

Zakroczym, 02.08.2024
place and date

MARKET INSIGHT FORM

I. Purpose of form:

In connection with the implementation of the project entitled “Development of a two-component medicinal product for the treatment of chronic obstructive pulmonary disease (COPD)”, co-financed from the state budget as part of a competition organised by the Medical Research Agency, **we would like to request the value of the planned order described in detail below, in section II, and to provide the information indicated in Annex 1.**

Please affix your signature to this Market Insight Form and send a scan of it (in pdf format) by email to: zapytaniaofertowe@lekam.pl by: 12.08.2024.

Please include in the subject line of your message: *COPD amorphous content determination - 2*

If you require any further information, please contact us by email: zapytaniaofertowe@lekam.pl

II. Description of the subject of the contract:

1. The planned order concerns the *performance of tests for the determination of amorphicity in the active substance indacaterol maleate by the technique of solution microcalorimetry. A detailed description of the subject of the order is provided in section II.4 of this form.*
2. CPV CODE: **73100000-3 - Research and experimental development services**
3. Deadline for completion of the subject of the contract:
 - testing the amorphous form content of the active substance indacaterol maleate by solution microcalorimetry, according to method description provided by the client, **by 31 January 2025 at the latest.**
 - Reproduction of the method for determining the content of the amorphous form according to method description provided by the client (if not already done by the bidder) **by 15 September 2024 at the latest.**

(Lead times do not affect the prices offered)

4. Detailed description of the subject of the contract:

Subject of the contract
<p>The subject of the contract will be:</p> <ol style="list-style-type: none">1. To test the amorphous form content of the active substance indacaterol maleate by solution microcalorimetry according to the method description provided and in accordance with the specification: amorphous form content $\leq 5\%$. Number of samples: 1 - 4. Samples will be supplied separately.2. Carry out verification of the solution microcalorimetry method according to the description of the analytical method*. <p>(Where the tenderer has already carried out method restoration work as part of a previous collaboration, this must be confirmed when submitting the tender in accordance with Appendix 1 of this market discernment form).</p>



**The description of the analytical method and the validation of the method will be made available after the signing of the confidentiality agreement, unless the parties have already concluded a confidentiality agreement in a previous collaboration. An electronically signed or a scan of the confidentiality agreement signed traditionally by the Bidder should be sent to zapytaniaofertowe@lekam.pl at the latest 3 days before the closing date of the market research. Upon receipt of the document, the Contracting Authority will send a description of the analytical method within maximum 1 working day of receiving the signed agreement. Please let us know via e-mail if you are interested in confidentiality agreement receipt.*

Additional requirements

1. As a result of the studies from point 1 of the detailed description of the subject of the contract, a research report will be issued in English each time, including raw data, results and conclusions.
2. The method verification (if applicable) must result in a study report in English, which must include at least:
 - description of the method (conditions under which measurement is carried out; method of sample preparation)
 - linearity in the LOQ range - 200% of the specification limit (approx. 1% to 10% amorphous form content); requirement: $R > 0.995$
 - specificity
 - precision (requirements for $n = 6$, $RSD \leq 2\%$)
 - limit of quantification and limit of detection (requirements: $LOQ < 2.5\%$, $signal/noise > 10$, $LOD\ signal/noise > 3$).
3. Upon completion of the work carried out by the subcontractor, upon payment of the amount due for the work carried out, all property rights in the results of the work carried out will be fully transferred to the contracting entity.
4. Materials provided by the contractor necessary to complete the subject matter of the contract:
 - reference standards

5. Conditions for participation in the market research

Requirements for the contractor		
Type of requirements	Description of requirements	Method of verification
Technical requirement	The contractor must be able to carry out tests on the TAM microcalorimeter equipment	The conditions will be verified on the basis of the bidder's declaration as per Annex 1 to this form.
Experience requirements	The contractor, at the closing date for submission of tenders, should have a minimum of 3 years' experience in carrying out studies analogous to the subject of the contract.	The conditions will be verified on the basis of the bidder's declaration as per Annex 1 to this form.
Personnel requirements	The contractor must have a team of persons meeting the following requirements in total:	The conditions will be verified on the basis of the bidder's



	<ul style="list-style-type: none">• experience in carrying out studies similar to the subject of this contract;• knowledge of the analytical tools necessary for the execution of this contract.	declaration as per Annex 1 to this form.
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Information to be completed by the bidder:

Full name of Contractor:

Contractor's address:

VAT No.:

Contact person:

Date of offer:

Please indicate the currency in the table below!

Lp.	Study	Performed as part of previous cooperation YES/NO**	Net price per sample****	Gross price per sample****	Completion date***
1.	Testing of the amorphous form content of the active substance indacaterol maleate by the method presented (point 1 of detailed description of the subject of the contract) and in accordance with the specification: amorphous form content $\leq 5\%$, number of samples: 1 - 4	X			
2.	Method verification for the determination of amorphous form content according to the description and validation provided*				

**description of the analytical method and validation of the method will be made available after signature of a confidentiality agreement following the selection of the bidder*

*** do not indicate price if completed YES*

**** counted in weeks from the date of conclusion of the contract/order*

***** in the case of the study "Method verification (...)" the service is one- off, without duplication of trials*

We declare that we will comply with the following conditions of the subject matter of the contract at the date of commencement of the work:

1. We will sign/ signed* a confidentiality agreement with the Principal prior to the commencement of the assignment.
2. We have the opportunity to carry out tests on a TAM microcalorimeter.
3. We have a minimum of 3 years' experience in carrying out studies analogous to the subject matter of the contract as at the deadline for submission of the tender.
4. We have at our disposal a team of people meeting the following requirements in total:
 - Experience in carrying out studies similar to the subject of this contract;
 - Familiarity with the analytical tools necessary for the execution of this contract.
5. We agree to sign a quality agreement with LEK-AM once our bid has been selected.

We declare that we are aware of the additional requirements presented for the subject matter of the contract in point. II.4 (market insight form) *Detailed description of the subject matter of the order* and will be fulfilled if our offer is selected.

** delete as appropriate*

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Date and place

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Signature