Expenditure co-financed in the project by the European Union funds under the European Regional Development Fund from the Smart Growth Operational Programme 2014-2020.
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Offer form

In response to the Request for Quotation No. 1/08/2023 (https://bazakonkurencyjnosci.funduszeeuropejskie.gov.pl No. (2023-31107-170925) of 24 August 2023, submitted by NEURO_OPIOMEL sp. z o.o. in connection with the implementation of the project entitled "Opioid-melanocortin peptidomimetics for the treatment of neuropathic pain" co-financed by the European Regional Development Fund under Sub-measure 1.1.1 of the Smart Growth Operational Programme 2014 - 2020, the Fast Track for Mazovia competition No. 3/1.1.1/2020, Project No. POIR.01.01.01-00-0576/20.

I/we the undersigned ..... *(First names and surnames of persons authorised to represent the Bidder)*

acting for and on behalf of:

.....

.....

(Full name and address of the Bidder)

I / we make the following offer for successive deliveries (the quantities given represent the target amount of the reagent / material to be achieved in the consecutive deliveries):

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Lp.	Our offer includes:	Net price* EUR	Gross price* EUR
GLP toxicology study			
1	**MTD/2-week DRF study**		
2	**4-week toxicity study with TK, local tolerance, safety pharmacology endpoints and 4-week recovery in rats**		
3	**4-week toxicity study with TK, local tolerance, safety pharmacology endpoints and 4-week recovery in dogs**		
4	**Safety pharmacology (respiratory system) in rats**		
5	**hERG assay in HEK cells**		
6	**A genetic toxicology battery of studies**		
7a	**Analytical part – application form analysis**		
7b	**Bioanalytical part – method for rat plasma**		
7c	**Bioanalytical part – method for dog plasma**		
	Total price:		

We commit ourselves / we do not commit ourselves *) to implement the subject matter of the contract with respect to the principle of sustainable development and with attention to limit the impact on the environment and climate – in particular by reducing energy consumption of the equipment used, reducing water consumption, amount of waste, as well as by striving to use recycled materials, etc.

Validity of the offer: The offer is valid until .....

I/We declare that I/we have got acquainted with information included in the Request for Quotation and I/we do not make any objections.

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I/we* attach to this offer:

1. Declaration of meeting the conditions for participation in the procedure - **YES/NO** *);
2. A completed Technical Information Sheet confirming that the surface offered meets the technical specifications required by the Ordering Party - **YES/NO** *);
3. Declaration of no capital and personal ties - **YES/NO** *);

…….

Signature of person/s authorised
to represent the Bidder

**) delete as appropriate*

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/place, date/

……..
/data, stamp of the Bidder/

Declaration of meeting the conditions for participation in the procedure (No. 2023-31107-170925)

1. In connection with the Offer submitted in response to the Request for Quotation No. 1/08/2023, I/we declare that I am/we are authorised to conduct activities related to the subject matter of the contract.

…….

Signature of person/s authorised
to represent the Bidder

2. In connection with the Offer submitted in response to the Request for Quotation No. 1/08/2023, I/we declare that I/we have technical capacity necessary for the implementation of the subject matter of the contract.

…….

Signature of person/s authorised
to represent the Bidder

3. In connection with the Offer submitted in response to the Request for Quotation No. 1/08/2023, I/we declare that I/we have economic and financial situation allowing for the implementation of the subject matter of the contract.

…….

Signature of person/s authorised
to represent the Bidder

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4. In connection with the Offer submitted in response to the inquiry No. 1/08/2023, I declare / we declare that I am not / are not an entity related directly or indirectly personally or capitally with the countries on which economic sanctions have been imposed.

…….

Signature of person/s authorised

to represent the Bidder

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/place, date/

.....
/data, stamp of the Bidder/

Completed Technical Information Sheets confirming that the service meets the technical specifications required by the Ordering Party

In connection with the Offer submitted in response to the Request for Quotation No. 1/08/2023 (2023-31107-170925), I/we declare that the offered products meets the requirements of the technical specification *(Provider fills the table for offered position of materials/chemicals)*:

GLP toxicology study

The substance (API) is planed to be administrated I.V (bolus injection) to patients with neuropathic pain already receiving standard pain therapy in order to treat their cases of exacerbation of disease symptoms (symptoms of neuropathic pain). In such a case, the administration will not be more than for 3 consecutive days a week. We are planning to use the results of these nonclinical toxicity studies in support of CTA/IND for both phase I and II clinical trials. The duration of the Phase II study will be 4 weeks: dosing 1-3 consecutive days, every week for 4 weeks to determine whether pain relief can be sustained through repeated infusions.

