Zakroczym, 10 June 2025 r.

**MARKET INSIGHT FORM**

**Purpose of the form:**

In connection with the implementation of the project titled ***"Development of a new combination medicinal product for the treatment of type 2 diabetes,"*** co-financed from the state budget under competitions organized by the Medical Research Agency, **we kindly request that you provide the estimated value of the planned procurement described in detail below under item II, as well as the information specified in Appendix no 1 to this market research form.**

**Please sign this Market Insight Form and send a scan (in the pdf format) by e-mail to: zapytaniaofertowe@lekam.pl by: 18 June 2025.**

If you need additional information, please contact us by e-mail: [zapytaniaofertowe@lekam.pl](mailto:zapytaniaofertowe@lekam.pl)

1. **Order specification:**
2. The planned order concerns the delivery *of* ***10 kg of the active substance Linagliptin****, as described in detail in the specification in Section II.7 of this market research form*.
3. The ordering party reserves that the indicated quantity is estimated as necessary to carry out the research and does not anticipate partial orders or deliveries.
4. CPV CODE: 24000000-4 Chemical products
5. Delivery deadline: up to **3 months from the date of placing the order.**
6. Offer validity period: 60 days.
7. Place of completion of the order:

Przedsiębiorstwo Farmaceutyczne LEK-AM sp. z o.o., Zakroczym

1. Detailed order specification:

|  |  |  |
| --- | --- | --- |
| **Lp.** | **Requirements** | |
| **1.** | **Specification** | |
| **1.1** | **Raw material name: Linagliptin**   1. Planned quantity to be purchased: 10 kg. Weight deviations are acceptable depending on the packaging used by the supplier. 2. Pharmaceutical-grade substance, compliant with the requirements for raw materials used in solid oral dosage forms. 3. Particle size distribution conforming requirements: D(0.9) not more than 25 µm 4. Polymorphic form: Form A+B 5. Retest period for micronized active substance: minimum 3 years, supported by stability test results for micronized form. | |
| **2.** | **Documentation** | |
| **2.1** | | Before delivery, the Contractor is obliged to provide the Ordering Party with the following documents for approval:  1. Certificate of analysis compliant with ICH Q6A specification requirements and current EU ASMF, including PSD results  2. PSD histogram  3. Confirmation of polymorphic form identity as a mix A+B form (if not included in CoA)  4. MSDS; 5. Declaration of batch size according to current EU ASMF  6. Declaration that tests listed in the CoA were performed using validated methods and in accordance with Ph. Eur. (for general requirements) and with the specification outlined in the current EU ASMF version  7. Declaration that the offered batch of active substance was produced and micronized using a validated process under GMP conditions |
| **3.** | **Additional requirements** | |
| **3.1** | Transport conditions: • in accordance with ASMF requirements, shipment under controlled conditions | |
| **3.2** | In order for the offer to be considered, the Bidder must have deliver together with the offer, created in accordance with the Information Template constituting by appendix No. 1 to the Market Research Form following documents or declare in this form that the documents were transferred  to LEK-AM as part of previous cooperation:   1. Complete EU ASMF documentation (open part) for the micronized substance, compliant with EMA and ICH guidelines 2. Nitrosamine risk assessment report in accordance with ICH and EMA guidelines (if not included in the EU ASMF) 3. Elemental impurity risk assessment report compliant with ICH Q3D and EMA requirements (if not included in the EU ASMF); 4. Stability studies for micronized batches (if not presented in the EU ASMF) 5. GMP compliance confirmation in the form of a GMP certificate for both the micronized active substance and its intermediates 6. Written confirmation of GMP compliance (WC) according to Directive 2011/62/EC if manufactured outside Europe | |

1. Assessment

The Contractor selection will be based on the offered price only.

*Appendix no. 1 to the Market Insight Form*

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

**Estimated value of the order regarding the items described in detail in point II.**

Full name of the Contractor: ………………………

Contractor’s address: ………………………

Tax Identification Number [Numer Identyfikacji Podatkowej, NIP]: ………..…………………

Contact person: ………………………

Offer drafting date: ………………………

|  |  |  |  |
| --- | --- | --- | --- |
| *Offered quantity (in kg)* | *Unit net cost (price per 1 kg)* | Order execution time from placement (no longer than 3 months) | Payment terms |
|  |  |  |  |

We declare that the quality of the offered subject of the order complies with the European Pharmacopoeia (Ph. Eur.), *Metformin Hydrochloride* monograph, and meets the requirements specified in point II.7 of the market research form.

I declare that the documents indicated in point 3.2 (detailed description of the subject of the order: additional requirements) have been delivered by the Contractor to Przedsiębiorstwo Farmaceutyczne LEK-AM sp. z o.o. as part of earlier cooperation YES/NO\*\*

\*\* If NO is selected, the complete documentation must be attached to the offer.

…………………………………… ..…….………………………………………

*Date and place Signature*