Warsaw, 26.05.2023r.

PRICE INQUIRY NO. NETLA/4/2023/API

In connection with the implementation of the project titled *"Design and development of an innovative solution – a complex, two-component medicinal product in the form of eye drops in a multi-dose package without preservatives, aimed at the treatment of open-angle glaucoma*", funded from the state budget by the Medical Research Agency, WZF Polfa S.A., you are kindly requested to submit a bid **for the purchase and delivery of the active substance netarsudil (in the form of netarsudil dimesylate), analytical standards of the active substance netarsudil dimesylate and impurities of the substance netarsudil.**

I. NAME AND ADDRESS OF THE BUYER

Warszawskie Zakłady Farmaceutyczne Polfa Spółka Akcyjna

ul. Karolkowa 22/24

01-207 Warszawa

II. PRICE INQUIRY PROCEDURE

1. This Price Inquiry 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 SUBJECT OF THE PRICE INQUIRY

3.1. The subject of this Price Inquiry is the purchase and delivery of the following quantities of the substance:

3.1.1. Part 1. Netarsudil dimesylate

The active substance, a Rho kinase inhibitor, reduces intraocular pressure by increasing aqueous humour outflow.

Active substance for pharmaceutical purposes, manufactured under GMP conditions (declaration of manufacturing under GMP conditions from the supplier is required).

Requirements:

- Appearance: colourless or light yellow powder,
- Identification: consistency with the spectrum of netarsudil dimesylate (FT-IR) standard,
- Water content: not more than 6.0%;
- Enantiomeric purity: not more than 0.15% of the netarsudil dimesylate R-isomer;
- Content: 97.0% – 102.0% (per anhydrous substance free from solvents);
- Related substances:
  - ✓ any specified impurity: not more than 0.2%,
  - ✓ any other impurity: not more than 0.10%,
  - ✓ sum of impurities: not more than 1.0%.

The manufacturer should declare the possibility of future deliveries of new batches conforming to the specification. Shelf life confirmed by stability testing: not less than 24 months.

Package 20 g; Total quantity: 1 package.

3.1.2. Part 2. Reference standard of the active substance netarsudil dimesylate:

Additional requirements: Certificate of analysis: Content: not less than 95.0%

Package 100 mg; Total quantity: 1 package

3.1.3. Part 3. Impurity standards of the active substance netarsudil dimesylate:

Any impurity specified by the supplier:
Additional requirements: Certificate of analysis: Content: not less than 95.0%

Package 25 mg; Total quantity: 1

3.1.4. Part 4. Standard of R-enantiomer of netarsudil dimesylate:

Additional requirements: Certificate of analysis: Content: not less than 95.0%

Package 25 mg; Total quantity: 1

3.2. Products shelf life:
Subsection 3.1.1. total shelf life calculated from the date of manufacture not shorter than 24 months. At the time of delivery, the substance should be no older than 12 months from the moment of manufacture.
Subsection 3.1.2., subsection 3.1.3. and subsection 3.1.4. total shelf life of the standard calculated from the date of manufacture or date of retest (if applicable) not shorter than 24 months. At the time of delivery, the standard should be no older than 12 months from the date of manufacture or date of retest (if applicable).

3.3. Additional requirement:
a) Documentation for subsection 3.1.1. to be delivered together with the bid CoA, MSDS (Material Safety Data Sheet)
b) Documentation for subsections 3.1.2.. 3.1.3., 3.1.4. to be delivered together with the bid CoA

3.4. The Buyer allows partial bids, i.e. each item may be covered by a separate bid, and delivery may be made at different times.

3.5. The Buyer accepts other package sizes than those indicated in the specification.

IV. PRICE INQUIRY DELIVERY SITE AND DATE

4.1. The subject of the Price Inquiry must be delivered to the Buyer's offices at: Warszawskie Zakłady Farmaceutyczne Polfa Spółka Akcyjna, ul. Barska 31, 02-315 Warsaw. Transport in conditions ensuring stability of the subject of the Price Inquiry.

