Zakroczym, on 13 November 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.**

Please sign this Market Insight Form and send a scan (in the pdf format) by e-mail to: zapytaniaofertowe@lekam.pl by: 21 november 2023.

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

II. **Order specification:**

1. The planned order concerns *the delivery of the micronized active substance: glycopyrronium bromide, as described in the detailed order specification.*
2. CPV CODE: 24000000-4 Chemical products
3. Deadline for completion of the order: **The subject of the order is planned to be delivered in full within a maximum of 2 months from the completion of the next campaign implementation.**
4. Place of completion of the order: Przedsiebiorstwo Farmaceutyczne LEK-AM sp. z o.o., Zakroczym
5. Detailed order specification:

Requirements
Specification
Raw material name: glycopyrronium bromide Quantity: 0.34 kg Raw material characteristics: • Micronized substance • Substance in crystalline form A • Particle size: ▶ 0(10) NMT 1 µm ▶ 0(50) NMT 2.0 µm ▶ 0(90) NMT 4.5 um
Documentation
I. The following documents concerning the subject of the order should be delivered to the Ordering Party along with the raw material delivery:

- Certificate of analysis meeting the requirements of a specification compliant with the ICH Q6A requirements and the current Ph. Eur. monograph No. 1783, containing the PSD results and microbiological testing data which confirm the microbiological quality for non-sterile substances for pharmaceutical purposes in accordance with the following requirements:
  - TAMC NMT 10^3 CFU/g or CFU/mL
  - TYMC NMT 10^2 CFU/g or CFU/mL
- PSD histogram and MSDS
- Declaration on the size of the manufactured batch
- Declaration stating that the tests presented in the CoA were conducted using validated methods or in accordance with the Ph. Eur. monograph.

Additional requirements

I. Retest period:
   - Retest period for the micronized active substance of at least 3 years, supported by stability testing results for the micronized substance, including particle size distribution results

2. Transport conditions
   - in accordance with ASMF requirements

6. In order for the bid to be considered, the Bidder is obliged to submit the following documents along with the bid created according to the Information Template specified under item III or to state in this form that the relevant documents have been submitted to LEK-AM during previous cooperation:

- EU ASMF documentation (open part) for the micronized substance with quality compliant with the requirements of EMA and ICH guidelines, available upon request, or (preferred option) current CEP certificate for the micronized substance
- Confirmation of meeting the GMP requirements for its manufacturing in the form of a GMP certificate for both the micronized active substance and the manufacturing of its intermediates (preferred confirmation by the European agency)
- Written confirmation of compliance with GMP (WC) in accordance with the Directive 2011/62/EU, if manufactured outside of Europe
- Nitrosamine risk analysis report compliant with ICH and EMA requirements
- Elemental impurity residue risk analysis report compliant with the ICHQ3D and EMA requirements
- Stability testing results confirming the retest period specified under item II for the micronized active substance batch. The provided results should include the particle size distribution **(PSD)** parameter.

7. Assessment

The Contractor will be selected based on the price criterion and quality criterion, according to the following formula:

Rating = score received for the price criterion + score received for the quality criterion

The bidder with the highest score will be selected.

a) The "Price" criterion will be calculated according to the following formula:

$$Pc = \frac{C_N}{C_a} * 70 \text{ pts.}$$

where:

PC - score for the "Price" criterion

CN-	the lowest total net bid price among the bids that have not been rejected
CB	total net price of the analyzed bid

b) The quality criterion will be rated as follows:
- Contractor holding a CEP certificate for the micronized substance - 30 pts
- no CEP certificate for the micronized substance - 0 pts

III. **Information template to be completed by the bidder:**

Value of the order concerning the *delivery of the active substance* described in detail under item II.

Contractor's full name:……..

Contractor's address: …….

NIP (Numer Identyfikacji Podatkowej [Tax ID Number]): ……..

Contact person:……..

Bid drafting date: ……

Next campaign date: ……

Net cost of one gram of the substance: ……

Total net cost of order completion: …….

Total gross cost of order completion: ……

Payment terms: ……

The Contractor holds a CEP certificate for the micronized substances YES / NO

I hereby declare that the documents specified under item II.6 have been submitted by the Contractor to Przedsiebiorstwo Farmaceutyczne LEK-AM sp. z o.o. during previous cooperation. YES/ NO*

**If NO is selected, please attach a complete document package to your bid.*

…… ……
Date and place *Signature*