Łomianki, 13.11.2019

Purchaser:

Celon Pharma SA
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REQUEST FOR QUOTATION (RfQ)no 04/2019/O/NoteSzHD/Z9

In relation to the planned implementation of the project “New therapy of psychotic disorders and Huntington's disease with particular focus on cognition deficits” by Celon Pharma S.A. as part of the 2nd edition of the contest in the research and development program Prevention and treatment of civilization diseases - STRATEGMED (hereinafter "the Project"), we hereby request your quotation for:

1. Conducting a multicenter, randomized, placebo controlled phase II clinical study with multiple administration of PDE10a inhibitor (molecule CPL500036, investigational medicinal product PG20) in patients with acute exacerbation of Schizophrenia to determine efficacy, safety and pharmacokinetics of PG20, including the recruitment of 90 patients.

CPV code:

- 73000000-2

CPV code name:

- Research and development services and related consultancy services

Additional information:

- Planned clinical study have to be conducted according to the Good Clinical Practice (GCP) and scientific guidelines of European Medicine Agency (EMA).
- Request for quotation concerns the clinical trial conducted by the scientific consortium consisting of, among others, Celon Pharma S.A. - the Purchaser, Medical University of

Lodz (MUL) and Medical University of Poznan (MUP). The participation of MUL and MUP in conducting the clinical trial is obligatory.

- The Bidder selected on the basis of conducted RfQ procedure will be obligated to provide in the clinical sites contracted by the Bidder (called "commercial sites") and in clinical sites subordinated/selected by the MUL and MUP (called "Consortium Sites') services according to the Scope of Work presented in Attachment no. 2.
- The clinical study could be conducted in Poland and in other European countries (also beyond the European Union), where the selected Bidder should contract commercial clinical centres
- MUL and MUP consortium members are obliged to recruit 75 patients.
- Clinical sites contracted by selected Bidder are obliged to recruit 90 patients.
- Estimated total number of patients required for the recruitment and randomization in all clinical sites (in the consortium members' sites and commercial clinical centres) is 165.
- During the study progress, in case of need, it might be allowed to decrease patients number in the consortium members' sites and increase by the same number patients in the commercial sites contracted by the selected Bidder. This change will need to meet the conditions for introducing changes in the agreement presented in this RfQ
- Preliminary Clinical Study Synopsis with details of the clinical study are presented in the Attachment no. 1.
- Scope of Work in the clinical study is presented in the Attachment no. 2.
- Clinical Study Synopsis and Scope of Work will be presented to the Bidder once the Mutual Confidentiality and Nondisclosure Agreement will be signed.

Requirements to be met by Bidders:

1. To obtain details regarding preparation of the Bid the Bidder must sign a Confidentiality and Non-disclosure Agreement with the Purchaser. The Bidder interested in participating in the procedure should send a request for a contract document by electronic means to the following address: anna.dulinska@celonpharma.com and send back the signed scan to the same address. Details of the Study will be sent not later than 48 working hours after receiving the signed document. The scan of the agreement will be countersigned by the Purchaser and sent back to the Bidder via electronic mail.
2. Bids can be submitted by Bidders who meet the following requirements:
    - The Bidder must run a business with the capacity of delivering the subject of the order and has knowledge, experience and technical capacity necessary to find and contract commercial Clinical Centres capable of conducting clinical trials and Laboratory/ies conducting medical laboratory tests .