4.2. Due to the fact that the time of delivery of the subject of the Price Inquiry constitutes a criterion for bids evaluation, the order shall be delivered in accordance with the submitted bid, however not later than within 90 calendar days from the date of placing the order.

V. GENERAL REQUIREMENTS

5.1. The Buyer does not accept equivalent products.

5.2. The Buyer accepts bids for parts of the order.

5.3. The contract award procedure is open to any Contractors who meet the following requirements:

5.3.1 The Bidders shall submit the declaration of conformity of the substance manufacturing process with the GMP requirements.

Assessment procedure:
The verification shall take place on the basis of the Bidder's declaration.

5.3.2 The Bidders shall enclose with the bid CoA and MSDSs.

Assessment procedure:
The Contracting Entity will consider the Contractor as meeting this condition if the required documents and certificates are enclosed with the bid.

5.3.3 Bids submitted by Contractors who demonstrate that they meet the specified requirements will be taken forward to the bid examination and assessment stage. The compliance with the above requirements will be assessed based on a 'meet – does not meet' basis. Bids submitted by Contractors who fail to meet any of the above requirements will be rejected.

5.3.4. Entities for which the following circumstances occur are also excluded from the tender:

a) as described in Article 7(1) of the Act of 13 April 2022 on Special Measures to Counteract Support for the Aggression against Ukraine and to Protect National Security;
b) as described in Article 5k of the Council Regulation (EU) No 833/2014 of 31 July 2014 concerning restrictive measures in view of Russia's actions destabilising the situation in Ukraine.

Method of verification of grounds/lack of grounds for exclusion:
The verification shall take place on the basis of the Bidder's declaration

VI. METHOD OF PRICE CALCULATION

6.1. Bid price calculation: the price should be calculated as a net and a gross amount.

6.2. Bids with the price given in a currency other than PLN will be converted to PLN at the average exchange rate of the National Bank of Poland (https://www.nbp.pl/) as at the final date for the submission of bids.

6.3. The price should include all the costs related to the preparation and performance of the subject of the Price Inquiry.

6.4. The price given in the bid cannot change during contract performance.

VII. CONTRACT AWARD CRITERIA

7.1. The bids will be evaluated based on the following criteria:
- Price – 70%,
- Time of delivery – 30%.

7.2. The evaluation criteria apply both to partial bids and bids covering all parts of the subject of the order. The evaluation will be performed and scores will be awarded for each part of the subject

of the order separately, regardless of whether the bid covers all or only some parts of the subject of the order.

7.3. The scoring of the bid will be calculated according to the following formula:

$$\boldsymbol{O_P = P_C + P_G}$$

where:

O_P	-	the bid score
P_C	-	score for the criterion 'price'
P_G	-	score for the criterion 'time of delivery'

7.4. The score (P_c) for the criterion 'price' will be calculated as follows:

$$P_C = \frac{C_N}{C_B} * 70 \text{ points}$$

where:

- P_C - score for the criterion 'price'
- C_N - the lowest total net price based on non-rejected bids
- C_B - total net price of the bid under evaluation

Bids with the price given in a currency other than PLN will be converted to PLN at the average exchange rate of the National Bank of Poland as at the final date for the submission of bids.

7.5. The score (P_G) for the criterion 'time of delivery' will be calculated as follows:

$$P_G = \frac{G_N}{G_B} * 30 \text{ points}$$

where:

- P_G - score for the criterion 'time of delivery'
- G_N - the shortest time of delivery based on non-rejected bids
- G_B - time of delivery of the bid under evaluation

The Buyer understands the time of delivery as time calculated in calendar days from the time when the Buyer receives a confirmation of acceptance of the order for delivery by the Seller.

The bid will be rejected if the time of delivery of the subject of the Price Inquiry is longer than 90 calendar days.

