

Warsaw, 22 April 2022

**PRICE INQUIRY No. 1**  
**being conducted as a market assessment study –**  
**extension of the deadline for submitting quotations**

In connection with the project titled: “Development of a universal fast-response platform, based on RNA technology, ensuring the national drug and epidemiological safety”, funded from the state budget by the Medical Research Agency, WZF Polfa S.A. kindly request to submit a quotation for services involving the development and manufacture of an active substance in the form of a modified oligonucleotide – an 18-mer RNA

### **I. NAME AND ADDRESS OF THE CONTRACTING PARTY**

Warszawskie Zakłady Farmaceutyczne Polfa S.A.  
ul. Karolkowa 22/24  
01-207 Warszawa

### **II. CONTRACT AWARD PROCEDURE**

1. This contract is not subject to the provisions of the Public Procurement Law of 11 September 2019 (consolidated text: Journal of Laws of 2019, item 2019).
2. The procedure is being conducted as an intentional and cost-efficient market assessment study while respecting the following rules:
  - 1) achieving the best possible outcomes using the available measures;
  - 2) choosing the best possible means and methods to meet the pre-defined objectives;
  - 3) ensuring transparency, fair competition and equal treatment of contractors.

### **III. DESCRIPTION OF THE CONTRACT**

**III.1.** This price inquiry relates to *the provision of services involving:*

*Development, manufacture and delivery of an active substance in the form of a modified oligonucleotide – an 18-mer RNA (nusinersen).*

**III.2.** Scope of the Price Inquiry

The request for quotation covers separately the price:

- A. Calculated per gram of active substance under non-GMP conditions, taking into account:
  - (1) development of the method for oligonucleotide synthesis and purification
  - (2) development of analytical methods
  - (3) transfer of analytical methods and
  - (4) manufacture of 8.5 g of the compound under non-GMP conditions
- B. Calculated per gram of active substance under GMP conditions, including the manufacture of 12 g of the substance.

**III.3.** Additionally, the contract will include as follows:

- *Development of specifications for the active substance as per ICH Q6 guidelines*
- *Development and transfer of analytical methods*

- *Manufacture of the material under non-GMP and GMP conditions in quantities specified in Section III.2*
- *Preparation of registration dossier for the active substance*
- *Supply of about 0.5 g of the compound by the end of 2022, about 8 g in 2023 (under non-GMP conditions) and about 12 g in 2024-2025 (material manufactured under GMP conditions).*

**III.4.** No partial or variant proposals will be accepted. The Contracting Party reserves the right to change the quantity of substances to be manufactured and delivered.

#### **IV. CONTRACT DELIVERY SITE AND DATE**

**IV.1.** The contract delivery period will be up to 90 days from the date when a partial production order is submitted. The contract delivery period will not include the time required for the supply of raw materials and other supplies to the Bidder's site as necessary to meet the request.

#### **V. REQUIREMENTS FROM CONTRACTORS**

- V.1.** The procedure is open to any Contractors who meet the following conditions:
- *have infrastructure that enables the manufacture of active substances under a quality system conditions*
  - *have/intend to acquire facilities for the synthesis, purification and freeze-drying of oligonucleotides*
  - *have access to analytical equipment that enables the determination of the quality of the active substance to be manufactured*
  - *have experience in preparing registration dossier for active substances*
  - *have staff with experience in the synthesis of active substances and, in particular, in the synthesis of oligonucleotides*

*Assessment procedure*

*The Contracting Party will consider Contractor as meeting this condition if Contractor submits a declaration of compliance with the conditions for participation in the procedure (Appendix 2 to the Request for Quotation).*

*The Contracting Party reserves the right to verify the fulfilment of the conditions at the Bidder's site.*

**V.2.** Quotations submitted by Contractors who demonstrate that they meet the specified conditions will be taken forward to the quotation evaluation stage. The compliance with the above conditions will be assessed based on a 'meet – does not meet' basis. Quotations submitted by Contractors who fail to meet any of the above conditions will be rejected.

#### **VI. CONTRACT AWARD CRITERIA**

- VI.1.** The quotations will be evaluated based on the following criteria:
- net price per gram of substance – 50%
  - date of completion of the contract – 25%
  - quality system conforming to GMP requirements – 25%.

**VI.2.** The quotation score will be calculated according to the following formula:

$$O_P = P_C + P_T + P_G$$

where:

- $O_P$  the quotation score
- $P_C$  score for the “net price per gram of substance”
- $P_T$  score for the “date of completion of the contract”
- $P_G$  score for “a quality system conforming to GMP requirements”

**VI.3.** The score ( $P_C$ ) for “Total Net Price” will be calculated according to the following formula:

$$P_C = \frac{C_{NnonGMP} + C_{NGMP}}{C_{BnonGMP} + C_{BGMP}} * 50 \text{ points}$$

where:

- $P_C$  - score for the “net price”
- $C_{NnonGMP}$  - among non-rejected quotations, the lowest net price quotation for non-GMP and GMP standard respectively
- $C_{NGMP}$  - net price of the quotation for non-GMP and GMP standard respectively
- $C_{BnonGMP}$  ,  $C_{BGMP}$

Quotation offering prices in currencies other than PLN will be converted to PLN using the exchange rate published by the National Bank of Poland (NBP) as at the final date for submitting quotations.

