Zakroczym, on 06 March 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 in point 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: 14 March 2023.

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

II. Order specification:

1. The planned partial order concerns *the non-pharmacopoeial standards described in detail below in point II.5.*
2. The Ordering Party allows for the placement of partial offers for the individual items defined in the Detailed Order Specification.
3. CPV CODE: 33696300-8 - Chemical reagents
4. Deadline for completion of the order: **all items listed in point II. 5 are planned to be ordered by 31 December 2023 and should be delivered to the Ordering Party within a maximum of 8 weeks from the date of concluding the contract / placing the order. The Ordering Party reserves the right to place partial orders until 31 December 2023.**
5. Detailed order specification:

Requirements	
Part of the order	**Specification**
Part 1	**name:** Indacaterol maleate reference standard spiked with impurities* (mixture) **quantity:** 40 mg (preferred 2 x 20 mg) **quality requirements:** • appearance: white or almost white powder • chemical impurities (by HPLC) as required: - known impurity (each) min. 0.08% relative to the main peak of the active substance - maximum other impurity ≤ 0.10% - total impurities < 1.0% • identification (using at least 2 methods) confirming the structure of the compound (e.g. NMR, MS, IR), data confirming the identity in the certificate or attached to the certificate • potency of standard ≥ 90% • 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:** Indacaterol maleate racemate (R isomer + S isomer 50% + 50%) reference standard** **quantity:** 50 mg (preferred 2 x 25 mg) **quality requirements:** • appearance: white or almost white powder • enantiomeric ratio 0.95–1.05 • identification of the standard components (using at least 2 methods) confirming the structure of the compounds (e.g. NMR, MS, IR), data confirming the identity in the certificate or attached to the certificate • purity (by HPLC) ≥ 90.0% • 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 and 2	For each of the deliveries, the Contractor must provide a quality certificate confirming the fulfillment of the quality requirements set out in the order specification for the ordered standards (in accordance with point II.5 of this form). The certificate should be delivered in paper form with the delivery.

**standard must contain Indacaterol maleate, i.e. (R)-5-(2-((5,6-diethyl-2,3-dihydro-1H-inden-2-yl)amino)-1-hydroxyethyl)-8-hydroxyquinolin-2(1H)-one maleate and the three impurities listed below:*

1 (IND 05)	*(R)-5-(2-((5,6-diethyl-2,3-dihydro-1H-inden-2-yl)amino)-1-ethoxyethyl)-8-hydroxyquinolin-2(1H)-one*
2 (IND 07)	*(R)-8-(benzyloxy)-5-(2-((5,6-diethyl-2,3-dihydro-1H-inden-2-yl)amino)-1-hydroxyethyl)quinolin-2(1H)-one*
3 (IND 08)	*(R)-5-(2-((5,6-diethyl-2,3-dihydro-1H-inden-2-yl)amino)-1-hydroxyethyl)-8-hydroxy-3,4-dihydroquinolin-2(1H)-one*

***standard must contain Indacaterol maleate as a mixture of:*
(R)-5-(2-((5,6-diethyl-2,3-dihydro-1H-inden-2-yl)amino)-1-hydroxyethyl)-8-hydroxyquinolin-2(1H)-one
and
(S)-5-(2-((5,6-diethyl-2,3-dihydro-1H-inden-2-yl)amino)-1-hydroxyethyl)-8-hydroxyquinolin-2(1H)-one

6. Assessment

The selection of the Contractor will be made from among the Offers meeting the quality requirements indicated in point II.5 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: ……

Contact person: ……

Contractor's address: ……

Contact details: ……..

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

Offer drafting date: ……

Quotation							Specification	Meeting the requirements of the specification YES/NO,[2)]
Part no.	Name of the subject of the order	Offered package size [mg]	Total net price for the whole (for each part)	Total gross price for the whole (for each part)	Delivery costs	Other costs[1)]		
1.	Indacaterol maleate reference standard spiked with impurities* (mixture) 40 mg (preferred 2 x 20 mg)						appearance: white or almost white powder	
							chemical impurities (by HPLC) as required: - known impurity (each) min. 0.08% relative to the main peak of the active substance - maximum other impurity ≤ 0.10% - total impurities < 1.0%	
							identification (using at least 2 methods) confirming the structure of the compound (e.g. NMR, MS, IR), data confirming the identity in the certificate or attached to the certificate	
							potency of standard ≥ 90%	

							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)	
2.	Indacaterol maleate racemate (R isomer + S isomer 50% + 50%) reference standard** 50 mg (preferred 2 x 25 mg)						appearance: white or almost white powder	
							enantiomeric ratio 0.95–1.05	
							identification of the standard components (using at least 2 methods) confirming the structure of the compounds (e.g. NMR, MS, IR), data confirming the identity in the certificate or attached to the certificate	
							purity (by HPLC) ≥ 90.0%	
							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)	
							appearance: white or almost white powder	

[1)] specify the type of cost and price

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

…… ……

Date and place *Signature*