



Zakroczym, on 02.06.2023
place and date

MARKET INSIGHT FORM

I. Purpose of the form:

In relation to the execution of the project entitled “Development of a two-component medicinal product used for the therapy of chronic obstructive pulmonary disease (COPD)” co-financed from the national budget funds as part of the competitions organized by the Medical Research Agency, **we would like to ask you to provide the value of the planned order described in detail under item II below and to provide information listed in Appendix no. 1 to this Form and complete Appendix no. 2 if necessary.**

Please sign this Market Insight Form and send a scan (in the pdf format) by e-mail to: zapytaniaofertowe@lekam.pl by: 19.06.2023

In the subject line, please enter: COPD amorphous content determination

If you need additional information, please contact us by e-mail: zapytaniaofertowe@lekam.pl

II. Order specification:

1. The planned order concerns *amorphous content determination in the active pharmaceutical ingredient, indacaterol maleate, by solution microcalorimetry. The detailed order specification is included in item II.4 of this form.*
2. CPV CODE: **73100000-3 – Research and experimental development services**
3. Deadline for completion of the order:
 - Replication and optimization of an amorphous content determination method according to the analytical method package, **no later than 31 July 2023**;
 - Amorphous content determination in the active pharmaceutical ingredient, indacaterol maleate, by the method described in the method replication report, **no later than 31 May 2024.**

(Completion date does not affect the prices offered)

4. Detailed order specification:

Subject of the order
<p>The services will include:</p> <ol style="list-style-type: none"> 1. Verification and optimization of the solution microcalorimetry method according to the analytical method description.* <p>(If the bidder has already performed method verification works as part of previous cooperation, this fact should be confirmed when submitting a bid.)</p> <ol style="list-style-type: none"> 2. Amorphous content determination in the active pharmaceutical ingredient, indacaterol maleate, by the method described in the method replication report (item I) and according to the specifications: amorphous content $\leq 5\%$, number of samples: 1–4. The samples may be delivered separately.



**The analytical method package and method validation will be disclosed upon signing of the non-disclosure agreement that constitutes an appendix (appendix no. 2) to this market insight form, unless the parties have already concluded a non-disclosure agreement as part of their previous cooperation. Please send the electronically signed non-disclosure agreement or a scan of the non-disclosure agreement with a handwritten signature of the Bidder to zapytaniaofertowe@lekam.pl no later than 4 days before the market insight deadline. Upon receiving the document, the Ordering Party shall send the analytical method description within 1 working day of receipt of the signed agreement.*

Additional requirements

1. As a result of the performed testing as described in item 1, a testing report in English must be generated and must include at least the following information:
 - Method description (measurement conditions, sample preparation method)
 - Linearity from LOQ to 200% of the specification limit (amorphous content approx. 1% to 10%); requirement: $R > 0.995$
 - Specificity
 - Precision (requirements for $n=6$, $RSD \leq 2\%$)
 - Limit of quantitation and limit of detection (requirements: $LOQ < 2.5\%$, signal-to-noise ratio > 10 , LOD signal-to-noise > 3)
2. After completion of the works by the subcontractor, all property rights to the work products shall be transferred in full to the ordering party upon payment of the amount due for the works performed.
3. As a result of the performed testing as described in item 2 of the detailed order specification, a testing report in English shall be issued each time which shall contain raw data, results and conclusions.
4. Materials provided by the contractor that are necessary to complete the order:
 - consumables
 - reagents and solvents
 - standards

5. Requirements for market insight participation

Requirements for the contractor		
Requirement type	Requirement description	Verification method
Technical requirements	The contractor must be able to perform testing with the use of the following instruments: TAM microcalorimeter, XRPD diffractometer, DSC instrument, TGA instrument – analytical scales	Requirements will be verified based on the bidder's statement as per appendix no. 1 to this form.
Experience requirements	As of the bid submission deadline, the contractor should have at a minimum 3 years of experience in performing testing similar to the subject of the order.	Requirements will be verified based on the bidder's statement as per appendix no. 1 to this form.