**VI.4.** The score ( $P_T$ ) for the “date of completion of the contract” will be calculated as follows:

$$P_T = \frac{T_N}{T_B} * 25 \text{ points}$$

where:

- $P_T$  - score for the “date of completion”
- $T_N$  - among the non-rejected quotations, the shortest delivery date of the contract (*number of days*)
- $T_B$  - date of completion of the contract as declared in the quotation (*number of days*)

The period for the completion of the contract will be counted in days. If the time limit for the completion will not be given in days in the quotation, the Contracting Party will convert it based on the following: one week = 7 days, two weeks = 14 days, three weeks = 21 days, one month = 30 days and as appropriate, based on such a conversion, for any other time limits given in weeks and/or months.

**Quotations offering a contract delivery period exceeding 90 days will be rejected.**

**VI.5.** The score ( $P_G$ ) for having in place “a quality system conforming to GMP requirements” will be calculated as follows:

$$P_G = T * 25 \text{ points}$$

where:

- $P_G$  - score for “a quality system conforming to GMP requirements”
- $T$  - score awarded: “0” if the Bidder does not have a quality system conforming to GMP requirements “1” if the Contractor has a quality system conforming to GMP requirements

**VI.6.** The maximum score that can be awarded is 100 points. Calculations will be made to two decimal places.

## **VII. PLACE AND CLOSING DATE FOR SUBMISSION OF QUOTATIONS**

**VII.1.** The final deadline for submitting quotations is **13 May 2022 by 6:00 p.m.**

– quotations can be sent in electronic format (in the form of a scan of the signed document) to the following address: **katarzyna.rusin@polpharma.com**

**VII.2.** A quotation will be considered to have been properly submitted if a complete quotation is delivered to the above e-mail address within the time limit stipulated in this section.

**VII.3.** No quotations submitted past the submission deadline will be taken into consideration.

## **VIII. PREPARATION OF QUOTATIONS**

**VIII.1.** The Bidder should draw up one quotation using the template attached as Appendix 1 hereto.

**VIII.2.** Quotations may be modified or withdrawn prior to the end of the time limit for the submission of quotations.

**VIII.3.** Bidders are required to carefully read the information contained in the Price Inquiry.

**VIII.4.** The costs of preparing and delivering quotations will be borne by the respective Bidder.

**VIII.5.** For any matters related to this Price Inquiry, please contact the Contracting Party, e-mail: katarzyna.rusin@polpharma.com.

## **IX. ADDITIONAL INFORMATION**

**IX.1.** Until the end of the time limit for the submission of quotations, the Contracting Party reserves the right to amend or add new information to this Price Inquiry.

**IX.2.** Submitted quotations will remain valid and binding for 60 days from the final date for submitting quotations.

## **X. LIST OF APPENDICES**

The following appendices are attached to this Price Inquiry:

<b>Appendix number</b>	<b>Appendix title</b>
Appendix 1	Bid form
Appendix 2	Declaration of compliance with the eligibility criteria for the participation in the procedure

**BID FORM**

**Bidder:**

<b>Name / Company</b>	
<b>Registered office/home address/address of the principal place of business</b>	
<b>E-mail address for the Contracting Party to send information related to the Price Inquiry</b>	
<b>NIP [Taxpayer ID Number]</b>	
<b>REGON [Business ID Number]</b>	
<b>Phone number</b>	
<b>Contact person for the Contracting Party</b>	

*We offer to perform the contract for the provision of services involving the development and manufacture of an active substance in the form of a modified oligonucleotide – an 18-mer RNA as per the requirements of the Price Inquiry for the total price of:*

**net amount: PLN/EUR\* .....**

applicable VAT at .....%: PLN/EUR\* .....

gross amount: PLN/EUR\* .....

(say: .....)

**Net price per gram of substance manufactured under non-GMP conditions: PLN/EUR\***

.....

**Net price per gram of substance manufactured under GMP conditions: PLN/EUR\***

.....

**The contract will be completed within up to .....days of the date when a partial production order is submitted.**

*\*Delete as appropriate.*

**We also declare as follows:**

- a. We have read the Price Inquiry and appendices thereto, we raise no objections and we have obtained the information necessary to prepare our quotation.
- b. Our bid price includes a lump sum that covers for all the obligations of the future Contractor as necessary to deliver the contract referred to hereunder.
- c. Our quotation will remain valid and binding for 60 days from the final date for submitting quotations.

.....  
(place and date)

.....  
(signature(s) of person(s) authorized to submit  
statements of will on behalf of the Bidder)

**Contracting Party:**

WZF Polfa S.A.  
ul. Karolkowa 22/24  
01-207 Warszawa

**Contractor's Declaration**

**OF COMPLIANCE WITH THE ELIGIBILITY CRITERIA FOR THE PARTICIPATION IN  
THE PROCEDURE**

By submitting this quotation for: **the provision services involving the development and manufacture of an active substance in the form of a modified oligonucleotide – an 18-mer RNA (nusinersen)**, funded from the state budget by the Medical Research Agency, I hereby declare as follows:

**INFORMATION ON THE CONTRACTOR:**

I declare that we meet the eligibility criteria for the participation in the procedure, as specified by the Contracting Party in section V of the Price Inquiry:

- we have infrastructure that enables the manufacture of active substances while using a quality system
- we have/intend to acquire \* facilities for the synthesis, purification and freeze-drying of oligonucleotides
- we have access to analytical equipment that enables the determination of the quality of the active substance to be manufactured
- we have experience in preparing the registration dossier for active substances
- we have staff with experience in the synthesis of active substances and, in particular, in the synthesis of oligonucleotides

.....  
(place and date)

.....  
(signature of the Contractor's representative)