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Tender

Batch manufacture of high titer/titre GMP (U.S.A.) compliant lentiviral vector for FDA approval

University Of Edinburgh

F02: Contract notice

Notice identifier: 2025/S 000-044163

Procurement identifier (OCID): ocds-h6vhtk-0568ca

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Section I: Contracting authority

I.1) Name and addresses

University Of Edinburgh

Charles Stewart House, 9-16 Chambers Street

Edinburgh

EH1 1HT

Email

jpik2@ed.ac.uk

Telephone

+44 1316502759

Country

United Kingdom

NUTS code

UKM75 - Edinburgh, City of

Internet address(es)

Main address

<http://www.ed.ac.uk>

Buyer's address

https://www.publiccontractsscotland.gov.uk/search/Search_AuthProfile.aspx?ID=AA00107

I.2) Information about joint procurement

The contract is awarded by a central purchasing body

I.3) Communication

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

<https://www.publictendersscotland.publiccontractsscotland.gov.uk/>

Additional information can be obtained from the above-mentioned address

Tenders or requests to participate must be submitted electronically via

<https://www.publictendersscotland.publiccontractsscotland.gov.uk/>

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

Batch manufacture of high titer/titre GMP (U.S.A.) compliant lentiviral vector for FDA approval

II.1.2) Main CPV code

- 85121200 - Medical specialist services

II.1.3) Type of contract

Services

II.1.4) Short description

We are planning a phase I/II clinical trial to treat a rare genetic disease that causes progressive dementia in children. Our therapy will use autologous CD34+ haematopoietic stem progenitor cells (HSPCs) which are modified ex vivo with LVV to express supraphysiologic levels of a secreted enzyme.

In order to progress this therapy, we require a high titre LVV produced to good manufacturing practice (GMP) standard. The supplier must have extensive previous experience manufacturing LVVs to this specification which have achieved regulatory approval for phase I/II clinical trials, ideally for use in human CD34+ HSPC transduction.

The QC defined must be performed in compliance with FDA regulations. The product of the initial delivery will be delivered directly to the University of California, LA, USA.

Note that throughout the document the British spelling 'Titre' has been used; this is analogous to the American English term 'Titer' and the spellings may be used interchangeably.

The University anticipates initially awarding for;

- Manufacture of concentrated lentiviral vector (LVV) from a 30L viral harvest
- Such award to include any warranties on quality, product replacement (for spoilage), transport, and other supplier project costs such as (but not limited to) quality control testing and audit.

The cost estimate of the procurement reflects the anticipated cost of the initial requirement plus contingency, for (for example but not limited to), 1. Scope extension, 2. Additional ad-hoc delivery to support further trials.

The time frame of the agreement – 3 years, reflects an initial delivery period expected to be no longer than 12 months post signature, and the option to buy additional deliveries for two years thereafter. The University may award additional deliveries to the awarded supplier via the Negotiated Procedure Without Prior Call for Competition.

For transparency we have a budget appetite of approximately USD560k for the delivery of the initial services. We may review this estimate from time to time.

Having posted this notice we reserve the right to repost any subsequent notice (including if the ultimate procurement procedure is re-run) under reduced timescales as set out in the regulations.

II.1.5) Estimated total value

Value excluding VAT: £900,000

II.1.6) Information about lots

This contract is divided into lots: No

II.2) Description

II.2.3) Place of performance

NUTS codes

- UKM75 - Edinburgh, City of
- US - United States

Main site or place of performance

Product is to be delivered to University of California, Los Angeles, U.S.A.

Contracting party University of Edinburgh is in Edinburgh, Scotland, UK.

II.2.4) Description of the procurement

See procurement documentation for all un-abridged description.

DEFINITIONS

FDA is the U.S Food and Drug Administration (FDA); the regulator for new clinical drugs

GMP means 'Good Manufacturing Practice'; U.S.A.

IND is an "Investigational New Drug Application"; a request to the FDA to be permitted to administer a new prototype drug on human patients for research purposes

Lentiviral vector (LVV) is a type of virus (retrovirus) that inserts its DNA into the cells of the organism/person it infects.

Plasmid is a small DNA molecule which stores non-chromosomal DNA.

Must-have capabilities

- Able to produce a 30L harvest of unconcentrated LVV-containing supernatant following transduction of 293T cells from a certified Master Cell Bank with genome and packaging plasmids supplied by the University
- Able to concentrate this supernatant by a factor of approx. 100-200x to produce a concentrated high titre LVV
- The supplier must have extensive prior experience of such manufacture and have achieved numerous regulatory approvals for use of their LVV products in phase I/II clinical trials. This is critical to ensure there is confidence that the supplier product will be acceptable and well-received for regulatory approval.
 - o 10 years prior experience of manufacturing GMP-compliant LVV products
 - o Achieved minimum of 50 prior regulatory approvals (ideally FDA) of GMP-compliant LVV products
- Supplier should follow all relevant legislation applicable to this engagement including in their location/s of manufacture, and the State of California, USA
- The supplier should demonstrate a manufacturing process which is compliant with GMP and that gives high confidence of their ability to deliver a high quality, compliant, product.
- For the purposes of greater transparency, collaboration and regulatory traceability and accountability we require a direct relationship with the manufacturing entity/lead and therefore bids proposed by an entity acting solely as a reseller/distributor will unfortunately not be acceptable for this requirement. It is our expectation that the bidder undertakes the manufacturing; however other functions like Quality Control may be undertaken by subcontractors providing that the bidder takes full ultimate responsibility for delivery of the contract.

- The supplier should demonstrate a reasonable and practicable solution for logistical delivery of the product.
- For transparency we have a budget appetite of approximately USD560k for the delivery of the initial services. We may review this estimate from time to time.

Desirable criteria

- It is desirable that the supplier can complete end to end delivery of initial requirement (including manufacture, quality control and regulatory pack preparation), within 12 months or faster from contract signature. Fast delivery times are desirable for the project.
- It is desirable that the supplier takes full accountability for the transport of the product from the site of manufacture to UCLA.

Quality control ('QC');

This will require comprehensive GMP compliance QC to be performed:

Supplier will be required to provide details of the GMP-compliant manufacturing process

Intellectual property

For avoidance of doubt; the intellectual property ("IP") the University provides during the project in relation to the product specification will remain vested in the University and its licensors and nothing in the awarded contract shall constitute granting a license, creating a joint endeavour, creating joint IP, or otherwise constituting a license or transfer of IP to the Supplier, that would entitle the Supplier to take any action utilising that IP beyond the bounds of the Services which will be agreed between the University and Supplier pursuant of this tender.

II.2.5) Award criteria

Quality criterion - