Appendix 2 to Inquiry

AGREEMENT No. IBD/U/....... /2023

between:

**M. Nencki Institute of Experimental Biology** acting on the basis of registration in the Register of Scientific Institutes, Registry No: RIN-II-21/98 at the address: 3 Pasteura Street, 02-093 Warsaw, NIP: 5250009269, REGON: 000325825

represented by:

- ...................................................................................

hereinafter referred to as **the Ordering Party**

a

................................................................................, with the registered office at: ...................................., ..........................., entered into the Central Registration and Information on Business Activity of the Republic of Poland/KRS,
NIP: ....................... , REGON: .....................................

represented by:

- ...................................................................................

hereinafter referred to as **the Contractor**

The contract is not subject to the provisions of the Act of September 11, 2019 (Journal of Laws of 2019, item 2019 as amended), as the value of the contract is less than the amount indicated in Article of the Public Procurement 2.1.1Law,

Funding: ………………………………………………………….

§ 1

1. The subject of the Agreement is: **Service of performing in vitro ADME studies for the drug candidate PKL-021, a small molecule chemical compound** according to the Contractor's offer to inquiry no. …../2023 of ............................... (constituting Attachment No. 1 to the Agreement), hereinafter referred to as the subject of the Agreement.

§ 2

1. The contractor undertakes to perform:

* **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
* **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
* **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
* **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
* **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

**Archiving of the full documentation including all data generated through the service and make it available for the Ordering Party or sent to Ordering Party upon request. until 31 December 2023.**

**hereinafter “Services”**

2. 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

§ 3

1. For executing the subject of the agreement, the Contractor shall receive from the Ordering Party a remuneration amounting ………………………… net (in words: ....................................................), paid in two installments: advance payment in the amount of 20% of the total amount of the order, and the remaining part of the remuneration (80% of the total amount of the order) will be settled on the basis of an invoice with the final service performance report.
2. The remuneration will be paid in parts within 21 days from the date of delivery to the Ordering Party of a correctly issued VAT invoice.
3. The Contractor is obliged to send an invoice in electronic form (PDF) to
**faktury@nencki.edu.pl** no later than within 7 days from the date of realization of the subject of the Agreement.
4. The Ordering Party declares that it agrees to receive VAT invoices in electronic form in PDF format (in accordance with the declaration constituting Appendix No. 2 this Agreement).
5. The Parties declare that electronic invoices shall be sent and received in a manner ensuring authenticity of origin, integrity of content and legibility of invoices, as well as easy retrieval.
6. Payment will be made within 21 days of receipt of a properly issued invoice in electronic format (PDF) to **faktury@nencki.edu.pl**, by transfer based on an invoice marked with the contract number, issued on the basis of an acceptance protocol signed without reservation by the parties, to the Contractor's account indicated on the invoice.
7. The date of payment shall be the date on which the bank holding the Ordering Party's account is instructed to make the transfer.
8. The Ordering Party declares that it is entitled to receive VAT invoices and has NIP 525 000 92 69.

§ 4

1. The Contractor agrees to pay the Ordering Party a contractual penalty in the event:

1. in the event of any delays in the performance of the subject of the contract, except for cases caused by force majeure, the Ordering Party is entitled to charge contractual penalties in the amount of 0.1% of the net value of the subject of the contract for each day of delay, but not more than 10% of the net value of the subject the contract.
2. for withdrawing from the Agreement for reasons beyond the control of the Ordering Party in the amount of 10% of the net value of the subject of the contract.
3. for delivery of an invoice after the deadline referred to in § 3 par. 3, i.e.: after 7 days from the order completion date, in the amount of 0.5% of the net price specified in § 3 par. 1, for each day of delay.

2. The Ordering Party reserves the right to claim compensation for damages exceeding the amount of contractual penalties on general terms.

3. In the event of delay in payment of an invoice, the Ordering Party shall pay statutory interest to the Contractor.

§ 5

1. The Contractor represents and warrants that it is and shall remain during the period of performance and settlement of the contract, registered as an active taxpayer of goods and services tax and has the NIP number ..............
2. The Ordering Party will make payments to the bank account no. .....................................................
3. The Contractor confirms that the bank account indicated by him, on the basis of which the Ordering Party is to make payments, is a settlement account referred to in art. 49 item 1 point 1 of the Act of 29 August 1997. - Banking Law and has been reported to the appropriate tax office.
4. The Contractor confirms that the bank account indicated in the invoice or other document issued hereunder, on the basis of which the Principal is to make payment, is recorded and disclosed throughout the duration and settlement of the Agreement in the list referred to in Article 96b(1) of the Tax on Goods and Services Act of 11 March 2004, maintained by the Head of the National Tax Administration (Journal of Laws 2020.0.106 hereinafter: the List).
5. The Contractor undertakes to notify the Principal within 24 hours of deletion of its bank account from the List or loss of its status as an active VAT payer. Breach of this obligation shall result in a claim for damages up to the amount of the loss incurred.
6. In the event that a bank account is not shown in the List, the Contracting Authority reserves the right to withhold payment until the situation is clarified and a bank account is identified that will allow the payment to be recognized as a deductible expense under tax law.
7. The suspension of payments referred to in the preceding paragraph shall not have any adverse consequences for the Ordering Party, including in particular the obligation to pay interest on arrears or contractual penalties to the Contractor.
8. When making payments, the Ordering Party may use the split payment mechanism referred to in the Act of March 11, 2004 on Goods and Services Tax (Journal of Laws 2020.0.106).

9. Contractor represents that it is on the taxpayer white list.

§ 6

1. Order completion date is ……………….. days from providing all required materials to the Contractor.
2. The agreement will be valid until December 31, 2023.
3. Upon termination of the Agreement, Contractor shall, at Ordering Party's option, (a) destroy the Records, (b) deliver the Records to Ordering Party, or (c) retain the Records for three years and then destroy them. If the Records are to be destroyed, then Contractor shall give 30-days' written notice to Ordering party, and Ordering Party may elect during the 30-day period to have the Records transferred to it. Notwithstanding the foregoing, the Records may be retained as required by applicable law or as otherwise necessary for regulatory or insurance purposes.

§ 7

1. All intellectual and/or industrial property rights, including copyrights, arising as a result of the performance of the Services and/or the terms and conditions of this Agreement, and all rights to the results of the research ("Results") generated during the performance of the Services, shall be exclusive property of the Ordering Party, without additional payment.

2. The Contractor shall transfer to the Ordering Party the rights to all works ("**Work**"), including reports mentioned in § 2 item 1, within the meaning of the Act on Copyright and Related Rights (the **"Act"**), created as a result of the performance of the Contract, including the rights to the documentation created as a result of the performance of the Contract. as soon as they are established with the possibility to use them worldwide, in the following fields of exploitation:

2.1 application, input, display, transmission, sharing and storage regardless of format, system, standard or medium;

2.2 permanent or temporary reproduction in whole or in part, by any means and in any form, regardless of format, system or standard, by magnetic recording technique by digital technique or by entering into computer memory, and permanent or temporary fixation or reproduction of such records, including the making of copies and any use and disposal of such copies (especially on magnetic tape, DVD, Blu-ray, CD-R, CD-RW, Video-CD, Mini Disc, computer hard disk, MP3, MP4 files);

2.3 creation of new versions and adaptations (translation, adaptation, rearrangement or any other changes), printing in the form of a book or publication in the press, in whole or in part;

2.4 public dissemination, in particular display, public performance, broadcasting and re-broadcasting in any system or standard, as well as making the Works available to the public in such a way that anyone can have access to it at a place and time of their own choosing;

2.5 making foreign language versions of the Work;

2.6 permission to create studies, alterations, adaptations of the Works, as well as to dispose of and use such studies in all fields of exploitation specified in this Agreement (subsidiary rights) by the Ordering Party or third parties acting on behalf of the Ordering Party;

2.7 The right to determine the names of the Works under which they will be used or distributed, including trade names, including the right to register in its favor the trademarks with which the Works will be marked or the trademarks used in the Works;

2.8 the right to use the Works for educational or training purposes, lease, rental.

