Zakroczym, on 27 June 2025
*place and date*

**MARKET INSIGHT FORM**

1. 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 provide the value of the planned order described in detail under item II below and to provide information listed in Appendix no. 1 to this Form and the price.**

**Please sign this Market Insight Form and send a scan (in the pdf format) by e-mail to:** **zapytaniaofertowe@lekam.pl** **by: 11 July 2025.**

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

1. **Order specification:**
2. The planned order concerns *the delivery of the non-pharmacopoeial standards, as described in the specification.*
3. The Ordering Party allows the submission of partial offers for individual items specified in the detailed description of the subject of the order.
4. CPV CODE: 33696300-8 - Chemical reagents
5. Deadline for completion of the order: **all indicated in point II. 6 should be delivered to the ordering party within a maximum of 6 weeks from the date of concluding the contract / placing the order.**
6. Place of completion of the order: Przedsiębiorstwo Farmaceutyczne LEK-AM sp. z o.o., Zakroczym
7. Detailed order specification:

|  |
| --- |
| **Requirements** |
| **Part of the order** | **Specification** |
| **Part 1** | **name:** Empagliflozin impurity standard **chemical name:** (3S)-3-[4-(2-chlorobenzyl)phenoxy]tetrahydrofuran**quantity:** 30 mg **quality requirements:*** solid state of standard
* standard potency ≥ 85% or purity by HPLC ≥ 90%
* identity confirmation of the standard at least one method, confirming the structure of the compound (e.g. IR, MS, NMR), data confirming the identity in the certificate or attached to the certificate
* expiration/re-test date - preferred min. 12 months (in the case of a re-test, information about the possibility of re-testing the standard yes/no)
 |
| **Part 2** | **name:** Empagliflozin impurity standard **chemical name:** :1-Chloro-4-(1-hydroxy-D-glucopyranos-1-yl)-2-(4-(S)-tetrahydrofuran-3-yloxy-benzyl)-benzene **quantity:** 30 mg **quality requirements:*** solid state of standard
* standard potency ≥ 85% or purity by HPLC ≥ 90%
* identity confirmation of the standard at least one method, confirming the structure of the compound (e.g. IR, MS, NMR), data confirming the identity in the certificate or attached to the certificate
* expiration/re-test date - preferred min. 12 months (in the case of a re-test, information about the possibility of re-testing the standard yes/no)
 |
| **Part 3**  | **name:** Empagliflozin impurity standard **chemical name:** 1-Chloro-4-(1-methoxy-D-glucopyranos-1-yl)-2-(4-(S)-tetrahydrofuran-3yloxy-benzyl)-benzene**quantity:** 30 mg **quality requirements:*** solid state of standard
* standard potency ≥ 85% or purity by HPLC ≥ 90%
* identity confirmation of the standard at least one method, confirming the structure of the compound (e.g. IR, MS, NMR), data confirming the identity in the certificate or attached to the certificate
* expiration/re-test date - preferred min. 12 months (in the case of a re-test, information about the possibility of re-testing the standard yes/no)
 |
| **Part 4** | **name:** Empagliflozin impurity standard **chemical name:** : 1-Chloro-4-(α-D-glucopyranos-1-yl)-2-[4-((S)-tetrahydrofuran-3-yloxy)benzyl]-benzene**quantity:** 30 mg * solid state of standard
* standard potency ≥ 85% or purity by HPLC ≥ 90%
* identity confirmation of the standard at least one method, confirming the structure of the compound (e.g. IR, MS, NMR), data confirming the identity in the certificate or attached to the certificate
* expiration/re-test date - preferred min. 12 months (in the case of a re-test, information about the possibility of re-testing the standard yes/no)
 |
| **Part 5**  | **name** Empagliflozin impurity standard **chemical name:** (3R,4R,5R)-2-(4-chloro-3-(4-(((S)-tetrahydrofuran-3-yl)oxy)benzyl)phenyl)5-((R)-1,2-dihydroxyethyl)tetrahydrofuran-3,4-diol**quantity:** 30 mg * solid state of standard
* standard potency ≥ 85% or purity by HPLC ≥ 90%
* identity confirmation of the standard at least one method, confirming the structure of the compound (e.g. IR, MS, NMR), data confirming the identity in the certificate or attached to the certificate
* expiration/re-test date - preferred min. 12 months (in the case of a re-test, information about the possibility of re-testing the standard yes/no)
 |
| **Part 6** | **name**: Empagliflozin standard R isomer **chemical name:** 1-chloro-4-(β-D-glucopyranos-1-yl)-2-[4-((R-tetrahydrofuran-3-yloxy)-benzyl]-benzene **quantity:** 20 mg **quality requirements:*** CAS number 864070-43-9
* standard potency ≥ 85%
* identity confirmation of the standard at least one method, confirming the structure of the compound (e.g. IR, MS, NMR), data confirming the identity in the certificate or attached to the certificate
* expiration/re-test date - preferred min. 12 months (in the case of a re-test, information about the possibility of re-testing the standard yes/no)
 |
| **Documentation** |
| **For parts** **1-6** | For each of the deliveries, the contractor must provide a quality certificate confirming the fulfillment of the quality requirements set out in the description of the subject of the contract for the ordered standards (in accordance with point II.6 of this form). The certificate should be delivered in paper form with the delivery. |

1. Evaluation

The selection of the Contractor will be made from among the Offers meeting the quality requirements indicated in point II.6 of this form. The offered price will be assessed.

