CONFIRMED: _____

Juris Bundulis
Chairman of the Board
JSC "Olpha"
Olaine, 22.08., 2025

Description of procurement subject ID No. 2025/08/9

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:

Genotoxicity testing of drug substance impurities.

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

1.	Scope of work	Genotoxicity testing of drug substance impurities (number of impurities = 2), including for each impurity: 1) *In vivo* mammalian alkaline comet assay and *in vivo* mammalian micronucleus test on bone marrow in rats, performed as one combined GLP study (regulations: comet assay OECD 489; micronucleus test OECD 474), including: • development of a protocol; • experimental part of the study, including: - dose-range finding study (both gender); - main study (one gender; 5 groups (positive control, negative control and 3 test item dose levels); a minimum of 5 analysable animals per group); - three daily treatments (at time 0, 24 and 45 hours); - route of administration: oral by gavage; - observations of the test animals; - bone marrow sampling time: 48 hours (3 hours after last treatment); - satellite group for bioanalysis (proof of absorption), (one gender, 3 animals per group (high dose)); - blood samples collection at three time points; - analysis of formulation samples at one time point; - comet assay on target organs – liver, colon and kidney; • samples analysis, evaluation of the study results and preparation of the final report.

		2) Formulation analysis for *in vivo* study, including: • analytical method development (non-GLP) and analytical method validation (GLP), including: - stability testing to assure stability of the analyte in the vehicle at the intended storage conditions for the duration of use and storage; • analysis of formulation samples (GLP). 3) Bioanalysis, including: • bioanalytical method development (non-GLP) and bioanalytical method validation (GLP), including: - stability testing to assure that concentration of the analyte is not affected during sample preparation, processing, analysis and the storage conditions used; • analysis of biosamples (GLP). 4) Study documents archiving.

3. <u>Requirements for Applicant:</u>

1.	Applicant´s experience	1. Applicant has sufficient experience in conducting the genotoxicity testing (*in vivo* mammalian alkaline comet assay and micronucleus test on bone marrow in rats), analytical and bioanalytical method development and validation, formulation and biosamples analysis. 2. Applicant is eligible to carry out the *in vivo* studies in accordance with legislation on the protection of animals used for scientific purposes or their equivalent.
2.	Applicant´s resources	1. Applicant has appropriate scientific staff. 2. Applicant has the necessary technical equipment to carry out the work in accordance with requirements of the present procurement subject.
3.	Final date of provision of work	Final date of provision of work will be confirmed mutually with the chosen applicant. The conditions will be set in agreement and study protocol.
4.	Amount of work	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 separately for each specific activity according to the section 1 "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.	Applicable documents to the offer	1. Details of the genotoxicity study design, analytical and bioanalytical method development and validation, formulation and biosamples analysis.

		2. Copy of documents verifying the applicant's legal status.
9.	Requirements for offer	1. Offer shall be submitted in accordance with the form "Offer" in Annex no. 1 to the Description of procurement subject. 2. Offer shall be written in English or Latvian languages. 3. Indicate the date of preparation of the document, place and signature with a clarification, as well as the company's legal address and registration number. 4. 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: [ ]
Address: [ ]

[Place], [Date]
No. _____

Offer

1.	**Customer**	JSC Olpha	
2.	**Customer address**	Rupnicu street 5, Olaine, Olaines district, LV-2114, Latvia	
3.	**Procurement subject**	Genotoxicity testing of drug substance impurities	
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:	Genotoxicity testing of drug substance impurities (number of impurities = 2), including for each impurity: 1) *In vivo* mammalian alkaline comet assay and *in vivo* mammalian micronucleus test on bone marrow in rats, performed as one combined GLP study (regulations: comet assay OECD 489; micronucleus test OECD 474), including: • development of a protocol; • experimental part of the study, including: - dose-range finding study (both gender); - main study (one gender; 5 groups (positive control, negative control and 3 test item dose levels); a minimum of 5 analysable animals per group); - three daily treatments (at time 0, 24 and 45 hours); - route of administration: oral by gavage; - observations of the test animals; - bone marrow sampling time: 48 hours (3 hours after last treatment);	

		- satellite group for bioanalysis (proof of absorption), (one gender, 3 animals per group (high dose)); - blood samples collection at three time points; - analysis of formulation samples at one time point; - comet assay on target organs – liver, colon and kidney; • samples analysis, evaluation of the study results and preparation of the final report. 2) Formulation analysis for *in vivo* study, including: • analytical method development (non-GLP) and analytical method validation (GLP), including: - stability testing to assure stability of the analyte in the vehicle at the intended storage conditions for the duration of use and storage; • analysis of formulation samples (GLP). 3) Bioanalysis, including: • bioanalytical method development (non-GLP) and bioanalytical method validation (GLP), including: - stability testing to assure that concentration of the analyte is not affected during sample preparation, processing, analysis and the storage conditions used; • analysis of biosamples (GLP). 4) Study documents archiving.	
7.	**Criteria for selection of offers**		
7.1.	Applicant's experience	1. Applicant has sufficient experience in conducting the genotoxicity testing (*in vivo* mammalian alkaline comet assay and micronucleus test on bone marrow in rats), analytical and bioanalytical method development and validation, formulation and biosamples analysis. 2. Applicant is eligible to carry out the *in vivo* studies in accordance with legislation on the protection of	

		animals used for scientific purposes or their equivalent.	
7.2.	Applicant´s resources	1. Applicant has appropriate scientific staff. 2. Applicant has the necessary technical equipment to carry out the work in accordance with requirements of the present procurement subject.	
7.3.	Final date of provision of work	Final date of provision of work will be confirmed mutually with the chosen applicant. The conditions will be set in agreement and study protocol.	
7.4.	Amount of work	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 separately for each specific activity according to the section 1 "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.	Applicable documents to the offer	1. Details of the genotoxicity study design, analytical and bioanalytical method development and validation, formulation and biosamples analysis. 2. Copy of documents verifying the applicant's legal status.	

[Company Name]
[Position] _____ [Signature, Name, Surname]