2.9 fixation, recording by means of analog, digital or optical technology, on any electronic, magnetic and digital media;

2.10 Reproduction, copying by means of specific technologies, at all scales, in two- and three-dimensional versions, using digital, analog or optical technologies;

2.11 use in advertising or promotion (including, in particular, use in advertising materials, publishing and distributing the Work or its elements as advertising materials, etc.), regardless of the form of advertising materials and their size, the materials from which they are made, the technique of fixation, and the place of display.), regardless of the form of advertising materials and their size, the materials from which they are made, the technique of fixation and the place of display, and in prospectuses, brochures, advertising leaflets and catalogs regardless of their quantity, circulation, technique of preparation and method of distribution, as well as the exploitation of part or all of the Work, consisting of fixation and distribution as part of advertising displays, and the reproduction and/or sale of publications or other advertising materials relating directly or indirectly to the advertised product or advertising campaign;

2.12 making public presentations, including, in particular, for marketing, promotional, advertising and production purposes;

2.13 Recording or reproduction in the memory of computers or computer networks (including, in particular, using the Internet or databases), including publicizing on the Internet, in particular by using or recording on websites and closed networks;

2.14 exploitation in all fields of exploitation specified in Article 50 of the Act, i.e.:

2.14.1 In terms of fixation and reproduction of the Work - production of copies of the Work by a specified technique, including the technique specified in this section, as well as by printing, reprography, magnetic recording and digital technique;

2.14.2 within the scope of trading in the original or copies on which the Work has been fixed - marketing, lending or leasing of the original or copies;

2.14.3 with respect to distribution of the Work in a manner other than that specified in item 2.14.2 above - public performance, exhibition, display, reproduction, as well as broadcasting and re-broadcasting, as well as making the Work available to the public in such a manner that everyone may have access to it at a place and time of their own choosing.

3. In the event of an intention to dispose of copyrights in fields of exploitation other than those indicated in § 7 item 2 of the Contract, the Ordering Party shall have the priority right to acquire the rights to exploit the Works in such fields.

4. With respect to all fields of exploitation listed in § 7 item 2 of the Agreement, the Contractor confirms to grant the Ordering Party irrevocable permission to use and dispose of all dependent works in all fields of exploitation indicated in § 7 item 2 of the Agreement.

5. The Contractor represents that it has obtained assurances from all creators of the Works ["**Creator**"] that they will not exercise their personal copyrights. For the avoidance of possible doubt, the Parties confirm that by the term Creator also means the Contractor, and consequently the Contractor makes the same representations and obligations in this Agreement as the Creator.

6. The Ordering Party, as of the date of acceptance of the Work, shall be authorized by the Contractor and the Creators on whose behalf the Contractor is acting to exercise on behalf of the Creators their moral rights and the Contractor's moral rights in the event of creation of any Work by the Contractor.

7. Upon delivery of the Works by the Contractor, ownership of the copies on which the Works are fixed shall pass to the Ordering Party.

8. The Contractor declares that it shall have the rights to each Work to the extent set forth in the provisions of this Agreement under the respective agreements, executed in writing, and confirms that such rights shall not be disposed of or restricted to the extent that would exclude or limit the rights of the Ordering Party that it acquires under this Agreement.

9. Upon establishment of the Work, all industrial property rights contained in or related to the elements of the Work shall pass to the Ordering Party, including, in particular, the right to obtain the right of protection for a trademark or the right to obtain the right of protection for an industrial design. Neither the Contractor nor the Creator shall be entitled to additional compensation for the acquisition of these rights. The rights indicated in this item shall be vested in the Ordering Party also when the elements of the Work do not constitute the Work, but may be subject to protection under the provisions of the Industrial Property Right Act of June 30, 2000.

10. In the event of termination of this Agreement, regardless of the reason, the Parties agree that such termination shall not affect the rights acquired by the Ordering Party up to the time of such declaration, which rights shall remain with the Ordering Party to the extent and in accordance with the provisions of this Agreement.

11. The remuneration referred to in § 3 item 1 of the Agreement includes, among other things, remuneration for the transfer of author's economic rights in accordance with the Agreement, consent to exercise and authorization to exercise author's dependent rights and moral rights, as well as remuneration for the transfer of copies of the Works and remuneration for the use of the Works or works that are industrial property goods.

12. The Contractor guarantees that in order to properly use the Works, the Ordering Party does not need to acquire any additional licenses or copyrights.