*Appendix no. 1 to the MARKET INSIGHT FORM*

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

|  |  |
| --- | --- |
| Contractor’s full name: ………………………Contractor’s address: ………………………NIP (Numer Identyfikacji Podatkowej [Tax ID Number]): ………..…………………Contact person: ……………………… | Contact details: ………………………...Payment terms: ………………………Date of the offer: …………………………… |

|  |  |  |
| --- | --- | --- |
| Quotation | Specification | Meeting the requirements of the specification YES/NO2) |
| Part no.  | Name of the subject of the order | The size of the offered package [mg] | Total net price for the whole (for each part) | Total gross price for the whole (for each part) | Delivery costs | Other costs1)  |
| 1.
 | **name:** Empagliflozin impurity standard **chemical name:** (3S)-3-[4-(2-chlorobenzyl)phenoxy]tetrahydrofuran**quantity:** 30 mg  |  |  |  |  |  | solid state of standard |  |
| standard potency ≥ 85% or purity by HPLC ≥ 90% |  |
| identity confirmation of the standard at least one method, confirming the structure of the compound (e.g. IR, MS, NMR), data confirming the identity in the certificate or attached to the certificate |  |
| expiration/re-test date - preferred min. 12 months (in the case of a re-test, information about the possibility of re-testing the standard yes/no) |  |
|  | **name:** Empagliflozin impurity standard **chemical name:** :1-Chloro-4-(1-hydroxy-D-glucopyranos-1-yl)-2-(4-(S)-tetrahydrofuran-3-yloxy-benzyl)-benzene **quantity:** 30 mg  |  |  |  |  |  | solid state of standard |  |
| standard potency ≥ 85% or purity by HPLC ≥ 90% |  |
| identity confirmation of the standard at least one method, confirming the structure of the compound (e.g. IR, MS, NMR), data confirming the identity in the certificate or attached to the certificate |  |
| expiration/re-test date - preferred min. 12 months (in the case of a re-test, information about the possibility of re-testing the standard yes/no) |  |
|  | **name:** Empagliflozin impurity standard **chemical name:** 1-Chloro-4-(1-methoxy-D-glucopyranos-1-yl)-2-(4-(S)-tetrahydrofuran-3yloxy-benzyl)-benzene**quantity:** 30 mg  |  |  |  |  |  | solid state of standard |  |
| standard potency ≥ 85% or purity by HPLC ≥ 90% |  |
| identity confirmation of the standard at least one method, confirming the structure of the compound (e.g. IR, MS, NMR), data confirming the identity in the certificate or attached to the certificate |  |
| expiration/re-test date - preferred min. 12 months (in the case of a re-test, information about the possibility of re-testing the standard yes/no) |  |
|  | **name:** Empagliflozin impurity standard **chemical name:** : 1-Chloro-4-(α-D-glucopyranos-1-yl)-2-[4-((S)-tetrahydrofuran-3-yloxy)benzyl]-benzene**quantity:** 30 mg  |  |  |  |  |  | solid state of standard |  |
| standard potency ≥ 85% or purity by HPLC ≥ 90% |  |
| identity confirmation of the standard at least one method, confirming the structure of the compound (e.g. IR, MS, NMR), data confirming the identity in the certificate or attached to the certificate |  |
| expiration/re-test date - preferred min. 12 months (in the case of a re-test, information about the possibility of re-testing the standard yes/no) |  |
|  | **name** Empagliflozin impurity standard **chemical name:** (3R,4R,5R)-2-(4-chloro-3-(4-(((S)-tetrahydrofuran-3-yl)oxy)benzyl)phenyl)5-((R)-1,2-dihydroxyethyl)tetrahydrofuran-3,4-diol**quantity:** 30 mg  |  |  |  |  |  | solid state of standard |  |
| standard potency ≥ 85% or purity by HPLC ≥ 90% |  |
| identity confirmation of the standard at least one method, confirming the structure of the compound (e.g. IR, MS, NMR), data confirming the identity in the certificate or attached to the certificate |  |
| expiration/re-test date - preferred min. 12 months (in the case of a re-test, information about the possibility of re-testing the standard yes/no) |  |
|  | **name**: Empagliflozin standard R isomer **chemical name:** 1-chloro-4-(β-D-glucopyranos-1-yl)-2-[4-((R-tetrahydrofuran-3-yloxy)-benzyl]-benzene **quantity:** 20 mg  |  |  |  |  |  | CAS number 864070-43-9 |  |
| standard potency ≥ 85%  |  |
| identity confirmation of the standard at least one method, confirming the structure of the compound (e.g. IR, MS, NMR), data confirming the identity in the certificate or attached to the certificate |  |
| expiration/re-test date - preferred min. 12 months (in the case of a re-test, information about the possibility of re-testing the standard yes/no) |  |

1) specify the type of cost and price

2) please enter YES or NO for each item of the specification.

…………………………………… ..…….………………………………………

*Date and place Signature*