7.6. The bid with the highest score out of all the non-rejected bids will be considered the best bid. The maximum score that can be awarded is 100 points. Calculations will be made to two decimal places.

VIII. PLACE AND DATES FOR SUBMITTING AND OPENING BIDS

8.1. The final **deadline for submitting bids is 02.06.2023r.**
- bids can be sent in electronic format as scanned documents to the following address: Barbara.wendolowska@polpharma.com

8.2. The date and the time when the bid is received by the Buyer determines whether the submission deadline has been complied with.
8.3. No bids submitted past the submission deadline will be considered.
8.4. The Buyer is not planning to hold a public opening of the bids.
8.5. Bids may be modified or withdrawn prior to the end of the time limit for the submission of bids.

IX. PREPARATION OF BIDS

9.1. The Seller must draw up a single price bid using the form attached as Appendix 1 hereto. Submitting more than one bid for a particular part will result in all bids submitted by the Seller being rejected.
9.2. A bid must be prepared in the Polish or English language version.
9.3. The bid complete with appendices must be signed by persons authorised to represent the Bidder in accordance with the representation resulting from the relevant register or pursuant to a power of attorney granted. If the person(s) signing the bid (representing the Bidder) is(are) acting under a power of attorney, the power of attorney must be attached to the bid.
9.4. Bidders are required to carefully read the information contained in the Price Inquiry.
9.5. Any costs and expenses incurred in connection with the preparation and submission of bids are to be paid by the respective Bidders.
9.6. Until the end of the time limit for the submission of bids, the Buyer reserves the right to amend or add new information to this Price Inquiry.
9.7. The Bidder submitting the bid remains bound by it for 30 calendar days from the end date of the time limit for the submission of bids.

X. COMMUNICATIONS BETWEEN THE BUYER AND SELLERS, PERSONS AUTHORISED FOR CONTACT

10.1. During the procedure, the Buyer and the Sellers submit all declarations, requests, notices and information in Polish.
10.2. The receipt of any notices, declarations, requests and information submitted electronically must be immediately confirmed at the request of each of the parties.
10.3. If the Seller has not confirmed the receipt of the correspondence, the Buyer will assume that the correspondence sent by the Buyer to the e-mail address provided by the Seller has been delivered in a way that enables the Seller to read it.
10.4. Any correspondence about this Price Inquiry should be sent to e-mail: barbara.wendolowska@polpharma.com
10.5. In any correspondence related to this Price Inquiry, the Seller should use the procedure number: Price Inquiry No. NETLA/4/2023/API.
10.6. Barbara Wendolowska is the person authorised to communicate with the Seller.
10.7. No information, clarifications or replies to any queries submitted to the Buyer will be provided orally or by phone.
10.8. Any questions about this Price Inquiry should be sent by e-mail to the address provided above, not later than 3 days before the end of the time limit for the submission of bids.
10.9. Replies to the questions and more detailed information on the Price Inquiry following from questions asked by prospective Sellers will be sent to the entity requesting that information.

XI. BID EVALUATION PROCEDURE AND PUBLICATION OF RESULTS

11.1. During the examination and evaluation of the submitted bids, the Buyer may request the Seller to provide additional information (if it does not infringe competitiveness) and clarifications related to the submitted bids. The Buyer may also ask the Seller to correct evident mistakes and calculation errors.

11.2. The Buyer reserves the right to verify, during the bid evaluation, the documents, statements, lists, data and information provided by the Sellers.

11.3. If two or more Sellers have the same score, the bid which is best in terms of the environmental and climate impact will be selected. For this purpose, the Buyer has the right to request the Bidders with the highest final score to supplement the bid with more information requested by the Buyer with respect to the environmental impact of the subject of the bid.

XII. ADDITIONAL INFORMATION

12.1. The Seller submitting the bid remains bound by it for 30 calendar days from the end date of the time limit for the submission of the bid. Following the procedure, the Buyer may conclude a Contract for the performance of the subject of the order with the Seller whose bid is considered the best. The selection of the best bid does not mean that the Buyer is obliged to conclude a Contract with the Contractor.