1. MTD/2-week DRF study

No.	Parameter or function name	Required response	Contractors Answer

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1.	Non-GLP MTD/2-week DRF study in rats, according to the EMA, FDA regulations.	YES Please indicate the price	
2.	Non-GLP MTD/2-week DRF study in dos, according to the EMA, FDA regulations.	YES Please indicate the price	
3.	Way of administration: intravenous	YES	
4.	MTD: single administration	YES	
5.	DRF: repeated administration for 3 consecutive day for 2 weeks	YES	
6.	Duration of observation period: - MTD: 14 days, - DRF: n/a	YES	
7.	The frequency of observation: - Mortality and clinical signs: twice a day; - Body weight: weekly - Food consumption: weekly (rats) and daily (dogs); - Clinical pathology (DRF) – haematology, serum chemistry: before the administration start and just before necropsy;	YES	

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	- Scheduled necropsy, gross and histopathology: 15 days MTD and DRF;		
8.	Draft report will be available for comments. Final report will be issued within 2 – 3 weeks after the comments are received.	YES	
9.	The earliest possible start time after signing the contract	Please specify Work days	
10.	Completion time per order	Please specify Work days	

2. 4-week toxicity study with TK, local tolerance, safety pharmacology endpoints and 4-week recovery in rats

No.	Parameter or function name	Required response	Answer Contractors
1.	GLP-compliant 4-week toxicity study with toxokinetic (TK), local tolerance, safety pharmacology endpoints and 4-week recovery. Based on: ICH S6 (R1), ICH M3 (R2)	YES Please provide the price	
2.	Test system: Wistar rats	YES	

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3.	Way of administration: intravenous bolus injection	YES	
4.	Duration of administration period: 4 weeks	YES	
5.	Duration of recovery period: 4 weeks	YES	
6.	Dosing: weekly for 3 consecutive days	YES	
7.	The frequency of mortality, morbidity checking: daily twice	YES	
8.	Clinical observation: daily	YES	
9.	Functional observation – week 4, week 8: - General evaluation; - Evaluation of behaviour of the animal after transfer to unknown area; - Evaluation of reflex after simple stimuli; - Evaluation performed in restrained animal; - Evaluation of grip, coordination, and locomotor activity.	YES	
10.	Local tolerance at the administration site	YES	
11.	Body weight and food consumption evaluation: weekly	YES	
12.	Ophthalamoscopy: week – 1, week 4, week 8	YES	
13.	Haematology, serum chemistry, urinalysis. Test site will be responsible for analysis.	YES	
14.	Blood sampling for antibody determination (TOX groups). Test site will be responsible for analysis.	YES	
15.	Toxikinetic study (TK): on the days of the first and last administration, at pre-dose and 8 time points per 24 hours after administration. Test site will be responsible for analysis of all samples.	YES	

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16.	Scheduled necropsy: day 28 (end of administration), day 56 (end recovery)	YES	
17.	Pathology and histopathology: - Macroscopic observation should be performed at the necropsy in all animals; - Full histopathology should be carried out on the preserved organs and tissues according to CPMP/SWP/1042/99 Rev 1, 2007, Annex 1. Examination should be performed in all animals of the control and high dose groups. These examinations should be extended to animals of all other groups, if treatment-related changes are observed in the high dose group.	YES	
18.	The test site is responsible for statistical evaluation	YES	
19.	Draft report will be available for comments. Final Report will be issued within 2 -3 weeks after the comments are received. Test site should be also responsible for reporting on analytical/bioanalytical/TK part of the study.	YES	
20.	The earliest possible start time after signing the contract	Please specify Work days	
21.	Completion time per order	Please specify Work days	

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3. 4-week toxicity study with TK, local tolerance, safety pharmacology endpoints and 4-week recovery in dogs

No.	Parameter or function name	Required response	Answer Contractors
1.	GLP-compliant 4-week toxicity study with toxicokinetic (TK), local tolerance, safety pharmacology endpoints and 4-week recovery. Based on: ICH S6 (R1), ICH M3 (R2)	YES Please provide the price	
2.	Test system: Beagle dogs	YES	
3.	Way of administration: intravenous bolus injection	YES	
4.	Duration of administration period: 4 weeks	YES	
5.	Duration of recovery period: 4 weeks	YES	
6.	Dosing: weekly for 3 consecutive days	YES	
7.	The frequency of mortality, morbidity checking: daily twice	YES	
8.	Clinical observation: daily Detailed clinical observation: weekly	YES	
9.	Local tolerance at the administration site	YES	
10.	Body weight and food consumption evaluation:	YES	

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	weekly		
11.	Ophthalamoscopy: week – 1, week 4, week 8	YES	
12.	Electrocardiography including heart rate: week 1, day 1(just before administration and 1-hour post dose), day 24 (just before administration and 1-hour post-dose), week 8	YES	
13.	Blood pressure, body temperature: week 1, day 1 (just before administration and 1 hour post dose), day 24 (just before administration and 1 hour post dose), week 8	YES	
14.	Haematology, serum chemistry, urinalysis. Test site will be responsible for analysis.	YES	
15.	Blood sampling for antibody determination (TOX groups). Test site will be responsible for analysis.	YES	
16.	Toxicokinetic study (TK): on the days of the first and last administration, at pre-dose and 8 time points per 24 hours after administration. Test site will be responsible for analysis of all samples.	YES	
17.	Scheduled necropsy: day 28 (end of administration), day 56 (end recovery)	YES	
18.	Pathology and histopathology: - Macroscopic observation should be performed at the necropsy in all animals; - Full histopathology should be carried out on the preserved organs and tissues according to CPMP/SWP/1042/99 Rev 1, 2007, Annex 1. Examination should be performed in all animals of the control and high dose groups. These examinations should be extended to animals of all other groups, if treatment-related changes are observed in the high dose group.	YES	
19.	The test site is responsible for statistical evaluation	YES	