Personnel requirements	<p>The contractor must have at its disposal a team of persons who cumulatively meet the following requirements:</p> <ul style="list-style-type: none"> • experience in performing testing similar to the subject of this order; • knowledge of the analytical tools necessary to complete this order. 	Requirements will be verified based on the bidder's statement as per appendix no. 1 to this form.
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6. Bid evaluation

- When evaluating bids, the Ordering Party shall use the following criteria:

- Price – 90%;
- Completion period for 1 sample – 10%.

- The bid score will be calculated according to the following formula:

$$O_P = P_C + P_T$$

where:

- O_P - bid score
- P_C - score awarded for the “Price” criterion
- P_T - score awarded for the “Completion period for 1 sample” criterion

- The score for the “Price” criterion (P_C) will be calculated according to the following formula:

$$P_C = \frac{C_N}{C_B} * 90$$

where:

- P_C - score for the “Price” criterion
- C_N - the lowest total net price for one sample among all evaluated bids
- C_B - total net price of the analyzed bid

- The score (P_T) for the “Completion period for 1 sample” criterion will be assigned in the following manner:

$$P_T = \frac{T_N}{T_B} * 10$$

where:

- P_T - score for the “Completion period for 1 sample” criterion
- T_N - shortest total completion period for 1 sample among all evaluated bids
- T_B - total completion period for 1 sample in the analyzed bid

The deadline for completion of the order should be expressed in weeks.

- The bid that is awarded the highest score will be considered the most advantageous. The maximum score a bid may be awarded is 100 points. The calculations will be rounded to two decimal places.



Rzeczpospolita
Polska



AGENCJA
BADAŃ
MEDYCZNYCH

Appendix no. 1 to the Market Insight Form

Information template to be completed by the bidder:

Contractor's full name:

Contractor's address:

Tax Identification Number [Numer Identyfikacji Podatkowej, NIP]:

Contact person:

Offer drafting date:

No.	Test	Performed as part of previous cooperation YES/NO**	Net price for one sample****	Gross price for one sample****	Completion period***
1.	Verification and optimization of an amorphous content determination method according to the analytical method package*				
2.	Amorphous content determination in the active pharmaceutical ingredient, indacaterol maleate, by the method described in the method replication report (item I of the order specification) and according to the specifications: amorphous content $\leq 5\%$, number of samples: 1–4.	X			
Total price for no. 1 and 2					

**analytical method description and method validation will be disclosed upon signing of the non-disclosure agreement, after the bidder is selected*

*** if YES is entered, the price does not need to be stated*

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

***** for no. 1 Replication and optimization of the method, the service is on a one-time basis, without sample replicates*

We hereby represent that as at the work commencement date, we will meet the following order requirements:

1. We are able to perform testing with the use of the following instruments: TAM microcalorimeter, XRPD diffractometer, DSC instrument, TGA instrument – analytical scales.
2. As of the date of bid submission, we have at a minimum 3 years of experience in performing testing similar to the subject of the order.
3. We have at our disposal a team of persons who cumulatively meet the following requirements:
 - experience in performing testing similar to the subject of this order;
 - knowledge of the analytical tools necessary to complete this order.

We agree to conclude a quality agreement with LEK-AM when our bid is selected.

We hereby represent that we are aware of the additional requirements for the subject of the order specified in item II.4 *Detailed order specification* (of the market insight form) and they will be fulfilled, should our bid be selected.

.....

.....

Date and place

Signature

Appendix no. 2 to the Market Insight Form

Non-Disclosure Agreement Template

NON-DISCLOSURE AGREEMENT

concluded in Zakroczym on by and between:

.....,
entered into the Register of Entrepreneurs of the National Court Register maintained by the District
Court for
.....,
under the KRS number, Tax Identification Number [Numer Identyfikacji
Podatkowej, NIP], National Official Business Register Number [Rejestr
Gospodarki Narodowej, REGON]:, with a share capital in the amount of
..... represented by:
..... (hereinafter referred to as the
“Partner”)

and

Przedsiębiorstwo Farmaceutyczne LEK-AM Sp. z o.o., with its registered office at ul. Ostrzykowińska
14A, 05-170 Zakroczym, entered into the Register of Entrepreneurs maintained by the District Court for
the Capital City of Warsaw in Warsaw, 14th Commercial Division of the National Court Register under
the National Court Register Number [Krajowy Rejestr Sądowy, KRS]: 0000089602, Tax Identification
Number [Numer Identyfikacji Podatkowej, NIP]: 5311495443, National Official Business Register
Number [Rejestr Gospodarki Narodowej, REGON]: 016295922, Waste Database [Baza Danych
o Odpadach, BDO] entry number: 000117403, with a share capital of PLN 3,373,400.00, represented
by:

Mr. Andrzej Wyrzykowski – President of the Management Board
(hereinafter referred to as “**Company**”)

The Company and the Partner are hereinafter referred to in this Agreement jointly as the “**Parties**” and
individually as a “**Party**” and “**Confidential Information Receiving Party**” or “**Confidential
Information Disclosing Party**”, depending on whether they receive or disclose confidential
information.

WHEREAS:

- The persons signing this Agreement are duly authorized and have legal capacity to submit statements of intent on behalf of the Party which they represent.
- The Parties are preparing to initiate or have already initiated the cooperation whose execution requires the mutual disclosure of Confidential Information between the Parties:
- Each Party has agreed to provide Confidential Information to the other Party, following the terms included within this Agreement.
- Each Party represents that it has the appropriate personnel and technical resources to properly secure the performance of this Agreement.

THE PARTIES HEREBY AGREE as follows:

Confidential Information

§ 1

- 1.1. For the purpose of this Non-Disclosure Agreement, hereinafter referred to as “**Agreement**”, “**Confidential Information**” shall mean any information (including, but not limited to: technical, commercial, scientific and other data, processes, procedures, technologies and documents), regardless of the form they are being disclosed in and the medium on which they are recorded, which the Confidential Information Receiving Party has received or will receive directly from the Confidential Information Disclosing Party or its associated entities within the meaning of the Polish Accounting Act, and which concern the company or operations of the Confidential Information Disclosing Party.
- 1.2. For the purpose of this Agreement, “Confidential Information” shall also include any copies, summaries, descriptions, modifications and duplicates of the above-mentioned data, processes, documents, other information or physical items received from the Confidential Information Disclosing Party. If the Confidential Information Receiving Party has any concerns regarding the confidential nature of any Confidential Information, it shall submit a relevant query in writing to the Confidential Information Disclosing Party. The Confidential Information Disclosing Party shall respond to such a query within five (5) business days from the day of receipt of the letter or fax.

Obligations of Confidentiality

§ 2

- 2.1. The Confidential Information Receiving Party agrees to:
 - (a) not disclose Confidential Information to any third party, except with explicit prior written permission from the Confidential Information Disclosing Party and only if such a third party has signed a Confidential Information non-disclosure agreement on the same terms as set forth in this Agreement;
 - (b) not copy any Confidential Information without the other Party’s permission, with the exception of the backup system described in the procedures;
 - (c) restrict the disclosure of Confidential Information only to its personnel, contractors, attorneys and other persons who should know this information by reason of the scope of their duties performed for the Confidential Information Receiving Party;
 - (d) not use Confidential Information for any purpose other than those resulting from Agreements between the Parties. The Confidential Information Receiving Party shall undertake any measures necessary to maintain the confidentiality of Confidential Information, not less than when keeping its own information confidential.
- 2.2. The Confidential Information Receiving Party shall be considered not to have violated this Agreement if the Confidential Information:
 - (a) is publicly known or is or will become publicly available without violation of this Agreement;
 - (b) is lawfully obtained by the Confidential Information Receiving Party from a third party;