13. The Contractor warrants that it has intellectual property rights in the Works at least to the extent that it is able to conclude this Agreement in a lawful manner and that such rights are not limited or encumbered in any way in favor of third parties.

14. The Ordering party shall also be entitled to exclusive rights to all Results, regardless of their form and type, whether patentable or not, whether in tangible or intangible form (including, in particular, information, data, know-how, images and samples), which originate from, are derived from, derive from or are created in connection with the performance of the Services or discovered, invented or otherwise created by the Contractor and/or third parties engaged by the Contractor in connection with the performance of the Services. The Contractor hereby assigns in advance, as part of the Remuneration referred to in § 3 item 1 of the Agreement, its rights to the Results to the Ordering Party, as of the time of their determination, has the fields of exploitation indicated in § 7 item 2 of the Agreement. The Contractor shall not be entitled to publish the Results without the prior written consent of the Ordering Party.

15. The Contractor agrees to promptly notify the Contracting Party of any discoveries or inventions made in connection with the performance of the Services. All such discoveries or inventions shall be the exclusive property of the Contracting Party. If for any reason rights to such discoveries or inventions are vested in the Contractor, the Contractor shall promptly assign all such rights to the Ordering Party, without additional compensation. The Ordering Party may use such discoveries or inventions for any purpose whatsoever without any obligation in connection therewith to the Contractor (including without any obligation to make any payment to the Contractor therefor).

16. For the avoidance of doubt, the Parties acknowledge that any Results satisfying the requirements for patent or other protection that constitute improvements, new uses, new dosages, or new dosage regimens of the test products and that originate from, are derived from, derive from, or are created in connection with the performance of the Services or that are discovered, invented, or otherwise created during the period of performance of the Services are the exclusive property of the Ordering Party.

17. Disclosure of data concerning the Results to third parties does not imply a transfer of rights to such Results to such third parties.

§ 8

1. The Contractor is obliged to keep confidential all that it learns in connection with the performance of the Contract, specifically informations and items mentioned in § 2 item 2, Results and Works. To the same extent, the Contractor shall be responsible for maintaining the confidentiality of the persons with whose assistance it executes the Contract. The obligation of secrecy applies both during the term of the Agreement, as well as 5 years after its expiry and/or termination.
2. The obligation referred to in paragraph 1 does not apply to situations in which the obligation to disclose information results from generally applicable regulations, court judgments or decisions of competent public authorities.

§ 9

1. Responsible for the implementation of the provisions of this Agreement, and in particular for signing the acceptance protocol without reservation and for ongoing contacts between the Parties are:

- On behalf of the Ordering Party:. ……………………… tel. ……………………… e-mail: ……………………………

 - From the Contractor's side: ............................., tel. .................................. , e-mail: ................

§ 10

In accordance with the requirements of Article 14 of Regulation 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data and repealing Directive 95/46/EC (RODO), where applicable,
the parties undertake to provide the information required under Article 14 of the RODO to their representatives and the persons employed by them whose personal data will be disclosed to the other party to the Agreement as Data Controller in connection with the conclusion and performance of this Agreement. For this purpose, the parties will provide the Information Clause to fulfil the information obligation concerning them, so that the other party can present it to the aforementioned persons.

The RODO information clause of the M. Nencki Institute of Experimental Biology of the Polish Academy of Sciences is included in Appendix No. 3 to the Agreement.

§ 11

1. Any amendment to this Agreement shall be in writing, otherwise being null and void.
2. Without the Contracting Authority's written consent, the Contractor may not assign the receivables arising under this Agreement to a third party.
3. In matters not regulated by the provisions of this Agreement, the relevant provisions of the Civil Code shall apply.
4. Any disputes that may arise under this Agreement, which cannot be resolved amicably within seven days after the other Party is provided with an invitation to talks, shall be settled by the court having jurisdiction over the Employer's registered office.
5. The Agreement has been drawn up in two counterparts, one copy for each Party.
6. The date of conclusion of the Agreement is the date of signing by the Ordering Party.