12.2. The Buyer reserves the right to place additional orders with the Seller, not covered by the Subject of the original Price Inquiry, up to 50% of the value of the Subject of the original Price Inquiry, necessary for the proper performance of the task and resulting among others from the following circumstances:

– due to technical or organizational reasons, the separation of the additional order from the Subject of the original Price Inquiry would incur excessively large costs,

– the performance of the Subject of the original Price Inquiry depends on the performance of the additional order.

12.3. The Buyer reserves the right to place a supplementary order with the Seller (consistent with the description of the subject of the original order) up to 50% of the value of the original order specified in the contract concluded with the Seller.

12.4. The Buyer makes the reservation that it has:

- the right not to choose any of the submitted Bids;
- the right to cancel the Tender Procedure at any time, without giving a reason or without prior notification of the Bidders;
- the right to change or supplement the documents making up the Price Inquiry, in which case such documents will become an integral part of the Inquiry;
- the right to extend the time limit for the submission of bids;

and the Bidders have no claims against the Buyer with respect to the above rights.

12.5. PERSONAL DATA PROTECTION.

As far as personal data contained in bids are concerned, the Buyer – as soon as the bid is submitted – will become the Data Controller as defined under Article 4(7) of Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC ("GDPR"). The Buyer will process the data for the purposes of bid evaluation, concluding an agreement with the awarded contractor and implementing the concluded agreement, i.e. under Article 6(1)(b) of the GDPR.

The Buyer will transfer the personal data contained in the submitted bids, under relevant regulations, to authorised bodies and institutions entitled to audit projects co-financed from the

funds of the Medical Research Agency. For more information on the processing of personal data by competent institutions, visit: https://abm.gov.pl/pl/wolnytekst/198,Polityka-dotyczaca-cookies.html
The Buyer will process the personal data throughout the period during which it is required, under relevant regulations, to store the whole documentation related to projects co-financed from the funds of the Medical Research Agency.

XIII. LIST OF APPENDICES

The following appendices are attached to this Price Inquiry:

Appendix number	Appendix title
Appendix 1	Bid Form

Appendix 1 to the Price Inquiry No. ***NETLA/4/2023/API***

BID FORM

Bidder:

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

We offer the delivery of the subject of the order **for purchase and delivery of the active substance netarsudil (in the form of netarsudil dimesylate), analytical standards of the active substance netarsudil and impurities of the active substance netarsudil,** in accordance with the requirements of the Price Inquiry, for **the price of:**

description of the subject of the Price Inquiry	**Units**	**Quantity**	**Expiry date**	**Net price per unit**	**total net value PLN / EUR***	**Lead time**
Part 1. Netarsudil dimesylate CoA YES/NO* MSDS YES/NO*						
Part 2. Reference standard of the active substance netarsudil dimesylate CoA YES/NO*						
Part 3. Impurity standards of the active substance CoA YES/NO*						

Part 4. Standard of R-enantiomer of netarsudil dimesylate CoA YES/NO*						

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 bid.

b. Our bid price includes a lump sum that covers all the obligations of the future Seller as necessary to deliver the subject of this Price Inquiry.

c. Our bid will remain valid and binding for 30 calendar days from the end date of the time limit for the submission of bids.

d. **The active substance netarsudil dimesylate is manufactured under GMP conditions.**

e. The following circumstances do not occur with respect to us:

a) as described in Article 7(1) of the Act of 13 April 2022 on Special Measures to Counteract Support for the Aggression against Ukraine and to Protect National Security;

b) as described in Article 5k of the Council Regulation (EU) No 833/2014 of 31 July 2014 concerning restrictive measures in view of Russia's actions destabilising the situation in Ukraine.

…… ……

(place and date) (signature(s) of person(s) authorised to submit statements of will on behalf of the Bidder)