- The Bidder commits to contract commercial Clinical Centres with the necessary medical and laboratory infrastructure to conduct the clinical trial according to GCP requirements. It is allowed to supplement the infrastructure in the Clinical Centre (in terms of renting of e.g. centrifuges, refrigerators/ freezers, cabinets) for the needs of the clinical trial which is the subject of this Request for Quotation (RfQ), if such a need arises.
- The Bidder commits to contract commercial Clinical Centres with experienced medical staff with a valid license to practice and Good Clinical Practice requirements training. It is allowed to conduct medical staff trainings on the requirements of GCP before starting a clinical trial.
- The Bidder commits to propose a Clinical Study Coordinator, with a specialization in psychiatry having min. 10 years of experience at work in a clinical study research team and being a Study Coordinator and/or an Investigator in min. 5 clinical trials. The decision on the final selection of the Coordinator will be made by the Purchaser in agreement with the selected Bidder.
- The Bidder has or commits to contract the Project Manager or a person in different, adequate position, responsible for the implementation of the subject of the RfQ on the Bidder's side (including responsibility for communication with potential subcontractors and the Purchaser), having at least 5 years of experience in managing clinical trials confirmed in CV.
- The Bidder has or commits to contract the person with a fluent English, to write a Clinical Study Report in English, in accordance with the ICH E3 guideline "Structure and content of clinical study reports".
- The Bidder's financial and economic situation should ensure successful implementation of the order and there cannot be any indications suggesting that this situation will change during the period covered by the agreement. The Bidder is not subject to insolvency proceedings initiated, nor his bankruptcy has not been declared, is not subject to liquidation proceedings, and his cases are not covered by a receivership or court order. The Bidder is not behind with taxes, fees or social insurance or health insurance contributions.

3. Excluded from the proceedings shall be those Bidders who are personally or equity related to the Ordering Party. By personal or capital ties the interactions between the Purchaser or persons authorized to enter into commitments on behalf of the Purchaser, or persons performing activities related to the preparation and the procedure for selecting the Contractor on behalf of the Purchaser and the Contractor, are meant, in particular, trough:
    - Participation in the company as a shareholder or partner,
    - Possession of at least 10% of the shares, unless a lower threshold arises from the law or has been defined by the Managing Authority for Operational Programs,
    - Acting as a member of the supervisory or management board of the company or the proxy or the attorney,

- Remaining married, in a consanguinity or affinity relationship in a straight line (parents, children, grandchildren, in-laws, son-in-law), the collateral line to the second degree (siblings, spouse relatives) or remain in the relationship of adoption, custody or guardianship.

4. The due date for each issued invoice should be at least 30 days.

Address and date for submitting the bids:

5. Bids must be submitted to the Purchaser's HQ office at Ogrodowa 2A Street, 05-092 Kiełpin/Łomianki if sent by traditional mail/courier, or to anna.dulinska@celonpharma.com if sent by electronic mail.
6. Bids must be submitted by **16.12.2019 till 15:00 (CET)** at the latest. If sent by traditional mail or courier, the bid is deemed to be submitted if day of it's delivery to the Purchaser's HQ is no later than on day indicated as the final date for Bid submission.
7. Bids submitted after the aforementioned date will not be considered.
8. For further information on this RfQ, please contact Mr Rafał Płatek, e-mail: rafal.platek@celonpharma.com.

Contract award notice:

9. Bids will be evaluated at the Purchaser's office up to and including **21.01.2020**
10. The final decision will be forwarded to all Bidders via email up to and including **22.01.2020** as well as published on the website: www.celonpharma.com

Presentation of the bids:

11. Each Bidder may submit only one bid.
12. The bid must be prepared and presented in Polish or in English.
13. The bid must contain the date of preparation, the Bidder's address, telephone number, email address, tax ID number (NIP number in Poland) (if available).
14. The bid should include the RfQ No. in the title. The RfQ No. should also appear in the titles of emails, headings of traditional mail and headings of consignments sent by courier.
15. The bid must remain valid **for at least 9 months** counted from the submission deadline.
16. Costs of preparing the bid shall be borne by the Bidder.
17. The bid should be initialled and signed by persons authorized to represent the Bidder.
18. The bid must contain:
    a. The price:
        i. Total price for the aforementioned Study should be presented specifying the prices for each part in accordance with the Scope of Work (Attachment no. 2 available after signing the confidentiality clause). The price can be expressed in PLN, EUR or USD. For the purpose of comparing the submitted pricing offers, the offer prices will

be converted into PLN according to the average exchange rate of the National Polish Bank applicable on the day on which this Request for Quotation is published.

ii. If submitted by a Bidder operating in Poland, the net and gross bid price and the due VAT offered for the delivery of the subject of the order in accordance with the requirements set forth herein.

iii. If submitted by a Bidder operating outside Poland, the net bid price and information that VAT or other taxes have not been included in the price quotation.

