Tender

Provision of Fasudil Hydrochloride Capsules

University of Exeter

F02: Contract notice
Notice identifier: 2021/S 000-016582
Procurement identifier (OCID): ocds-h6vhtk-02c838
Published 15 July 2021, 11:08am

Section I: Contracting authority

I.1) Name and addresses

University of Exeter

Northcote House

Exeter

EX4 4QH

Contact

Jodie Underhay

Email

j.underhay@exeter.ac.uk

Country

United Kingdom

NUTS code

UKK4 - Devon

National registration number

RC000653

Internet address(es)

Main address

http://www.exeter.ac.uk

Buyer's address

https://uk.eu-supply.com/ctm/Company/CompanyInformation/Index/53042

I.3) Communication

The procurement documents are available for unrestricted and full direct access, free of charge, at

https://uk.eu-supply.com/app/rfq/rwlentrance_s.asp?PID=38809&B=EXETER

Additional information can be obtained from the above-mentioned address

Tenders or requests to participate must be submitted electronically via

https://uk.eu-supply.com/app/rfq/rwlentrance_s.asp?PID=38809&B=EXETER

Tenders or requests to participate must be submitted to the above-mentioned address

I.4) Type of the contracting authority

Body governed by public law

I.5) Main activity

Education

Section II: Object

II.1) Scope of the procurement

II.1.1) Title

Provision of Fasudil Hydrochloride Capsules

Reference number

UOE/2021/046/JU

II.1.2) Main CPV code

- 33000000 - Medical equipments, pharmaceuticals and personal care products

II.1.3) Type of contract

Supplies

II.1.4) Short description

The University of Exeter requires an end-to-end solution for Fasudil Hydrochloride Capsules. The product will be used as clinical supply for a Phase IIa study. The clinical trial will likely be conducted in the USA and/or Europe (United Kingdom and Norway), therefore all formulation components and finished product must meet the regulatory requirements of USP/EP/BP and any required Norwegian pharmacopeia standards. The supplier must also comply with Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP) and ensure that all supplies are released for clinical use by a duly certified Quality Person (QP).

II.1.5) Estimated total value

Value excluding VAT: £500,000

II.1.6) Information about lots

This contract is divided into lots: No

II.2) Description

II.2.2) Additional CPV code(s)

- 33000000 - Medical equipments, pharmaceuticals and personal care products

II.2.3) Place of performance

NUTS codes

- UKK4 - Devon

II.2.4) Description of the procurement

The University of Exeter requires an end-to-end solution for Fasudil Hydrochloride Capsules. The product will be used as clinical supply for a Phase IIa study. The clinical trial will likely be conducted in the USA and/or Europe (United Kingdom and Norway), therefore all formulation components and finished product must meet the regulatory requirements of USP/EP/BP and any required Norwegian pharmacopeia standards. The supplier must also comply with Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP) and ensure that all supplies are released for clinical use by a duly certified Quality Person (QP).

The supplier will undertake an evaluation of 3rd party suppliers for the procurement of the Drug Substance (DS) Fasudil Hydrochloride. It is anticipated that approximately 8.5kg of DS will be required for use in Drug Product development and manufacturing activities. This includes approximately 1kg DS for non-GMP activities and 7.5kg DS for GMP activities related to the project.

The supplier will perform development activities in order to establish suitable capsule formulations for 20mg and 40mg active dose strengths and matching placebo. These development activities will include the manufacture of up to six development batches at a batch size of approximately 750g -1.5kg. The lead and back-up formulations will be subjected to a short-term stability evaluation. The purpose of this effort is to manufacture sufficient supplies of prototypes to illustrate the likely process for clinical supply, and to prepare samples for accelerated stability testing so that suitable formulations of active and placebo tablets can be identified.

To fulfil clinical supply, the CTM active and placebo batches will be manufactured in three separate campaigns.

First Campaign:

one CTM Placebo batch at approximately 43,000 units

one CTM Active 20mg dose strength batch at 6,000 units

one CTM Active 40mg strength batch at approximately 40,000 units

Second campaign:

one CTM Placebo batch at approximately 43,000 units

one CTM Active batch at approximately 40,000 units

Third campaign:

one CTM Placebo batch at approximately 43,000 units

one CTM Active batch at approximately 40,000 units

Each CTM batch will be bulk packaged, labelled (in English and Norwegian) and shipped to enable delivery of the final QP released batches to the locations requested by Client (anticipated to be in the UK and Norway, 3 or 4 sites in total). The supplier will be responsible for any customs clearance required. The supplier will be required to provide all necessary supporting services including, but not limited to, sourcing materials and the active pharmaceutical ingredient/drug substance, production, storage, labelling, packaging, quality control, qualified person release, packing, transport, loading/unloading, import/export, delivery and waste disposal.

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

Value excluding VAT: £500,000

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

Duration in months

18

This contract is subject to renewal

No

II.2.10) Information about variants

Variants will be accepted: No

II.2.11) Information about options

Options: No

II.2.13) Information about European Union Funds

The procurement is related to a project and/or programme financed by European Union funds: No

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

Section IV. Procedure

IV.1) Description

IV.1.1) Type of procedure

Open procedure

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

The procurement is covered by the Government Procurement Agreement: Yes

IV.2) Administrative information

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

Date

16 August 2021

Local time

12:00pm

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

English

IV.2.7) Conditions for opening of tenders

Date

16 August 2021

Local time

12:00pm

Section VI. Complementary information

VI.1) Information about recurrence

This is a recurrent procurement: No

VI.4) Procedures for review

VI.4.1) Review body

Royal Courts of Justice

London

Country

United Kingdom