

Netherlands-Maarssen: Health services
OJ S 114/2020 15/06/2020
Contract notice
Services

Legal Basis:

Directive 2014/24/EU

Section I: Contracting authority

I.1. Name and addresses

Official name: CR2O B.V.
Postal address: Bisonspoor 3002-C701
Town: Maarssen
NUTS code: NL310 Utrecht
Postal code: 3605 LT
Country: Netherlands
Contact person: Nick van den Bulk
E-mail: nick.vandenbulk@cr2o.nl
Telephone: +31 850717450
Internet address(es):
Main address: www.cr2o.nl

I.2. Information about joint procurement

The contract is awarded by a central purchasing body

I.3. Communication

Access to the procurement documents is restricted. Further information can be obtained at:
www.cr2o.nl
Additional information can be obtained from the abovementioned address
Tenders or requests to participate must be submitted to the abovementioned address

I.4. Type of the contracting authority

Other type: Privately owned company

I.5. Main activity

Health

Section II: Object

II.1. Scope of the procurement

II.1.1. Title

GMP Manufacturing of Monoclonal Antibodies (IMP) using Transient and Stable CHO Expression Systems for Pre-clinical and Clinical Phase I Study (MANCO)

II.1.2. Main CPV code

85100000 Health services

II.1.3. Type of contract

Services

II.1.4. Short description

The MANCO consortium is developing monoclonal antibodies against 2019-nCoV. CR2O is a partner within this consortium and responsible for the clinical operations. For pre-clinical and clinical Phase I study we require a GMP manufacturing company for the production of monoclonal antibodies (IMP) using transient and stable CHO expression systems.

II.1.5. Estimated total value

II.1.6. Information about lots

This contract is divided into lots: no

II.2. Description

II.2.3. Place of performance

NUTS code: NL310 Utrecht

II.2.4. Description of the procurement

The procurement includes the following:

- vector construction will be outsourced to a third-party laboratory (CHO cells should be provided);
- selected clone will be transferred directly to 10 L scale bioreactor systems via standard fed-batch and purification process with process recoveries of 20-40 %;
- performance of two 10 L bioreactor runs;
- purification at the end of culture or moment of harvest (clarification, UF/DF, two or three chromatography steps (anion exchange, cation exchange, Size exclusion), low pH treatment, virus filtration and a final filtration step;
- QC testing for the purpose of process monitoring (IPC) and GMP release (mAb quantification by Prot A analysis, SDS-PAGE (reduced and non-reduced), Host Cell DNA quantification by qPCR, Host Cell Protein quantification by ELISA, Isoelectric point confirmation (Isoelectric Focusing), Charge variant distribution by HP-CEX, Glycan mapping, pH, Osmolality (buffers used), Sterility, Mycoplasma, Endotoxin);
- scale-up the process to 50 L scale in GMP (no engineering run will be performed);
- prepare required GMP documentation (process description, Bill of Materials (BOM), Bill of Equipment (BOE), Bill of Testing (BOT) and the Drug substance (USP and DSP) batch production records (MPRs));
- Master Cell Bank (MCB) at > 1 x 10⁶ cell/vials (testing to be performed, like sterility, mycoplasma and cell recovery after thawing);
- QC testing (described above);
- certificate of analysis will be prepared and QP will perform the batch disposition;
- Max. 200 vials drug product and max. 100 vials of the MCB;
- each process step will be documented in a study plan and report.

II.2.5. Award criteria

Price is not the only award criterion and all criteria are stated only in the procurement documents

II.2.6. Estimated value

II.2.7. Duration of the contract, framework agreement or dynamic purchasing system

Duration in months: 10

This contract is subject to renewal: no

II.2.10.

Information about variants

Variants will be accepted: yes

II.2.11. Information about options

Options: no

II.2.12. Information about electronic catalogues

Tenders must be presented in the form of electronic catalogues or include an electronic catalogue

II.2.13. Information about European Union funds

The procurement is related to a project and/or programme financed by European Union funds:
yes

Identification of the project: The Manco study is funded by Horizon 2020.

II.2.14. Additional information

Section III: Legal, economic, financial and technical information

III.1. Conditions for participation

III.1.2. Economic and financial standing

Selection criteria as stated in the procurement documents

III.1.3. Technical and professional ability

Selection criteria as stated in the procurement documents

III.2. Conditions related to the contract

III.2.3. Information about staff responsible for the performance of the contract

Obligation to indicate the names and professional qualifications of the staff assigned to performing the contract

Section IV: Procedure

IV.1. Description

IV.1.1. Type of procedure

Open procedure Accelerated procedure Justification:

As the project was already started, an accelerated selection procedure is required.

IV.1.3. Information about a framework agreement or a dynamic purchasing system

The procurement involves the establishment of a framework agreement

Framework agreement with a single operator

IV.1.8. Information about the Government Procurement Agreement (GPA)

The procurement is covered by the Government Procurement Agreement: no

IV.2. Administrative information

IV.2.2. Time limit for receipt of tenders or requests to participate

Date: 23/06/2020 Local time: 23:59

IV.2.3. Estimated date of dispatch of invitations to tender or to participate to selected candidates

IV.2.4. Languages in which tenders or requests to participate may be submitted

English, Dutch

IV.2.6. Minimum time frame during which the tenderer must maintain the tender

Tender must be valid until: 31/07/2020

IV.2.7. Conditions for opening of tenders

Date: 26/06/2020 Local time: 23:59

Place:

Maarsse.

Information about authorised persons and opening procedure: Tenders are open for application and will be addressed by Bart Hendriks.

Section VI: Complementary information

VI.1. Information about recurrence

This is a recurrent procurement: no

VI.2. Information about electronic workflows

Electronic invoicing will be accepted

Electronic payment will be used

VI.3. Additional information

VI.4. Procedures for review

VI.4.1. Review body

Official name: Bart Hendriks

Postal address: Bisonspoor 3002-C701

Town: Maarsse

Postal code: 3605 LT

Country: Netherlands

E-mail: bart.hendriks@cr2o.nl

VI.4.3. Review procedure

Precise information on deadline(s) for review procedures:

Review will be completed before 23 Jun 2020.

VI.5. Date of dispatch of this notice

11/06/2020