Approved by K.Porins
SIA Pharmidea
Cheaf Operating Oficer

SIA PHARMIDEA
Reg.No.: 40003791173

CFCA (CFLA) and SIA"FBMTKC" Contract No. 5.1.1.2.i.0/2/24/A/CFLA/005

Procurement Object Description

1. General Information on the Funding Recipient:
Name: PHARMIDEA SIA
TAX number: 40003791173
Address: Rūpnīcu iela 4, Olaine, Latvia LV-2114
Contact person: Inguna Grinsteine, tel: +371-29123827, e-mail: inguna@pharmidea.lv

2. Description of the Procurement Object:

Pharmacokinetic (PK) biosimilarity and bioanalytical research study for a generic medicinal product intended for the treatment of diabetes.

a)	**Technical Specification (Scope of Work)**	
1.	Scope of Work	Conducting comparisional biosimilarity research study for the purpose of pharmacokinetic **(**PK) biosimilarity of PharmIdea's Semaglutide 2,68 mg/ml solution for injection in pre-filled pen (Test Medication) versus Ozempic® 2,68 mg/ml solution for injection in pre-filled pen (Reference Medication). including study preparation services (study design, protocol development, preparation of case report forms (CRFs), drafting of informed consent forms and subject information sheets, preparation and submission of study documentation to regulatory authorities and the Ethics Committee), the clinical phase of the study, bioanalytical services, data management, pharmacovigilance, calculation of pharmacokinetic parameters, statistical planning, statistical processing and analysis of data, and preparation of the final study report.
2.	Applied Methodology:	Contractor has to perform single-dose, open-label, laboratory-blinded, randomised, two-sequence, two-treatment, two-period crossover pharmacokinetic **(**PK) biosimilarity research study. The Contractor must apply a validated bioanalytical methods for quantifying the active substance in human plasma.
b)	**Additional Requirements:**	

1.	Delivery Requirements:	The Contractor shall conduct the study in strict compliance with any applicable EU laws, regulations, directives and guidelines, including but not limited to the Declaration of Helsinki, the guidelines for Good Clinical Practice (GCP) and Good Laboratory Practice (GLP). The Contractor shall have at least 5 (five) years of experience in conducting human biosimilarity research studies in any of EU country. The Contractor shall have been inspected by the European Medicines Agency (EMA) and/or the competent authorities of EU Member States and the US Food and Drug Administration (US FDA) within the last 5 (five) years, with no critical findings reported; The Principal Investigator shall have experience in conducting at least 3 (three) biosimilarity research studies; The Contractor's personnel shall be trained in the principles of Good Clinical Practice (GCP); The Contractor shall conduct the study in compliance with Good Laboratory Practice (GLP) requirements; If necessary, the Contractor shall hold a valid license permitting studies with substances included in controlled substances lists.
2.	Delivery Period:	The Contractor shall complete the study **not later than by 31 March 2027** (with the approved final study report).
3.	Validity of the Proposal:	The Proposal shall remain valid at least until 10 July 2026.
4.	Payment Conditions:	The Bidder acknowledges that the payment terms will be determined in the contract. Advance payment shall not exceed 30% of the total contract amount, and the final payment shall be no less than 5% of the total contract amount.
5.	Price:	Amounts shall be indicated in EUR, excluding VAT.
6.	Compliance:	If an equivalent solution exists for the requirements listed in this description of the procurement subject, which the funding recipient has not specified, the Bidder may submit an Proposal with an equivalent that meets the requirements. The Bidder may also submit an Proposal that meets higher-level requirements.
7.	Requirements for Proposal Submission:	The Proposal shall be prepared in accordance with the Technical Proposal Form attached as Annex 1 to the Description of the Procurement Subject; The Proposal must include the following documents: 2.1. Confirmation of 5 (five) years experience of pharmacokinetic **(**PK) biosimilarity research study and/or clinical Phase I/II studies and/or bioequivalence studies conducted in the last 5 (five) years; 2.2. A list of inspections conducted on the Contractor by the European Medicines Agency (EMA) and/or the competent authorities of EU Member States and the US Food and Drug Administration (US FDA) within the last 5 (five) years;

		2.3. Curriculum vitae of the Principal Investigator and GCP certificate or an equivalent document; 2.4. A brief study plan with justification for the number of volunteers required to obtain reliable study results. The signed Proposal with annexes shall be submitted in 1 (one) copy, prepared in a computer-typed format in English. The signed original Proposal with annexes must be sent in scanned form by the end of the date of procurement procedure to Inguna Grinsteine at the email address: inguna@pharmidea/lv OR sent in a sealed envelope by post to: "PHARMIDEA SIA, Rūpnīcu iela 4, Olaine, Latvia, LV-2114," marked "Pharmacokinetic (PK) biosimilarity and bioanalytical research study for a generic medicinal product" or delivered personally to the same address. The Proposal must indicate the date and place of preparation, document number, signature, and printed name of the signatory. The first page of the Proposal shall be printed on the company letterhead (if available).

