Individual contract IBA2016-1

for biostatistics and medical writing services for the trial no. PALIP3ZG16EU

04 August 2016

between

SanaClis s.r.o.
Lermontovova 10,
81103, Bratislava, Slovakia
ICO: 35 804 084
DIC: 2021558143
IC DPH: SK2021558143

(hereinafter referred to as "SanaClis")

and

Masarykova univerzita
Žerotínovo nám. 617/9, 601 77 Brno, Czech Republic
IC: 00216224
DIC: CZ00216224
DIC DPH: CZ00216224
Department: Institut biostatistiky a analýz
Kamenice 126/3, 625 00 Brno, Czech Republic
Represented by: doc. RNDr. Ladislav Dusek, Ph.D., Director

(hereinafter referred to as "Contractor")

composed according to Section 1.2 of Framework agreement dated 05 Feb 2014 between SanaClis and Contractor.

Subject

This Agreement shall apply to execution of the services and operation of biostatistics and medical writing for the trial no. PALIP3ZG16EU: **AN OPEN-LABEL, RANDOMIZED, TWO-WAY CROSSOVER, MULTIPLE-DOSE COMPARATIVE BIOAVAILABILITY STUDY OF TWO FORMULATIONS OF INTRAMUSCULARLY ADMINISTERED PALIPERIDONE PROLONGED RELEASE SUSPENSION FOR INJECTION**

Scope of the services:

1. Study documents:
   - Review of the Clinical trial protocol
2. Programming and statistics:
   - Clinical outputs (analytic reports)
   - Statistical analysis plan (SAP) - general definition, protocol deviations, endpoints, descriptions of statistical methods, specification of statistical outputs
3. Data management – review and approval of:
   - Data Management Plan
   - Case Report Forms
   - Study Database Design
   - Edit Checks Specification
   - Data Entry Guidelines
   - Review the data and authorize Database Lock
   - Review & Authorize Data Transfer Specifications
4. Study closure activities:
   - Clinical study report (CSR)

Detailed description of the required services:

All the documents related to Data management mentioned in section 3 of the section "**Scope of the services**" should be created by SanaClis Data management team and approved by Contractor. Contractor has to check that SanaClis approach to data collection is right and would allow Contractor to perform the bio-analysis based on the collected data.

Contractor is responsible for:

- Review the data and authorize Database Lock
- Review & Authorize Data Transfer Specifications

Contractor should also verify the Test Data Transfer and acknowledge that the transferred data is complete, properly formatted and analyzable. This should be done prior to go-live with eCRFs.

For provision of biostatistics services the Contractor should:

1. Allocate personnel responsible for carrying out the Services listed in the Scope of the services. The name of the manager of the Contractor Trial Team and the names of the key functions in the Contractor Trial Team to whom all urgent matters can be referred (as well as any replacement therefor) shall be submitted in writing to SanaClis prior to the commencement of the Services. CVs of key team members (Biostatistician, Senior Biostatistician, Medical Writer) should be provided to SanaClis.
2. Set-up analysis plans with selection of appropriate statistical methods.
3. Perform analysis of trial data according to analysis plans previously developed by the contractor. The outputs to be delivered in the form of summary tables, graphs and listings with results of the analyses performed.
4. Use licensed Software and maintain applicable licenses throughout the study
5. The Services listed in the Scope of the services should be performed according to applicable local and international laws (International Conference on Harmonization (ICH) of Technical Requirements for Registration of Pharmaceuticals for Human Use, Statistical Principles for Clinical Trials (E9), ICH General Considerations for Clinical Trials (E8), etc

Dates to be adhered to

	Critical Deadline *	Comments
Final Protocol available	01-May-2016	
1st submission done	12-May-2016	
Study duration	01-Jul-2016- 01-Nov-2017	
Final SAP	one week before DBL	
Database Lock	30-Nov-2017	
Final analysis ver. 1	up to 4 weeks after DBL 31Dec2017	Provided all final data are available at DBL (including external data)
Final analysis ver. 2	up to 2 weeks after sponsor's review 31-Jan-2018	
First draft of Clinical Trial Report	up to 1 month after final analysis ver. 2 28-Feb-2018	
Final Clinical Trial Report	up to 2 weeks after sponsor's review 31-Mar-2018	IBA is responsible for body of CTR and relevant statistical appendices. Final CTR will complete SanaClis (including all appendices)

* Note: all critical deadlines are approximate, relative time intervals are binding. Week equals five working days.