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20.	Draft report will be available for comments. Final Report will be issued within 2 -3 weeks after the comments are received. Test site should be also responsible for reporting on analytical/bioanalytical/TK part of the study.	YES	
21.	The earliest possible start time after signing the contract	Please specify Work days	
22.	Completion time per order	Please specify Work days	

4. Safety pharmacology (respiratory system) in rats

No.	Parameter or function name	Required response	Answer Contractors
1.	Safety pharmacology (respiratory system) in rats, according to the ICH S7A	YES Please provide price	
2.	Way of administration: intravenous bolus injection	YES	
3.	Dose levels: minimum 3 dose levels, dose levels should include and exceed therapeutic range	YES	
4.	The earliest possible start time after signing the contract	Please specify	

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		Work days	
5.	Completion time per order	Please specify	

5. hERG assay in HEK cells

No.	Name of parameter or function	Required response	Answer Contractors
1.	GLP-compliant study hERG assay in HEK cells.	YES Please provide the price	
2.	HEK293 cells – transfected with hERG potassium channel	YES	
3.	All testes should be performed using 6 cells per group	YES	
4.	Reference item	YES	
5.	Phase 1 – effect of a high concentration	YES	
6.	Phase 2 – dose-response to TI and estimation of IC50	YES	
7.	Draft report should be available for comments. Final report should be issued 2 – 3 weeks after the comments are received	YES	

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8.	The earliest possible start time after signing the contract	Please specify Work days	
9.	Completion time per order	Please specify Work days	

6. A genetic toxicology battery of studies

No.	Parameter or function name	Required response	Answer Contractors
1.	GLP-compliant Ames test	YES Please provide the price	
2.	GLP-compliant micronucleus test in vitro	YES Please provide the price	
3.	GLP-compliant micronucleus test in vivo, mouse, males, 4000 cells/animal	YES Please specify the price	

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4.	GLP-compliant, Chromosomal abberation in vitro, 300 metaphase chromosomes	YES Please specify the price	
5.	GLP-compliant MLA, L5178Y (mutation TK)	YES Please specify the price	
6.	The earliest possible start time after signing the contract	Please specify Work days	
7.	Completion time per order	Please specify Work days	

7a. Analytical part – application form analysis

No.	Parameter or function name	Required response	Answer Contractors
1.	GLP-compliant method development and validation (validation protocol and report included)	YES Please provide	

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		price	
2.	Sample analysis	YES Please provide the price per sample per study and price for all samples	
3.	Analytical report	YES	
4.	The earliest possible start time after signing the contract	Please specify Work days	
5.	Completion time per order	Please specify Work days	

7b. Bioanalytical part – method for rat plasma

No.	Parameter or function name	Required response	Answer Contractors
1.	GLP-compliant method development and validation for rat plasma (development of the method and validation, validation protocol and rat blank plasma included)	YES	

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2.	Sample analysis – rat study	YES Please provide the price per sample per study and the price for all samples	
3.	TK evaluation and report	YES Please provide the price	
4.	The earliest possible start time after signing the contract	Please specify Work days	
5.	Completion time per order	Please specify Work days	

7c. Bioanalytical part – method for dog plasma

No.	Parameter or function name	Required response	Answer Contractors
1.	GLP-compliant method development and validation for dog plasma (development of the method and validation, validation protocol and dog blank plasma	YES	

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	included)		
2.	Sample analysis – dog study	YES Please provide the price per sample per study and the price for all samples	
3.	TK evaluation and report	YES Please provide the price	
4.	The earliest possible start time after signing the contract	Please specify Work days	
5.	Completion time per order	Please specify Work days	

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……., day …… …….

(signature of the authorised

Contractor's representative)

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/place, date/

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/data, stamp of the Bidder/

Declaration of no capital and personal ties

I/we declare that there are no prerequisites regarding personal or capital ties with the Contracting Party (NEURO-OPIOMEL sp. z o.o.),

i.e. capital or personal ties shall be understood as mutual ties between the Ordering Party or persons authorised to incur liabilities on behalf of the Ordering Party or persons carrying out activities related to the execution of the selection procedure of the Contractor on behalf of the Ordering Party and the Contractor (Bidder), consisting in particular of:

a) participation in a partnership as a partner of a professional partnership or registered partnership;

b) possession of 10 % or more of stocks and shares,

c) being a member of a supervisory or management body, proxy, attorney,

d) maintaining a legal or factual relation that may arouse justified doubts as to the impartiality in selecting the Contractor, including, without limitation, marriage, straight-line relationship by blood or affinity, collateral-line relationship by blood or affinity up to the second degree, or adoption, custody or guardianship.

……..

Signature of person/s authorised
to represent the Bidder