Zakroczym, on 13 July 2023
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: 20 July 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 55 kg of an active substance: empagliflozin, as described in the detailed order specification under item II.5 of this Market Insight Form.*
2. The ordering party reserves that the order shall be carried out in tranches – each time the required quantity of the substance will be indicated in a written order.
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 1.3 kg (for the purpose of carrying out the first part of the research).
4. CPV CODE: 24000000-4 Chemical products
5. Deadline for completion of the order: Each tranche of the ordered substance shall be delivered within **3 months from the order submission/contract conclusion.**
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	Raw material name: Empagliflozin Quantity planned for purchase: 55 kg. Quantity of the substance per each order will be determined at the stage of placing an order. Deviations from the weight of the substance due to the differences in package size at the provider's disposal shall be allowed. Allowed deviation per each order is +/- 0.5 kg.

	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: • in accordance with ASMF requirements
3.2	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: 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).

Appendix no. 1 to the Market Insight Form

Information template to be completed by the bidder:

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: ……

ORDER VALUATION			
Offered quantity (in kg)	*Net unit cost (Price per 1 kg) for R&D orders(up to 2 kgs)*	Period of the order execution from the date of its placing (no longer than 3 months)	Payment terms:

I hereby declare that the documents specified under item 3.2 have been submitted by the Contractor to Przedsiębiorstwo 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*