b. Declared recruitment rate (in Patients/Month) in commercial Clinical Centres planned to be contracted by the Bidder. To determine the recruitment rate, the Bidder should take into account the recruitment of 90 patients provided for in this Request for Quotation. Patients recruitment in Consortium centres should not be taken into account when estimating the recruitment rate.

c. Declared time (in days) needed for "First Patient In - FPI" (randomization of the first patient) in the commercial Clinical Centre, counted from the moment the last of the two was obtained - approval for the clinical trial from the competent regulatory authority or the positive opinion of the competent Bioethical Committee.

d. Declared time (in days) needed to provide the Clinical Study Report, calculated from the moment of delivery of the bioanalytical and the statistical analysis results by the Purchaser.

e. The statement of compliance with the requirements (Attachment 3):

i. The Bidder runs a business with the capacity of conducting the activities which are the subject of the order and has knowledge, experience and technical capacity necessary to find and contract commercial Clinical Centres capable of conducting clinical trials and Laboratory/ies conducting medical laboratory tests.

ii. The Bidder commits to contract commercial Clinical Centres with the necessary medical and laboratory infrastructure to conduct the clinical trial according to GCP requirements. It is allowed to supplement the infrastructure in the Clinical Centre (in terms of renting of e.g. centrifuges, refrigerators/freezers, cabinets) for the needs of the clinical trial which is the subject of this RfQ, if such a need arises.

iii. Clinical Centres contracted by the Bidder must have employed experienced medical staff with a valid license to practice and Good Clinical Practice requirements training. It is allowed to conduct trainings on the requirements of GCP before starting a clinical trial.

iv. The Bidder must propose a Study Coordinator who has expertise and experience provided in the RfQ.

v. The Bidder has employed or will contract the Project Manager, or a person in different, adequate position, responsible for the implementation of the subject of the RfQ on the Bidder's side (including

responsibility for communication with potential subcontractors and the Purchaser) who has experience provided in the RfQ.

vi. The Bidder has employed or will contract a person with a fluent English, to write a Clinical Study Report in English, in accordance with the ICH E3 guideline ”Structure and content of clinical study reports”.

vii. The Bidder’s financial and economic situation ensures successful implementation of the order and there are no indications suggesting that this situation will change during the period covered by the agreement. The Bidder is not subject to insolvency proceedings initiated, nor his bankruptcy has not been declared, is not subject to liquidation proceedings, and his cases are not covered by a receivership or court order. The Bidder is not behind with taxes, fees or social insurance or health insurance contributions.

f. CV of the proposed Study Coordinator showing his/her specialization in psychiatry, having min. 10 years of experience at work in a clinical study research team and being a Study Coordinator and/or an Investigator in min. 5 clinical trials. The decision on the final selection of the Coordinator will be made by the Purchaser in agreement with the selected Bidder.

g. CV of the Project Manager or a person in different adequate position, responsible for the implementation of the subject of the RfQ on the Bidder’s side, having at least 5 years of experience in managing clinical trials.

h. The Statement on the absence of personal or capital ties with the Purchaser should be submitted along with the bid (Attachment no. 4).

i. A copy/scan of the Bidder’s current Registration Document.

Note:

19. The Purchaser will place an order with the Bidder whose bid meets all the requirements set forth in this RfQ and has been deemed the best with regard to the selection criteria set forth herein. The signing of the agreement is planned for the QI - QII of 2020. The expected order execution time – up to 11 months from the time the Purchaser obtain the last of the two: approval for the clinical trial from the competent regulatory authority or the positive opinion of the competent Bioethical Committee.
20. The Purchaser reserves the right to prolong the expected order execution time including time reserved for patients’ recruitment for the Study.
21. The Purchaser allows the possibility of negotiating with Bidders who submit offers in the Bidder process before the selection of the winning bid.
22. The Purchaser reserves the right to cancel the bidding process.
23. The Purchaser reserves the right to close the bidding process without selecting the winning Bidder. The Purchaser is not obliged to give the reason for closing the procedure.
24. In the course of evaluation and assessment of the bids, the Purchaser may request that the Bidders provide clarification regarding their bids. In such a case, the Purchaser

reserves the right to postpone the final evaluation and notification about the evaluation of quotes.

