CONFIRMED: _____

Juris Bundulis
Chairman of the Board
JSC "Olpha"
Olaine, 12.11., 2025

Description of procurement subject ID No. 2025/11/13

1. General information about the customer:

Name of customer:	JSC „Olpha"
Commercial registration No.:	40003007246
Address:	Rupnicu street 5, Olaine, Olaines district, LV-2114, Latvia
Contact person:	Vadims Ķīsis, Head of Medicine & Clinical Research Department, E-mail: Vadims.Kisis@olpha.eu

2. Procurement subject technical specification:

Full-service bioequivalence study.
Additional information about the procurement subject is available from the customer, by writing to the above-indicated e-mail.

1.	Study design and key requirements	Type of study: Pivotal Design: An open label, balanced, randomized, single-dose, two-treatment, two-period crossover Condition: Fed Participants: Healthy adult volunteers (approx. 80% males and 20% females). The final number of participants will be based on a sample size calculation, including an appropriate drop-out reserve, to ensure that a sufficient number of participants complete both study periods. The same participants shall participate in both study periods, with an adequate washout. Investigational Products: Test and Reference; immediate release film-coated tablets. Additional comments: Ensure hypoglycemia prevention and monitoring. The meal plan must remain consistent across both study periods. Sampling period covering up to 72 hours post-dose, with up to 25 samples per period. Sampling should be densest around the expected t max and duration sufficient to capture ≥80–90% AUC for both analytes. Analytes to measure: Parent in plasma.

2.	Scope of work	Full scope bioequivalence study as detailed above, including following activities: 1. Study documentation preparation - protocol and other study documents (e.g. Informed consent Form (including translations), Case report form etc.), study insurance. 2. Obtaining the required study permits. 3. Clinical phase of the study, including healthy volunteers' recruitment and enrolment in the study, clinical phase conduct and execution, safety laboratory samples collection and analysis, medical coordination and supervision. 4. Clinical trial supply services - receipt (incl. custom clearance), accountability and storage of investigational products (IPs), preparation for dispensing and distribution to the volunteers, reconciliation and destruction of unused IPs. 5. Bioanalytical phase, including bioanalytical study plan preparation, analysis of biosamples (determination of parent compounds plasma concentrations using a validated bioanalytical method fully compliant with ICH guideline M10 on bioanalytical method validation and study sample analysis), incurred sample reanalysis, preparation of a Bioanalytical report. 6. Data management and statistics services, including formal sample size calculation, generation of randomization list, statistical analysis, and statistical report. 7. Preparation of Final Clinical study report and CTD 2.7.1 module. 8. Project management. 9. Study document archiving. The proposal must include all costs associated with the performance of the services, including costs for regulatory charges, estimated costs of working and internal standards, analytical columns and consumables, study-related insurance and approximate costs of one (1) SAE handling.

3. Requirements for Applicant:

1.	Applicant's experience	1. Applicant has sufficient experience in conducting bioequivalence studies, including the analytical phase (bioanalytical method development and validation, and biosample analysis). 2. Applicant is eligible to conduct above mentioned bioequivalence study in compliance with GCP, GLP, European Medicines Agency (EMA) and applicable local regulations.

		3. Applicant holds a valid Gulf Cooperation Council (GCC) approval/certificate of compliance.
2.	Applicant's resources	1. Applicant has qualified scientific personnel. Key team members are trained in GCP principles. 2. Applicant has access to suitable study population to ensure conduct of proposed study. 3. Applicant has the necessary technical facilities and equipment to conduct above mentioned study in accordance with technical specification.
3.	Date of completion	The date of completion refers to mutually accepted (final) Clinical trial report. This date will be confirmed with the selected applicant and set in service agreement.
4.	Amount of work	For the purpose of this procurement, applicant shall apply for all activities presented in the technical specification.
5.	Compliance	In case of possible equivalent for requirements listed in the description of procurement subject, unforeseen by the customer, the applicant can submit equivalent offer in conformity with requirements. The applicant can also submit the offer, which corresponds to higher (better) requirements.
6.	Price	Total amount of the contract (including Pass Through Costs) and cost breakdown per activity according to section 2 "Scope of work", indicated in EUR (excluding VAT).
7.	Schedule of payment	The applicant agrees that the payment conditions will be set in the contract. The applicant can indicate the desired payment schedule in the application.
8.	Documents / information to be submitted	1. Details of the bioequivalence study design, bioanalytical method development and validation, biosamples analysis. 2. Copy of documents verifying the applicant's legal status and GCC certification.
9.	Requirements for offer preparation	1. Offer shall be prepared on the form "Offer" in Annex no. 1 to the Description of procurement subject with all details completed. 2. Offer shall be written in English or Latvian languages. 3. The signed and scanned offer should be sent to: Vadims Ķīsis, Head of Medicine & Clinical Research Department, e-mail: Vadims.Kisis@olpha.eu

Annex no.1: Technical offer form on 3 (three) pages.