- (c) must be disclosed in accordance with legal regulations or pursuant to a court ruling, decision, judgement or ruling of another authorized national authority. In such cases the Confidential Information Receiving Party shall immediately notify the Confidential Information Disclosing Party of the requirement to disclose Confidential Information. The Parties shall agree on the manner and scope of disclosure of information as permitted by the applicable laws. Any disclosures of Confidential Information to a competent authority must include a request to treat this information as confidential.
- 2.3. The Confidential Information Receiving Party shall ensure that its employees, contractors, attorneys and other persons to whom is has granted access to Confidential Information as per the provisions of this Agreement comply with the obligations of confidentiality resulting from this Agreement. In particular, the Confidential Information Receiving Party shall inform those of the above-mentioned persons who will have access to the disclosed information of its confidential nature and shall ensure that those persons submit a written confidentiality statement reflecting the provisions of this Agreement.
- 2.4. The Confidential Information Disclosing Party shall have exclusive legal title to Confidential Information at all times.
- 2.5. Upon a written request of the Confidential Information Disclosing Party, the Confidential Information Receiving Party shall, if technically and formally feasible, immediately return all Confidential Information provided to it under this Agreement and any copies thereof.

Term of the Agreement

§ 3

- 3.1. The Agreement shall enter into force on the day of signature by the last Party hereto and shall continue for 5 years, subject to item 3.2.
- 3.2. The Confidential Information Receiving Party shall be required to maintain the confidentiality of Confidential Information also after the term of the Agreement or in the event of its early termination. After the term of the Agreement or its early termination, the Confidential Information Receiving Party shall, at the discretion of the Confidential Information Disclosing Party, destroy the documents containing Confidential Information, delete this information from its databases, as well as return or destroy information carriers in the form of any duplicates, electronic records etc., within ten (10) days from the submission of the relevant request, unless the storage thereof is required by the applicable laws.

Breach of Agreement

§ 4

- 4.1. The Confidential Information that has been or is to be disclosed to the Confidential Information Receiving Party under this Agreement constitute valuable proprietary commercial information whose misuse or unauthorized disclosure may cause substantial damage to the Confidential Information Disclosing Party; therefore, the Confidential Information Receiving Party understands that without prejudice to other rights and measures which may be available to the Confidential Information Disclosing Party in connection with a violation of this Agreement, the Confidential Information Disclosing Party has the right to obtain an injunction, including a temporary injunction issued by a court competent for this Agreement.
- 4.2. The Confidential Information Receiving Party understands that any violation of this Agreement may cause an immediate termination of its right to use the Confidential

Information, without the right to recourse or compensation, even if such a termination would expose the Confidential Information Receiving Party to compensation claims from third parties. Upon such a termination or within ten (10) days from the submission of the relevant request by the Confidential Information Disclosing Party, regardless of the reason, the Confidential Information Receiving Party shall destroy any Confidential Information (with written confirmation by an authorized representative of the Confidential Information Receiving Party) or, if physically feasible, return it to the Confidential Information Disclosing Party, at the discretion of the Disclosing Party.

Contractual Penalties

§ 5

- 5.1. Should the Confidential Information Receiving Party violate this Agreement, it shall be obliged to pay a contractual penalty of PLN 50,000.00 (in words: fifty thousand zloty) for each and every disclosure of Confidential Information in contradiction of the Agreement.
- 5.2. Should the Confidential Information Disclosing Party become aware of any violation of this Agreement, it shall notify the Confidential Information Receiving Party within 60 days from becoming aware of it and shall request the Confidential Information Receiving Party to pay a contractual penalty. The Confidential Information Receiving Party shall pay a contractual penalty within 30 days from receiving the notice.
- 5.3. The Parties agree that the Confidential Information Disclosing Party has the right to claim damages in excess of the amount of the stipulated contractual penalty.

Notices

§ 6

Any notices and correspondence submitted under this Agreement (or in connection herewith) shall be in writing. The Parties shall also acknowledge actions executed with the use of a trusted profile as executed in writing and indisputable.

Miscellaneous

§ 7

- 7.1. This Agreement shall be governed by and construed in accordance with the Polish law. In the event of any dispute, discrepancies or disagreement arising from this Agreement or resulting from any of its provisions, the Parties agree to seek amicable resolution thereof and only if such a resolution cannot be achieved, the dispute shall be resolved by the court competent for the seat of the Confidential Information Disclosing Party.
- 7.2. Any and all amendments to this Agreement shall be made in writing, otherwise being null and void.
- 7.3. The Agreement has been executed in two identical counterparts, one for each Party.

COMPANY

PARTNER