Łomianki, 20.03.2017r.

Purchaser:

Celon Pharma S.A.
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REQUEST FOR QUOTATION (RfQ)no.11/2017/M/CELONKO

In relation to the planned implementation of the project Development of novel biomarkes and innovative FGFR kinases inhibitor as an anti-cancer therapy 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:

Conducting the following subcontracted general toxicology, safety pharmacology and analytical support studies program necessary to complete the Project:

A. General toxicology:
– Appropriate dose range finding studies in two species (one rodent and non-rodent: NHP *(Non-Human Primate*), using the intended route of administration.
– Repeat dose toxicology studies in two species (one rodent and non-rodent: NHP), using the intended route of administration.
B. Safety pharmacology:
– An assessment of vital organ functions, including cardiovascular, respiratory and central nervous systems - parameters incorporated into general toxicology studies. Detailed clinical observations following dosing including qualitative examination for behavior and respiratory functions in both rodent and non-rodent: NHP species. Appropriate electrocardiographic measurements in non-rodents.
C. Analytical Support:
– Development and validation of an analytical method for the formulation and analysis of Test Item (TI) in dose formulation.

- Development, establishment and validation of a suitable bioanalytical method, and subsequent routine sample analysis. Development and validation of method in two toxicology species (one rodent and non-rodent: NHP).

Additional information:

- The planned studies program will be conducted in accordance with both Good Laboratory Practices (GLP) and non-GLP.
- The planned studies program will be conducted in accordance with The European Medicines Agency's scientific guidelines on the non-clinical testing of medicines.
- The English language must be used for all purposes in preparing documents and reporting.
- Further details of the request for quotation will be presented to the Bidder once the confidentiality clause is signed.

Requirements to be met by bidders:

1. The Bidder must sign the Mutual Confidentiality and Nondisclosure Agreement with the Purchaser to get details enabling to create a required bid.
2. The Bidder should demonstrate the ability to conduct the study referred to in this RfQ in the shortest possible term. *Submission of Bidder's experimental time schedule (time plan) is required.* This is to include the estimated commencement date of the first study to the estimated primary completion date of the studies program. The signing of the contract is planned for April 2017.
3. The Bidder should hold all licences required by law to deliver the subject of the order.
4. The Bidder should have the necessary experience and potential to deliver the subject of the order. Submission of the confirmed references form 3 pharmaceutical companies concerning the experience in similar studies are highly recommended.
5. The Bidder should have the necessary technical and laboratory infrastructure to conduct the studies referred to in this RfQ and be able to conduct the selected studies in accordance with GLP.
6. The Bidder should demonstrate it has scientific personnel specialised in areas related to the subject of this RfQ. *Submission of Bidder's folder, presentation or monograph is allowed*.
7. Furthermore, the Bidder should demonstrate experience in the form of research and development projects implemented over the last 5 years. *Submission of Bidder's folder, presentation or monograph is allowed.*
8. "The Statement on absence of personal or capital ties with the Purchaser" should be submitted along with the bid.

9. Unless otherwise stated, all invoices will be payable within 30 days of the date of issuance of the invoice.
10. Finally, the Bidder's financial and economic position should ensure successful implementation of the order.

Address and date for submitting the bids:

11. Bids must be submitted to the purchaser's office at ul. Mokra 41a, 05-092 Kiełpin, if sent by traditional mail or by currier, or to dominika.kasprowiak@celonpharma.com if sent by electronic mail.
12. Bid must be submitted by 2.04.2017 at the latest. If sent by traditional mail or courier, the bid is deemed to be submitted on the day of its delivery to the purchaser's office.
13. Bids submitted after the aforementioned date will not be considered.
14. Bids will be evaluated at the Purchaser's office by 10.04.2017.
15. The final decision will be communicated to all Bidders by electronic mail and published on the website: http://celonpharma.com/category/zapof/, on 11.04.2017.
16. For further information on the Project, please contact Paulina Dera, email: paulina.dera@celonpharma.com.
17. This request for quotation is available at: http://celonpharma.com/category/zapof/

Presentation of the bids:

18. Each Bidder may submit only one bid.
19. The bid must be in English.
20. The bid must show the date of preparation, the Bidder's address, telephone number, email address, tax ID number NIP (if available).
21. The bid must include the RfQ no. in the title. The RfQ no. must also appear in the titles of electronic, traditional and courier mail.
22. The bid must remain valid for at least 3 months counted from the submission deadline.
23. The bid must contain:
    a. The price:
        i. should be presented for each single planned study including total price for this study excluding procedures specified in the section "Additional procedures to the above outline", which are to be priced separately (according to the Detailed Studies Scope – available after signing the confidentiality clause),

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

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

b. Information about the proposed study program in accordance with a *Detailed scope of the studies*, available only after the signature of confidentiality clause.

c. Declaration that the Bidder has scientific experience and personnel specialised in areas related to the subject of this RfQ. *Submission of Bidder's folder, presentation or monograph is allowed*.

d. Declaration that the Bidder has the ability to conduct the studies referred to in this RfQ in 2017. *Submission of Bidder's experimental time schedule (time plan) is required.*

e. The Statement on absence of personal or capital ties with the Purchaser should be submitted along with the bid.

