Zakroczym, 01/03/2024
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 Insight Form and send a scan of it (in pdf format) by email to: zapytaniaofertowe@lekam.pl by: 15/03/2024

Please include in the subject line of your message: *COPD XRPD-3 study*

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 relates to **XRPD testing of model mixtures containing indacaterol maleate (IM), glycopyrronium bromide (GB) and lactose monohydrate (L) in various proportions, followed by confirmation of the stability of the crystalline form of both active substances in the selected mixtures in accelerated ageing tests and validation of the analytical method.**

   A detailed description of the subject matter of the contract can be found in section II.4 of this form.
2. CPV code: **73100000-3 - Research and experimental development services**
3. Deadline for completion of the subject matter of the contract: **31/12/2024 at the latest.**
4. Detailed description of the subject of the contract:

Subject of the contract
The order will consist of the following stages: **Stage I:** conduct a pilot study of model mixtures with the following concentrations: 2% 5% and 10% (w/w) of each active substance in a mixture with lactose and in a mixture with equal proportions of the ingredients (IM:GB:L 1:1:1) in order to select a suitable mixture for accelerated persistence testing. **Stage II:** validation of the method for testing the polymorphism of model mixtures of a medicinal product by the XRPD technique in terms of specificity, detection limit (defined as the limit of the desired crystalline form of each active substance detectable by the technique used) and SST. **Stage III**: testing of IM:GB:L 1:1:1 mixture and one with a lower proportion of API, selected in stage I after 3 and 6 months of storage under accelerated ageing conditions (40°C/75% RH). Each drug product sample to be tested must be compared with the diffractograms of the active substance standards and lactose monohydrate. The analysis of the standards needs to be performed only once. Number of trials tested: stage I – 2-4 samples; stage III – 2 samples after 3 months + 2 samples after 6 months

Additional requirements
The process of recording the diffractograms must be carried out on X-ray diffractometer equipped with the detector and software necessary for recording and processing the data in accordance with Ph. Eur. 2.9.33. At each stage of the research reports in English will be prepared, including at least: ➢ After completion of stage I: • test conditions of measured model mixtures; • the diffractograms recorded, together with the numerical values of the 2Θ angles of the samples examined; • comparison with active substances and lactose standards and confirmation of the identity of the polymorphic form of each active substance; • conclusions regarding the choice of the mixture for stability studies. ➢ After stage II – analytical method validation report according to ICH Q2 guidelines. ➢ At stage III – separate reports for the mixtures after 3 and 6 months: • conditions of the measured model mixtures; • the diffractograms recorded, together with the numerical values of the 2Θ angles of the samples examined; • comparison with active substances and lactose standards and confirmation of the identity of the polymorphic form of each active substance; • conclusions on the observed changes in the diffractograms compared to studies at previous time points. The subcontractor undertakes to sign: • Confidentiality Agreement (if not previously signed); • Consent to conduct Quality survey (if not previously conducted).
Materials provided by the principal: • Diffractograms of the reference substances indacaterol maleate and glycopyrronium bromide; • Reference standards necessary for analyses; • Model mixtures of the indicated concentrations for the tests in stages I and III and mixtures necessary for the validation of the analytical method (stage II).

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 polymorphism using XRPD technique (X-ray diffractometer) under GMP conditions and validate the method according to ICH Q2 guidelines.	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: • a university degree in chemistry or physics; • experience in carrying out studies similar to the subject of this contract; • knowledge of the analytical tools necessary for the execution of this contract;	The conditions will be verified on the basis of the bidder's declaration as per Annex 1 to this form.

Annex 1 to the market insight form

Information to be completed by the bidder:

Full name of Contractor: .....

Contractor's address: .....

Contact person: .....

Date of offer: .....

Note: Please indicate the currency of the offer!

Study	Net price per sample	Gross price per sample	Completion date (in weeks)
Conduct a pilot study of model mixtures with the following concentrations: 2% 5% and 10% (w/w) of each active ingredient in a mixture with lactose monohydrate and in a mixture with equal proportions of the ingredients (IM:GB:L 1:1:1) Total number of samples: 2-4			
Testing of IM:GB:L 1:1:1 mixture and one mixture selected in stage I after 3 and 6 months of storage under accelerated ageing conditions. Total number of samples: 4			
Analysis of active substances reference standards (indacaterol maleate or glycopyrronium bromide)			
Placebo (lactose monohydrate) analysis			
	Net price per service	**Gross price per service**	**Completion date (in weeks)**
Validation of XRPD polymorphism test method for a medicinal product			

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/have signed* a confidentiality agreement with the Principal prior to the commencement of the assignment.
2. We will sign/have signed* consent to conduct Quality survey.
3. We have the possibility to perform tests on a GMP-standard XRPD (X-ray diffractometer) polymorphism analysis device.

   *YES/NO**
4. We have the opportunity to carry out validation of the XRPD polymorphism test method.

   *YES/NO**
5. 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.

   *YES/NO**
6. We have at our disposal a team of people meeting the following requirements in total:
   - 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.

   *YES/NO**

* *delete as appropriate*

.....	.....
Date and place	*Signature*