

Zakroczym, 18.01.2024  
*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 therapy of chronic obstructive pulmonary disease (COPD)”, co-financed by the national budget as part of competitions held by the Medical Research Agency, **we would like to request the value of the planned order described in detail below, under point II, and the information indicated in Annex 1 to this form.**

**Please affix your signature to this Market Discernment Form and send a scan of it (in pdf format) by email to: [zapytaniaofertowe@lekam.pl](mailto:zapytaniaofertowe@lekam.pl) by: 01.02.2024**

**Please include in the subject line of your e-mail: *COPD Raman study-2***

If you require any further information, please contact us by email: [zapytaniaofertowe@lekam.pl](mailto:zapytaniaofertowe@lekam.pl)

### II. Description of the subject of the contract:

1. The planned order relates to *Raman imaging studies to determine the content of the amorphous component of both active substances, i.e. indacaterol maleate and glycopyrronium bromide, in an inhalation medicinal product containing both substances during stability studies.*
2. CPV CODE: **73100000-3 - Research and experimental development services**
3. Deadline for completion of the subject of the contract: **31.12.2024 at the latest.**
4. Detailed description of the subject of the contract:

#### Subject of the contract

The subject of the service will be:

1. Raman imaging study to determine the percentage of the amorphous component of both the active substances indacaterol maleate and glycopyrronium bromide in the Indacaterol/Glycopyrronium combo inhalation medicinal product, 85 µg / 43 µg (powder for inhalation in hard capsules), containing both these active substances and lactose monohydrate.

Number of samples tested: 4 - 8 (each in triplicate), min. 2 samples per order

Tests should be performed in the 3000 x 3000 µm area, with a spectral resolution of approx. 3 cm<sup>-1</sup>.

2. to analyse the Raman spectra of the standard substances: indacaterol maleate (crystalline form) - one sample; indacaterol maleate (amorphous form) - one sample; glycopyrronium bromide (crystalline form) - one sample; glycopyrronium bromide (amorphous form) - one sample; lactose monohydrate - one sample in order to determine the marker bands of the above standard substances.

Analyses are not required if they have been carried out as part of an existing collaboration.



<b>Additional requirements</b>
<p>The process of recording Raman mapping must be carried out on a Raman spectrometer equipped with the detector and software necessary to record and process the data in accordance with the requirements of Ph. Eur. 2.2.48.</p> <p>The research described above in the subject of the contract will produce a research report in English, which must include at least:</p> <ul style="list-style-type: none"> <li>• the conditions of the measurement carried out;</li> <li>• the percentage of amorphous forms of the active substances in the samples;</li> <li>• recorded images (maps) showing the samples under study</li> </ul>
<p>The subcontractor undertakes to sign:</p> <ul style="list-style-type: none"> <li>• Confidentiality Agreement (if not already signed)</li> <li>• A quality agreement defining the scope of activities and responsibilities, which is necessary for the qualification of the subcontractor according to the GMP quality system (if not already signed)</li> <li>• Consent to conduct a qualitative survey (if not previously conducted)</li> </ul>
<p>Materials provided by the principal:</p> <ul style="list-style-type: none"> <li>• Raman spectra of standards: indacaterol maleate (crystalline and amorphous form), glycopyrronium bromide (crystalline and amorphous form), lactose; results of the reference product.</li> </ul>

#### 5. Conditions for participation in the market research

<b>Requirements for the contractor</b>		
<b>Type of requirements</b>	<b>Description of requirements</b>	<b>Method of verification</b>
Technical requirement	<p>The contractor must be able to carry out tests on a Raman mapping spectrometer equipped with:</p> <ul style="list-style-type: none"> <li>• confocal microscope and a fast and sensitive imaging detector;</li> <li>• software for particle distribution and size analysis, particle differentiation and identification</li> </ul>	<p>The conditions will be verified on the basis of the bidder's declaration as per Annex 1 to this form.</p>
Experience requirements	<p>The contractor should have a minimum of 3 years' experience in carrying out studies analogous to the subject of the contract at the closing date for submission of tenders.</p>	<p>The conditions will be verified on the basis of the bidder's declaration as per Annex 1 to this form.</p>
Personnel requirements	<p>The contractor must have a team of persons meeting the following requirements in total:</p> <ul style="list-style-type: none"> <li>• a university degree in chemistry or physics;</li> </ul>	<p>The conditions will be verified on the basis of the bidder's declaration as per Annex 1 to this form.</p>



	<ul style="list-style-type: none"><li>• experience in carrying out studies similar to the subject of this contract;</li><li>• knowledge of the analytical tools necessary for the execution of this contract;</li><li>• knowledge of the Raman spectroscopic method.</li></ul>	
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*Annex 1 to the market inquiry form*

**Information to be completed by the bidder:**

Full name of Contractor: .....

Contractor's address: .....

NIP: .....

Contact person: .....

Date of offer: .....

*Please indicate the currency of the offer!*

Study	Performed during previous cooperation YES/NO	Net price per sample	Gross price per sample	Completion date*
Carrying out Raman imaging studies to determine the percentage of the amorphous component of both active substances indacaterol maleate and glycopyrronium bromide in the Indacaterol/Glycopyrronium combo inhalation medicinal product, 85 µg / 43 µg (powder for inhalation in hard capsules), containing both active substances and lactose monohydrate. Number of samples tested: 4 – 8 (each in triplicate), min. 2 samples per order Tests should be performed in the 3000 x 3000 µm area, with a spectral resolution of approx. 3 cm <sup>-1</sup>	X			
Analysis of Raman spectra of the reference substances indacaterol maleate (crystalline and amorphous form), glycopyrronium bromide (crystalline and amorphous form), lactose, if necessary (e.g. not performed as part of previous cooperation) **. Number of samples and standards tested: 5				

\* *calculated in weeks from the date of conclusion of the contract/order*

\*\* *the price does not need to be stated if carried out in the context of existing cooperation*



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\*\*\* a confidentiality agreement with the Principal prior to the commencement of the assignment.
2. We will sign/have signed\*\*\* the quality agreement necessary to qualify the subcontractor according to the GMP quality system.
3. We will sign/have signed\*\*\* consent to conduct a qualitative survey.
4. We have the opportunity to carry out research on a Raman mapping spectrometer equipped with a confocal microscope and a fast and sensitive imaging detector, as well as software to analyse the distribution and size of particles, their discrimination and identification.
5. As at the closing date for submission of tenders, we have a minimum of 3 years' experience in carrying out studies analogous to the subject of the contract.
6. We have people available who meet the following requirements:
  - a university degree in chemistry or physics;
  - Experience in carrying out studies similar to the subject of this contract;
  - Familiarity with the analytical tools necessary for the execution of this contract;
  - knowledge of the Raman spectroscopic method.

\*\*\* *delete as appropriate*

.....  
*Date and place*

.....  
*Signature*