24. Costs of preparing the bid shall be borne by the Bidder.

Note:

25. The Purchaser will place the order with the bidder whose bid meets all the requirements set forth in this RfQ and is deemed the best relative to the selection criteria set forth herein.
26. When substantiated, the purchaser reserves the right to cancel the bidding process.
27. The Purchaser reserves the right to close the bidding process without selecting the successful Bidder. The Ordering party is not bound to give the reason for closing the procedure.
28. In the course of evaluation and assessment of the bids, the Purchaser may request that the bidders provide clarifications regarding their bids. In such a case, the Ordering party reserves the right to postpone the final evaluation and notification about the evaluation of quotes.
29. The Bidder may alter or withdraw its bid before the submission deadline.
30. Bids submitted past the submission deadline will not be considered.
31. Bids that do not meet the formal requirements set forth herein will not be considered.
32. The Purchaser accept variant bids. The proposed studies program will be conducted in accordance with the guidelines of the European Medicines Agency. The Provider, offering a method of testing the TI which is equivalent to the testing method

described in the request for quotation, is obligated to prove, on the basis of available experimental data and a written declaration, that the study it offers (each study individually) is equivalent to the study described in the request for quotations and fulfils the requirements to obtain the necessary results in accordance with the guidelines of the European Medicines Agency without requiring additional steps, including, for example, bridging studies.

33. The Purchaser accept partial bids. Information on partial bids:
    a. In this tender procedure, the Ordering Party accepts partial bids.
    b. The Contractor may submit a bid for a selected part of the order, any selected parts of the order or all parts of the order.
    c. Each part of the order is autonomous. In each single procedure, the Ordering Party will apply the above said provisions separately to each respective part, i.e. actions regarding, but not limited to, exclusion from the procedure, rejection of a bid, selection of the most advantageous bid and invalidation of the procedure shall be made separately for each respective part.
    d. The Ordering Party shall sign a contract with the Contractor that has submitted the most advantageous bid for a respective part of the tendering procedure.
34. The Purchaser permits rejecting bids whose essential content clearly raises reasonable doubts.
35. The absence of submission of the experimental time schedule (time plan) both with the estimated commencement date of the first study and the estimated primary completion date of the studies program is the base to reject the application and grant 0 points for the subsequent evaluation criteria.

The successful bid will be selected on the basis of the following criteria:

No.	CRITERIA	WEIGHT IN %
1.	Price	50
2.	Time	45
3.	References	5

Points scoring systems during selection process will be as follows:

No.	CRITERIA	Points scoring system
1.	Price	**Price "P" – 100 pkt (weight of criterion 50%)** Scoring in the price criterion will be as follows: the lowest price for conducting all studies proposed by the Tenderer will be considered 100%, which is the maximum number of points. The points will be given based on the formula: $$\frac{Price_{lowest}}{Price\ _{service}} \times 100\ pkt$$ Where: $Price_{lowest}$ – the lowest price among quotes. $Price_{service}$ – price for the given tenderer. ***Criterion "P" = number of points x 50% (weight of criterion)***
2.	Time	**Time "T" – 100 pkt (weight of criterion 45%)** 100 pkt - will be given to the Bidder who will provide the earliest estimated primary completion date of the studies program. The next Bidders will receive 100 pkt with subtracted 3 pkt for every week of delay in completion date of the studies program compared to the earliest one. If the estimated primary completion date of the studies program will be later than 34 weeks compared to the earliest one, the Bidder will receive 0 pkt. ***Criterion "T" = number of points x 45% (weight of criterion)***
3.	References	**References "R" – 100 pkt (weight of criterion 5%)** 100 pkt - will be given if the Tenderer will provide references from 3 pharmaceutical companies concerning the experience in similar studies, 60 pkt - will be given if the Tenderer will provide references from 2 pharmaceutical companies concerning the experience in similar studies, 30 pkt - will be given if the Tenderer will provide references from 1 pharmaceutical company concerning the experience in similar studies,

		0 pkt - will be given if the Tenderer will not provide any references from pharmaceutical companies concerning the experience in similar studies. ***Criterion "R" = number of points x 5% (weight of criterion)***

The final score will be calculated by substituting the data obtained above to the following formula:

Total points = *Criterion "P" + Criterion "T" + Criterion "R"*