 **ORDERING PARTY CONTRACTOR**

**Appendix No. 2**

**DECLARATION
ON CONSENT TO ELECTRONIC TRANSMISSION OF INVOICES**

*RECEIVER DATA:*

**Marceli Nencki Institute of Experimental Biology, Polish Academy of Sciences**

3 Pasteura St., 02-093 Warsaw

REGON: 000325825, NIP 525-000-92-69, RIN: RIN-II-21-98

Contact phone : 22 5892498

*INVOICE ISSUER DETAILS:*

**Company name**

Address

KRS ................., NIP ......................

Contact Tel :

1. We hereby declare that we consent to receive in electronic form VAT invoices in PDF format (including duplicate VAT invoices) issued for services rendered and goods supplied, pursuant to art. 106n paragraph 1 of the Law on tax on goods and services of 11.03.2004r. (consolidated text - Journal of Laws of 2021, item 685 as amended).
2. Please send invoices via email to the email address below:

|  |
| --- |
| E-mail address: faktury@nencki.edu.pl |

Invoices sent to this address shall be deemed effectively delivered

1. Electronic transmission of invoices will be done from the email addresses of the Exhibitor's Customer Service Team employees, with the domain :

|  |
| --- |
| Exhibitor domain: ................................... |

1. A change of the e-mail address indicated for receipt of electronic invoices or withdrawal of this declaration must be made in writing. This shall take effect from the day following receipt of the declaration. In case of failure to comply with this obligation, invoices sent to the address as set out in section 2 will be deemed effectively delivered.
2. We undertake to accept the invoices referred to in point 1 of this declaration in paper form, in case technical or formal obstacles make it impossible to send invoices electronically.
3. Correction invoices and correction notes will be sent both electronically and in hard copy to the Recipient's address with a note to the Office.

Warsaw, day of....

 Recipient's signature

**Appendix No. 3 the Agreement to which the M. Nencki Institute of Experimental Biology PAS is a party - Information clause regarding the rules of processing personal data in connection with the conclusion of the agreement**.

In accordance with Article 14 of Regulation EU 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data and repealing Directive 95/46/EC (RODO), we inform you that:

1. the Marceli Nencki Institute of Experimental Biology of the Polish Academy of Sciences, with its headquarters at 3 Ludwik Pasteur Street, 02-093 Warsaw, Poland, has received your personal data from your Employer (the source of the data) and has become its Administrator under the contract in force for the provision of services in order to contact you as its executors or representatives.

(2) The Administrator has appointed a Data Protection Officer who can be contacted at telephone number (22) 5892 275 or e-mail address: iod@nencki.edu.pl

(3) Your personal data has been obtained from your Employer for the purpose of entering into and performing the contract and for the purpose of contacting you as an enforcer or representative of the entity.

 4 The legal basis for processing your personal data is:

- Article 6(1)(b) of the RODO - i.e. processing is necessary for the performance of a contract to which the data subject is a party or in order to take steps at the request of the data subject prior to entering into a contract:

- Article 6(1)(f) of the RODO - the Administrator's legitimate interest to contact you as the person responsible for the performance of the contract on the part of your employer, your personal data will be processed for the purpose of contact and performance of the contract.

5 The scope of the data processed: name and linked business email and phone.

The personal data will be processed for the period necessary for the realization of the objective mentioned in point 3 (i.e. realization of the agreement) and for the expiration of claims resulting from it, as well as for fulfilling other legal obligations of the Administrator, among others archiving obligations.

(7) Access to personal data may have only authorized employees and associates of the Data Controller and entities that have a separate legal basis under applicable law.

 (8) Personal data will not be transferred to a third country or international organization.

(9) Personal data will not be subject to profiling and automated decision-making with significant legal consequences for you.

10 You have the following rights:
- The right to require the Controller to access personal data concerning you, to rectify it if it is inaccurate, to erase or restrict processing (if applicable), and the right to object to processing (if applicable) and the right to data portability (if technically possible). The scope of each of the above rights and the situations in which you may exercise them are determined by law. The possibility of exercising some of the above rights may depend on, among other things, the legal basis, purpose or manner of processing of personal data.

- The right to lodge a complaint to the supervisory authority: The President of the Office for Personal Data Protection, if you consider that the processing of your data is unlawful.

To exercise the above rights, please send an email to: iod@nencki.gov.pl or contact us by phone: (22) 5892 275.

If you are not satisfied with the way the Administrator processes your personal information, please notify us of the problem and we will investigate any irregularities that arise.