This procurement is organized within the framework of project No. 5.1.1.2.i.0/2/24/A/CFLA/005

Annex no.1
to the Description of procurement subject

[Applicant name]
Registration number: [ ]
Legal address: [ ]

[Place], [Date]
No._____

Offer

1.	**Customer**	JSC Olpha	
2.	**Customer address**	Rupnicu street 5, Olaine, Olaines district, LV-2114, Latvia	
3.	**Procurement subject**	Full-service bioequivalence study	
4.	**Place of study conduct**	[*Applicant address*]	
5.	**Information about applicant**	[*Short description of the applicant*]	
6.	**Description of procurement subject**		
		Requirements	Offer
6.1	Scope of work:	Full scope bioequivalence study as detailed above, including following activities: 1. Study documentation preparation - protocol and other study documents (e.g. Informed consent Form (including translations), Case report form etc.), study insurance. 2. Obtaining the required study permits. 3. Clinical phase of the study, including healthy volunteers' recruitment and enrolment in the study, clinical phase conduct and execution, safety laboratory samples collection and analysis, medical coordination and supervision. 4. Clinical trial supply services - receipt (incl. custom clearance), accountability and storage of investigational products (IPs), preparation for dispensing and distribution to the volunteers, reconciliation and destruction of unused IPs. 5. Bioanalytical phase, including bioanalytical study plan preparation, analysis of biosamples (determination of parent compounds plasma concentrations using a validated bioanalytical method fully compliant with ICH guideline M10 on	

		bioanalytical method validation and study sample analysis), incurred sample reanalysis, preparation of a Bioanalytical report. 6. Data management and statistics services, including formal sample size calculation, generation of randomization list, statistical analysis, and statistical report. 7. Preparation of Final Clinical study report and CTD 2.7.1 module. 8. Project management. 9. Study document archiving. The proposal must include all costs associated with the performance of the services, including costs for regulatory charges, estimated costs of working and internal standards, analytical columns and consumables, study-related insurance and approximate costs of one (1) SAE handling.	
7.	**Criteria for selection of offers**		
7.1.	Applicant's experience	1. Applicant has sufficient experience in conducting bioequivalence studies, including the analytical phase (bioanalytical method development and validation, and biosample analysis). 2. Applicant is eligible to conduct above mentioned bioequivalence study in compliance with GCP, GLP, European Medicines Agency (EMA) and applicable local regulations. 3. Applicant holds a valid Gulf Cooperation Council (GCC) approval/certificate of compliance.	
7.2.	Applicant's resources	1. Applicant has qualified scientific personnel. Key team members are trained in GCP principles. 2. Applicant has access to suitable study population to ensure conduct of proposed study. 3. Applicant has the necessary technical facilities and equipment to conduct above mentioned study in accordance with technical specification.	

7.3.	Date of completion	The date of completion refers to mutually accepted (final) Clinical trial report. This date will be confirmed with the selected applicant and set in service agreement.	
7.4.	Amount of work	For the purpose of this procurement, applicant shall apply for all activities presented in the technical specification.	
7.5.	Compliance	In case of possible equivalent for requirements listed in the description of procurement subject, unforeseen by the customer, the applicant can submit equivalent offer in conformity with requirements. The applicant can also submit the offer, which corresponds to higher (better) requirements.	
7.6.	Price	Total amount of the contract (including Pass Through Costs) and cost breakdown per activity according to section 2 "Scope of work", indicated in EUR (excluding VAT).	
7.7.	Schedule of payment	The applicant agrees that the payment conditions will be set in the contract. The applicant can indicate the desired payment schedule in the application.	
7.8.	Documents/ information to be submitted	1. Details of the bioequivalence study design, bioanalytical method development and validation, biosamples analysis. 2. Copy of documents verifying the applicant's legal status and GCC certification.	

[Company Name]

[Position] _____ [Signature, Name, Surname]