**STATEMENT**

**REQUIREMENTS FOR THE TENDERER**

**no. RFP 026130/** **Manufacturing of Drug Substance and Drug Product according to 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: **28.04.2025 - 30.11.2032**, in accordance with the detailed study plan provided by the Ordering Party to the selected Contractor.  | Wybierz element. |
| At least 5 years of experience in contract manufacturing and analytics of biological 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 biological drug products (DP) for clinical and commercial studies in compliance with cGMP standards. | Wybierz element. |
| Possibility of Drug Substance manufacturing in bacterial expression system in 300L scale | Wybierz element. |
| Possibility of Drug Product manufacturing and sterile fill | Wybierz element. |
| Possession of the necessary infrastructure and personnel resources to perform to perform or subcontract analytical methods listed in Appendix A, Table 1 and Table 2. | Wybierz element. |
| Possession of the necessary infrastructure and personnel resources to store samples under controlled conditions at -80°C ±10°C and -20°C ± 5°C in compliance with cGMP standards. | Wybierz element. |
| Possession of the necessary infrastructure and personnel resources to prepare DP labeling and store samples under controlled conditions at -80°C ±10°C and conduct clinical trial release 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. |
| Ability to perform and validate all analytical methods listed in Annex A, Table 1 and Table 2 | 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)*