Workload & Costs

ACTIVITIES	Number of units	Unit	Unit Cost, EUR	Total Cost, EUR
STUDY DOCUMENTS				**222.50**
PROTOCOL	5	hour	44.5	222.50
PROGRAMMING AND STATISTICS				**13,200.00**
PROGRAMMING AND STATISTICS - maximum 30 unique tables, 25 unique listings and 3 unique figures	80	hour	48.0	3,840.00
CLINICAL OUTPUTS	155	hour	48.0	7,440.00
SAP - IBA template and layout of outputs will be used	40	hour	48.0	1,920.00
DATA MANAGEMENT				**1344.00**
Review and approval of: - Listed documents - Review the data and authorize Database Lock - Review & Authorize Data Transfer Specifications	28	hour	48.0	1344.00
STUDY CLOSURE ACTIVITIES				**6,604.00**
CLINICAL STUDY REPORT (CSR)	Assumption of 40h of PM + 30h of ME + 8h of SA	hour	44.5/PM 148/ME 48/SA	6,604.00

TOTAL	**21,370.50**

Conditions and issuing of invoices

The actual provision of prescribed services shall be described in the Billing Tracker (hereinafter, BT), which shall include the amounts defined in Section "Workload & Costs" of this Agreement. BT will be sent by Contractor to SanaClis along with an invoice. Contractor shall issue an Invoice once services are finished and delivered to the SanaClis. The Invoice shall include a list of services rendered for the relevant period.

Payment shall be made by a wire transfer to the bank account of Contractor indicated in Section "Bank details" of this Agreement within thirty (30) business days after acceptance or partial acceptance (acceptance regarding industrial services is defined in the section 6 of the Framework agreement dated 05 Feb 2014 between SanaClis and Contractor). If the receipt of the relevant invoice occurs after the acceptance date, the running of the 30-day period shall commence upon the receipt of the invoice by SanaClis from Contractor.

The payment made by SanaClis on invoices shall be deemed effective upon receipt of the relevant monetary funds in the bank account of Contractor.

All invoices issued by Contractor to SanaClis shall be in the euro (sign: €; code: EUR). "SHA" instructions by international wire transfer shall apply.

Contractor agrees, that sums above mentioned include all applicable taxes which have to be paid in accordance with actual legislation. Contractor is entitled to input tax and issue a proper invoice.

Duration of the contract

This Agreement shall come into effect when signed and sealed by the Parties.

Except for early termination by either Party or by mutual agreement, the Agreement shall be valid until Provision of Final Study Report, unless the term of the Agreement is continued on SanaClis's initiative, which should be confirmed by a written notice sent to Contractor before the expiry of the Agreement.

Final provisions

This Agreement is executed in 2 (two) copies in English.

Any amendments in the provisions of this Agreement shall be made by the Parties' mutual consent and shall be executed as an addendum hereto. Accordingly, the Addenda executed and signed by the Parties hereto shall constitute an integral part of this Agreement.

This Individual contract shall apply to Framework agreement dated 05 Feb 2014 between SanaClis and Contractor and does not contain any statements contrary to Framework agreement.

Bank details

Bank title: xxxxxxxxxxxx
Bank address: xxxxxxxxxxxx
IBAN: xxxxxxxxxxxxxxxx
SWIFT: xxxxxxxxxxxxxx
Bank account №: xxxxxxxxxxxxxxx

In case of changes in the bank details, Contractor is obliged to inform SanaClis in 15 (fifteen) banking days term from the moment when such changes come in force, by sending a written notification. Parties agree that in case of any changes in bank details of the Contractor, addendum to this Contract will be issued.

Signatures of the parties

SanaClis s.r.o.

Address: Lermontovova 10, Bratislava, 81103 Slovakia

Ing. Arch. Juraj Fecanin
Chief Executive Officer

Date_____

Signature_____

Masarykova univerzita
Address: Žerotínovo náměstí 617/9, 601 77 Brno, Czech Republic
Institut biostatistiky a analýz
Department: Kamenice 3, 625 00 Brno, Czech Republic

doc. RNDr. Ladislav Dušek, Ph.D.
Director

Date_____

Signature_____