**STATEMENT**

**REQUIREMENTS FOR THE TENDERER**

**no. RFP 026413** **LONG-TERM STABILITY STUDY OF DRUG PRODUCT IN CGMP STANDARD**

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| **REQUIREMENTS** | **CONFIRMATION [YES/NO]** |
| Broad expertise and a track record in performing and completing research described in Section I Request for Proposal evidenced by at least 5 years of activity of CMO on the market in terms of this specific service | Wybierz element. |
| The ability to perform the specified studies within the timeframes: **01.03.2026 - 30.11.2027** in accordance with the detailed study plan provided by the Ordering Party to the selected Contractor.  | Wybierz element. |
| Availability (in-house or outsourced) of all validated analytical methods indicated in Appendix A, Table 1  | Wybierz element. |
| At least 5 years of experience in contract manufacturing and analytics of drug substances (DS) for clinical and commercial studies in compliance with cGMP standards. | Wybierz element. |
| At least 5 years of experience in contract manufacturing and analytics of drug products (DP) for clinical and commercial studies in compliance with cGMP standards. | Wybierz element. |
| Possession of the necessary infrastructure and personnel resources to perform to perform or subcontract analytical methods listed in Appendix A, Table 1. | Wybierz element. |
| Possession of the necessary infrastructure and personnel resources to store samples under controlled conditions at -80°C ±10°C in compliance with cGMP standards. | Wybierz element. |
| A current GMP certificate for DS manufacturing and analytics. | Wybierz element. |
| A current GMP certificate for DP manufacturing and analytics. | Wybierz element. |
| Necessary resources to carry out all listed activities. The bidder should provide a list with descriptions of the equipment and personnel. | Wybierz element. |
| Validated testing methods as specified in Appendix A, Table 1 | Wybierz element. |
| Using a quality management system as well as an auditing and quality control system to ensure compliance with relevant regulations. | Wybierz element. |
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 *(date and signature of Tenderer's authorized representative)*