25. The Bidder may alter or withdraw its bid before the submission deadline.
26. Bids which do not meet the formal requirements set forth herein will not be considered.
27. The Purchaser does not accept variant bids.
28. The Purchaser does not accept partial bids.
29. The Purchaser reserves the right to reject bids the contents of which raise reasonable doubts.
30. Not declaring the recruitment rate in the commercial Clinical Centres planned to be contracted by the Bidder and/or time needed for FPI (randomization of the first patient) and/or time needed for Clinical Study Report delivery is the basis for rejecting the offer and awarding 0 (zero) points for subsequent evaluation criteria.

Conditions for introducing changes in the agreement concluded as a result of the conducted RfQ procedure - in case it is necessary to introduce such changes:

31. The Bidder selected on the basis of conducted RfQ procedure will be obligated to enter into the agreement on terms set out in the present RfQ.
32. The Purchaser reserves the right to make changes to the provisions of the contract (contract annexing) in relation to the content of the offer, based on which the selection of the Bidder was made when there are circumstances independent of the Purchaser, forcing such changes, like opinions of the Bioethical Committee, recommendations of the competent regulatory authority or European Medicines Agency - forcing changes in the Study protocol or changes in therapy standards or unexpected deterioration in the health of the study participants.
33. In case of necessity of change of primary plan of the clinical trial (which may be the case after: analysis of data from the currently ongoing preclinical studies and safety pharmacology studies as well as data from the phase I clinical study, changes to regulatory guidelines, opinion of the Study Coordinator and other mentioned in section 32), it will be necessary to change the description of the subject of the contract, particularly of the Clinical Study Synopsis what is in Attachment no. 1 to this RfQ and the Bidder's flat-rate remuneration.
34. In the above cases the introduction of the necessary changes will be limited to:
    a. Introducing changes covering implementation of additional services by the Bidder not covered by the basic contract provided they are necessary (based on the circumstances referred to in section 32 and 33) and that the following conditions have been met:
        i. The change of the Bidder cannot be made for economic or technical reasons, in particular regarding the interchangeability or interoperability of the equipment, services or installations ordered in relation to the basic contract.

ii. The change of the Bidder would cause a significant inconvenience or a substantial cost increase to the Purchaser.
iii. The value of any subsequent change does not exceed 50% of the basic contract value.

b. Introducing changes which do not lead to a change in the nature of the contract; the following conditions must be met:
   i. The necessity to introduce the change is due to circumstances which the Purchaser, acting with due diligence, could not have predicted.
   ii. The value of the change does not exceed 50% of the basic contract value.
c. Introducing changes that do not lead to a change in the nature of the contract and the total value of changes is less than the value specified in provisions issued based on Article 11 Paragraph 8 of Public Procurement Law, and at the same time is less than 10% of the basic contract value.
d. Changes introduced to the description of the subject of the contract will remain closely related to the changes in the clinical study plan, and the parties will determine the amount of the flat-rate remuneration based on the changes made in the description of the subject of the contract and fixed subtotals, provided by the Bidder in accordance with Attachment no. 2. A change in the flat-rate remuneration will only be possible to the extent that it is directly related to the change in the study plan/description of the subject of the contract. In the event of changes to the clinical trial protocol, the price may be changed only for the item 'clinical costs per patient'.
e. Changes introduced cannot lead to a change in the nature of the contract.
f. If a serious adverse event or adverse drug reaction occurs during the clinical trial, and extention of the scope of the order and increase of the Bidder's flat-rate remuneration will be necessary. In this case:
   i. Changing the description of the subject of the contract will remain closely related to the occurrence of a serious adverse event or adverse drug reaction during the study.
   ii. The parties are to determine the amount of the flat-rate remuneration based on the changes to be made to the description of the subject of the contract and subtotals provided by the Bidder in accordance to Attachment no. 2.
   iii. A change in the flat-rate remuneration will only be possible to the extent that it is directly related to the change in the description of the subject of the contract.
   iv. Changes cannot lead to a change in the nature of the contract.