Annex1: Final Proposal Form, consisting of 5 (five) pages

DOCUMENT SIGNED WITH A SECURE ELECTRONIC SIGNATURE

ANNEX 1
To the Procurement Object Description

FINAL PROPOSAL FORM

LETTERHEAD OF THE COMPANY

FINAL PROPOSAL (doc.Nr.____)

Prepared and submitted by

*COMPANY NAME*_____

ADDRESS_____

for

SIA Pharmidea

Rupnicu 4, Olaine, LV -2114

procurement

Pharmacokinetic (PK) biosimilarity and bioanalytical research study for a generic medicinal product intended for the treatment of diabetes.

PROPOSAL

Date_____

General information of the Company:

Legal Form	
Commercial Register	
VAT number	
Name, surname and tittle of the signatory person	

a)	**Technical Specification (Scope of Work)**		**PROPOSAL**
1.	Scope of Work	Conducting comparisional biosimilarity research study for the purpose of pharmacokinetic (PK) biosimilarity of PharmIdea's Semaglutide 2,68 mg/ml solution for injection in pre-	

		filled pen (Test Medication) versus Ozempic® 2,68 mg/ml solution for injection in pre-filled pen (Reference Medication). including study preparation services (study design, protocol development, preparation of case report forms (CRFs), drafting of informed consent forms and subject information sheets, preparation and submission of study documentation to regulatory authorities and the Ethics Committee), the clinical phase of the study, bioanalytical services, data management, pharmacovigilance, calculation of pharmacokinetic parameters, statistical planning, statistical processing and analysis of data, and preparation of the final study report.	
2.	Applied Methodology:	Contractor has to perform single-dose, open-label, laboratory-blinded, randomised, two-sequence, two-treatment, two-period crossover pharmacokinetic (PK) biosimilarity research study. The Contractor must apply a validated bioanalytical methods for quantifying the active substance in human plasma.	
b)	**Additional Requirements:**		
1.	Delivery Requirements:	The Contractor shall conduct the study in strict compliance with any applicable EU laws, regulations, directives and guidelines, including but not limited to the Declaration of Helsinki, the guidelines for Good Clinical Practice (GCP)	

		and Good Laboratory Practice (GLP). The Contractor shall have at least 5 (five) years of experience in conducting human biosimilarity research studies in any of EU country. The Contractor shall have been inspected by the European Medicines Agency (EMA) and/or the competent authorities of EU Member States and the US Food and Drug Administration (US FDA) within the last 5 (five) years, with no critical findings reported; The Principal Investigator shall have experience in conducting at least 3 (three) biosimilarity research studies; The Contractor's personnel shall be trained in the principles of Good Clinical Practice (GCP); The Contractor shall conduct the study in compliance with Good Laboratory Practice (GLP) requirements; If necessary, the Contractor shall hold a valid license permitting studies with substances included in controlled substances lists.	
2.	Delivery Period:	The Contractor shall complete the study by **31 March 2027** (with the approved final study report).	
3.	Validity of the Proposal:	The Proposal shall remain valid at least until **10 July 2026**.	
4.	Payment Conditions:	The Bidder acknowledges that the payment terms will be determined in the contract. Advance payment shall not exceed 30% of the total contract amount, and the final payment shall be no less than 10% of the total contract	

		amount.	
5.	Price:	Amounts shall be indicated in EUR, excluding VAT.	
6.	Compliance:	If an equivalent solution exists for the requirements listed in this description of the procurement subject, which the funding recipient has not specified, the Bidder may submit an Proposal with an equivalent that meets the requirements. The Bidder may also submit an Proposal that meets higher-level requirements.	
7.	Requirements for Proposal Submission:	The Proposal shall be prepared in accordance with the Technical Proposal Form attached as Annex 1 to the Description of the Procurement Subject; The Proposal must include the following documents: 2.1. Confirmation of 5 (five) years experience of pharmacokinetic (PK) biosimilarity research study and/or clinical Phase I/II studies and/or bioequivalence studies conducted in the last 5 (five) years; 2.2. A list of inspections conducted on the Contractor by the European Medicines Agency (EMA) and/or the competent authorities of EU Member States and the US Food and Drug Administration (US FDA) within the last 5 (five) years; 2.3. Curriculum vitae of the Principal Investigator and GCP certificate or an equivalent document;	

		2.4. A brief study plan with justification for the number of volunteers required to obtain reliable study results. The signed Proposal with annexes shall be submitted in 1 (one) copy, prepared in a computer-typed format in English. The signed original Proposal with annexes must be sent in scanned form by the end of the date of procurement procedure to Inguna Grinsteine at the email address: inguna@pharmidea/lv OR sent in a sealed envelope by post to: “PHARMIDEA SIA, Rūpnīcu iela 4, Olaine, Latvia, LV-2114,” marked “Pharmacokinetic (PK) biosimilarity and bioanalytical research study for a generic medicinal product” or delivered personally to the same address. The Proposal must indicate the date and place of preparation, document number, signature, and printed name of the signatory. The first page of the Proposal shall be printed on the company letterhead (if available).	

TOTAL Price	**_____EUR (without VAT)**

_____

Signature, Name, Surname of the signatory person

Annexes..

Confirmation

of bioavailability and bioequivalence studies conducted in the last 5 (five) years;