall be awarded (to two decimal places) according to the following formula:

Points for price criterion = the lowest net price/net price of the bid under consideration x 100 x 90%

1. Order completion date (D)

For the criterion “Order completion date”, points shall be awarded according to the following formula:
10 points – when the order completion date is 35 days from providing all required materials to the Contractor,
5 points – when the order completion date is 40 days from providing all required materials to the Contractor,
0 points –when the order completion date is 45 days from providing all required materials to the Contractor.

**III Description of Bid Preparation and Evaluation:**

1. The bid should be prepared on the form attached as Appendix No. 1 to this request for quotation.
2. The bid should contain information about the total net and gross value of the contract: The Bidder, whose bid will be selected, shall provide before signing the agreement the scans of: the certificate of entry into the register of economic activity, REGON certificate and NIP certificate.
3. The price of the bid is the price for the entire order performed.
4. The price indicated in the bid has to include all of the Ordering Party's requirements specified in the request for quotation and all costs that shall be incurred by the Contractor due to proper execution of the subject matter of the order, in accordance with the agreement and the binding regulations, as well as any possible discounts and rebates applied by the Contractor.
5. The price in the offer should be specified to two decimal places.
6. The Economic Operator is obliged to indicate in the Form - Template Offer the price for the execution of the contract without VAT and the price with VAT calculated according to the Polish tax regulations in force (with the reservation that the foreign entrepreneur writes only the price without Polish VAT - as the total price to be paid. The foreign entrepreneur is obliged to indicate on the invoice the Ordering Party's NIP number with the PLN prefix - VAT number - PL 5250009269 ).
7. If a tender is submitted, the selection of which leads to the creation of a tax obligation for the Contracting Authority in compliance with VAT regulations (e.g. a foreign entrepreneur), the Contracting Authority, in order to evaluate such a tender (comparison with other tenders), will add VAT to the price presented in it, which it would be obliged to calculate in compliance with these regulations.
8. In the case of foreign Economic Operators not covered by intra-Community trade, the Contracting Authority will also add customs duty (if there is customs duty in this procurement as an additional cost for the Contracting Authority) for comparison of tenders.
9. Bids must be submitted electronically as a scanned original bid via email to:
b.pijet@nencki.edu.pl.
10. Please mark your bid by adding in the subject line of your email: **research service.**
11. Only the bids containing all of the elements listed above will be evaluated.
12. Bids not meeting the requirements specified in this request for quotation will be rejected (the Contracting Authority will inform the Bidder of the rejection of their bid by sending an e-mail to the address of the Bidder indicated in the bid).
13. Should there be any obvious miscalculations, typing errors or other obvious mistakes in the bid, the Contracting Authority shall correct them pursuant to the rules defined in the PPL Act (by sending appropriate e-mail information to the Bidder's address indicated in the bid).
14. In case of inconsistencies in the submitted bids or issues requiring clarification (especially when an abnormally low price is suspected), the Contracting Authority shall ask the Bidder to provide the relevant clarifications and additions (by sending the relevant e-mail information to the Bidder's address indicated in the bid) – setting the deadline for response – 2 working days from the date of sending the request.
15. If the Bidder fails to respond to the request referred to above or if the explanations provided by the Bidder are not complete and exhaustive, the Contracting Authority shall reject the bid (the Contracting Authority shall inform the Bidder that their bid has been rejected by sending an e-mail to the Bidder's address indicated in the bid).
16. Only non-rejectable bids will be evaluated.

**IV Additional Information:**

1. An agreement will be signed with the selected Bidder for the purpose of carrying out the contract.
2. The agreement will be valid until December 31, 2023.
3. The Contracting Authority reserves the right not to select any Bidder.
4. The selection of the Contractor will be announced on the Contracting Authority's website as soon as the procedure is completed.
5. Pursuant to Article 7 (1) of the Act of April 13, 2022 on special solutions to prevent support for aggression against Ukraine and to protect national security (Journal of Laws of 2021, item 835), the following are excluded from the public procurement procedure:

*(a)* a contractor and a participant in the competition listed in the lists set out in Regulation 765/2006 and Regulation 269/2014 or included in the list on the basis of a decision on inclusion in the list deciding on the application of the measure referred to in Article 1(3) of the Act;

*(b)* a contractor and a participant in the competition whose beneficial owner within the meaning of the Anti-Money Laundering and Countering the Financing of Terrorism Act of 1 March 2018 (Journal of Laws of 2022, items 593 and 655) is a person listed in the lists set out in Regulation 765/2006 and Regulation 269/2014 or listed or being such a beneficial owner as of 24 February 2022, provided that he or she has been listed on the basis of a decision on listing that resolves the measure referred to in Article 1(3) of the Act;

*(c)* a contractor and a participant in the competition whose parent entity, within the meaning of Article 3(1)(37) of the Accounting Act of 29 September 1994 (Journal of Laws of 2021, item 217, 2105 and 2106), is an entity included in the lists set out in Regulation 765/2006 and Regulation 269/2014 or included in the list or being such a parent entity as from 24 February 2022, provided that it has been included in the list on the basis of a decision on inclusion in the list deciding on the application of the measure referred to in Article 1(3) of the Act."

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