35. Any changes to the contract must be made in writing, otherwise being null and void.

Contractual penalties

36. The Bidder is obliged to declare the recruitment rate (in Patients/Month). In the event of slower recruitment rate by 50% number of patients per month declared, for reasons attributable to the Bidder, the Bidder shall pay the Purchaser a contractual penalty in

the amount of 1% of the net offer price. The justification of the penalty will be assessed every 3 months from the date of first randomized patient in the first clinical centre based on the sum of recruited number of patients from 3 consecutive months.

37. In the event of exceeding the time needed for FPI (randomization of the first patient) declared by the Bidder, for reasons attributable to the Bidder, by at least 30 calendar days, the Bidder shall pay the Purchaser a contractual penalty in the amount of 1% of the net offer price, and then subsequent 1% of the net offer price for each subsequent 20 calendar days of delay.
38. In the event of exceeding the time to provide the Clinical Study Report declared by the Bidder, for reasons attributable to the Bidder, by at least 30 calendar days, the Bidder shall pay the Purchaser a contractual penalty in the amount of 1% of the net offer price, and then subsequent 1% of the net offer price for each subsequent 20 calendar days of delay.
39. The purchaser will also have the right to withdraw from the contract if the Bidder fails to comply with its terms, including in particular in the case of:
    a. not to provide services within the period specified in the contract;
    b. delivering the subject of the contract that does not comply with the requirements set out in the contract and its annexes.

    If the Purchaser exercises its right to withdraw from the contract referred to above, the Bidder will be obliged to pay the Purchaser a contractual penalty of 5% of the net offer price.
40. Termination of this contract may only occur for important reasons. As an important reason justifying the termination of this contract, the parties consider in particular:
    a. lack of cooperation between the parties preventing or significantly hindering the implementation of the provisions of this contract;
    b. gross violation by a party of its basic obligations under this contract.
41. Contractual penalties will be charged on the basis of the Purchaser's encumbrance note delivered to the Bidder. The Purchaser shall be entitled to offset contractual penalties against the payments due to the Bidder.
42. The Purchaser has the right to claim damages based on general principles in the amount exceeding contractual penalties.
43. Contractual penalties will be paid within 7 days from the debit note receipt date.
44. Bidders applying jointly for the contract have joint and several liabilities for the performance of the contract and are jointly obligated to ensure its proper performance.

Assessment criteria and description of how the points are awarded

The winning bid will be selected based on the following criteria:

No.	Criterion	Points	Weight (%)
1.	**TOTAL PRICE OF THE STUDY**	**P1**	**60**
2.	**CLINICAL COSTS PER PATIENT**	**P2**	**20**
3.	**RECRUITMENT RATE IN THE COMMERCIAL SITES**	**P3**	**10**
4.	**TIME FROM LAST OF THE TWO – APPROVAL FOR THE CLINICAL TRIAL OR POSITIVE OPINION OF THE BIOETHICAL COMMITTEE TILL FPI IN THE COMMERCIAL SITE**	**P4**	**5**
5.	**TIME FROM DELIVERY BY THE PURCHASER OF BIOANALITYCAL AND STATISTICAL ANALYSIS RESULTS TILL PROVIDING CLINICAL STUDY REPORT**	**P5**	**5**
	Total points:	***Max 100***	***100%***

Points will be awarded in the selection process as follows:

No.	Criterion	Scoring system
1.	**TOTAL PRICE OF THE STUDY**	**Number of points for Total price for the study ("P1") – criterion weight: 60%, maximum 60 pt** The grade will be expressed by the number of points, which will be calculated according to the following formula: **P1** = a/b x60 points where: **P1** – means the number of points, rounded to two decimal places, that the offer under consideration will receive for the total price for the study.

