Zakroczym, 06th May 2025
place and date

MARKET INSIGHT FORM

I. Purpose of the form:

In relation to the execution of the project entitled "***Development of a novel combination medicinal product for use in the treatment of type 2 diabetes mellitus",*** 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 indicate the value of the planned order described in detail under item II below and to provide information listed in Appendix no. 1 to this Market Insight Form.**

Please sign this Market Insight Form and send a scan (in the pdf format) by e-mail to: zapytaniaofertowe@lekam.pl by: 14th May 2025

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 39 kg of an active substance: empagliflozin, as described in the detailed order specification under item II.7 of this Market Insight Form.*
2. The ordering party reserves does not allow partial bids. **(Bid validity one year from the date of issue)**.
3. The ordering party reserves that the indicated quantity of the substance is estimated as necessary to carry out research. Ultimately, the required quantity of the substance may differ from the indicated one – the minimum quantity of the substance to be ordered as part of this procedure equals 11 kg.
4. CPV CODE: 24000000-4 Chemical products
5. **The ordering party is planning procurement according to the following schedule:**
    - **May 2025 => order of 28 kg**
    - **September 2025 => order of 11 kg**
6. Place of completion of the order:
   Przedsiębiorstwo Farmaceutyczne LEK-AM sp. z o.o., Zakroczym
7. Detailed order specification:

No.	Requirements
1.	**Specification**
1.1	**Substance name: Empagliflozin** Planned quantity to be purchased: 39 kg. The quantity of the substance within each order will be determined at the stage of placing the given order. Deviations regarding the weight of the substance are allowed for each order due to the size of the packaging that the supplier will have. The permissible deviation is +/- 0.5 kg for each order. 1. Substance of a pharmaceutical quality meeting the requirements for starting materials for use in solid oral medication; 2. Micronized material 3. Particle size distribution conforming requirements: D(0.9) not more than 25 µm. 3.1 Potential subsequent deliveries of a batch of material with a given particle size distribution, i.e. a requirement included in the specifications or a bidder's consent for including the requirement into the specification. 4. Polymorphic form: anhydrous crystalline form (in accordance with the patent EP1888552B1). 5. Retest period for the micronized active substance of at least 3 years, supported by stability testing results for the micronized substance.
2.	**Documentation**
2.1	Prior to the delivery, the Contractor is obliged to provide the Ordering Party with the documents for approval concerning the order: 1. Certificate of analysis meeting the requirements of a specification compliant with the ICH Q6A requirements, 2. PSD histogram, 3. Confirmation of the identification of the polymorphic form, 4. MSDS, 5. Declaration on the size of the manufactured batch, 6. Declaration stating that the tests presented in the CoA were conducted using validated methods and in accordance with Ph. Eur. (for general requirements) according to the specification presented in a recent version of EU AMSF, 7. Declaration stating that the offered batch of the active substance was produced and micronized using validated methods according to GMP.
3.	**Additional requirements**
3.1	Transport conditions: • controlled condition, temperature below T=25°C
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 with quality compliant with the requirements of EMA and ICH guidelines 2. 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; 3. Written confirmation of compliance with GMP (WC) in accordance with the Directive 2011/62/EU, if manufactured outside of Europe; 4. Nitrosamine risk analysis report compliant with ICH and EMA requirements; 5. Elemental impurity residue risk analysis report compliant with the ICHQ3D and EMA requirements; 6. Stability testing results for the micronized active substance batch (if not included in ASMF).

8. Assessment

The Contractor will be selected on the basis of the price offered (the lowest net price per kg of substance).

Appendix no. 1 to the Market Insight Form

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

Contractor's full name: ……

Contractor's address: ……

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

Contact person: ……

Offer drafting date: ……

VALUATION OF THE SUBJECT OF THE ORDER – Empagliflozin				
Offered quantity (in kg) with indication of the size of a single package	Net unit cost (Price per 1 kg)	Net cost of the entire order	Period of the order execution from the date of its placing (no longer than 3 months)	Payment terms:

Specification	**Specification requirements YES/ NO***
1. Substance of a pharmaceutical quality meeting the requirements for starting materials for use in solid oral medication;	
2. Micronized material	
3. Particle size distribution conforming requirements: D(0.9) not more than 25 µm. Potential subsequent deliveries of a batch of material with a given particle size distribution, i.e. a requirement included in the specifications or a bidder's consent for including the requirement into the specification.	
4. Polymorphic form: anhydrous crystalline form (in accordance with the patent EP1888552B1).	
5. Retest period for the micronized active substance of at least 3 years, supported by stability testing results for the micronized substance.	

* Please enter YES or NO for each specification item.

I declare that the documents indicated in point II.7 - Detailed description of the subject of the contract (in the section: "additional requirements" point 3.2) were delivered by the Contractor to Przedsiębiorstwo Farmaceutyczne LEK-AM sp. z o.o. as part of previous cooperation YES/NO**

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

…… ……

Date and place *Signature*