		a – means the lowest total net price for the study in PLN among Bidders. **b** – means the total net price for the study in PLN of the evaluated offer. The total price for the study proposed by the given Bidder (including clinical costs for 90 patients) is the amount resulting from the sum of subtotals, in accordance to the Table 1 in the Scope of Work (Attachment no. 2)
2.	**CLINICAL COSTS PER PATIENT**	**Number of points for Clinical costs per patient ("P2") – criterion weight: 20%, maximum 20 pt** The grade will be expressed by the number of points, which will be calculated according to the following formula: **P2** = c/d x 20 points where: **P2** - means the number of points, rounded to two decimal places, that the offer under consideration will receive for the clinical costs per patient. **c** - means the lowest net price for the clinical costs per patient in PLN among Bidders. **d** - means the net price for the clinical costs per patient of the study in PLN of the evaluated offer. Clinical cost per patient proposed by the given Bidder – according to the Scope of Work (Attachment no.2).
3.	**RECRUITMENT RATE IN THE COMMERCIAL SITES** (declaration of number of patients per month)	**Number of points for recruitment rate ("P3") – criterion weight: 10%, maximum 10 pt** The Bidder is obliged to declare the number of patients recruited per month P/M (in Patients/Month) in the Commercial clinical sites. The grade will be expressed by the number of points, which will be calculated according to the following formula **P3** = e/f x 10 points where: **P3** - means the number of points, rounded to two decimal places, that the offer under consideration will receive for the recruitment rate. **e** - means the recruitment rate "P/M" of the evaluated offer **f** - means the highest number of patients per month "P/M" among Bidders . In the declared recruitment rate the start of the clinical study should be consider as a day after the last of the two was obtained - approval for the

		clinical trial from the competent regulatory authority or the positive opinion of the competent Bioethical Committee. For recruitment rate estimation the Bidder should take into account , as stated in the RfQ, recruitment of 90 patients in the commercial sites. For recruitment rate estimation patients recruited in the Consortium Sites should not be consider.
4.	**TIME FROM LAST OF THE TWO – APPROVAL FOR THE CLINICAL TRIAL OR POSITIVE OPINION OF THE BIOETHICAL COMMITTEE TILL FPI IN THE COMMERCIAL SITE**	**Number of points for time from last of the two – approval for the clinical trial or positive opinion of the Bioethical Committee till FPI in the commercial site ("P4") – criterion weight: 5%, maximum 5 pt** The Bidder is obliged to declare the time describe in the criterion (in days). The grade will be expressed by the number of points, which will be calculated according to the following formula **P4** = g/h x 5 points where: **P4** - means the number of points, rounded to two decimal places, that the offer under consideration will receive for the time from last of the two – approval for the clinical trial or positive opinion of the Bioethical Committee till FPI in the commercial site. **g** - means the shortest time declared among Bidders. **h** - means the time declared in the evaluated offer . In the criterion the start of the clinical study should be consider as a day after the last of the two was obtained - approval for the clinical trial from the competent regulatory authority or the positive opinion of the competent Bioethical Committee. For the purpose of this RfQ, it is assumed that 1 month = 30 calendar days.
5.	**TIME FROM DELIVERY BY THE PURCHASER OF BIOANALITYCAL AND STATISTICAL ANALYSIS RESULTS TILL PROVIDING CLINICAL STUDY REPORT**	**Number of points for time from delivery by the Purchaser of bioanalytical and statistical analysis results till providing clinical study report ("P5") – criterion weight: 5%, maximum 5 pt** The Bidder is obliged to declare the time describe in the criterion (in days). The grade will be expressed by the number of points, which will be calculated according to the following formula **P5** = i/j x 5 points where:

		P5 - means the number of points, rounded to two decimal places, that the offer under consideration will receive for the time from delivery by the Purchaser of bioanalytical and statistical analysis results till providing clinical study report. **i** - means the shortest time declared among Bidders. **j** - means the time declared in the evaluated offer . The Bidder will receive from Purchaser the raw bioanalytical data and statistical analysis results without it's interpretation. For the purpose of this RfQ, it is assumed that 1 month = 30 calendar days.

The winning offer will be selected based on the highest total points: P1 + P2 + P3 + P4 + P5.

Attachments to the Request for Quotation:
Attachment no. 1 - *Clinical study synopsis.*
Attachment no. 2 - *Scope of Work.*
Attachment no. 3 - *The statement of compliance with the requirements.*
Attachment no. 4 - *The Statement on the absence of personal or capital ties with the Purchaser.*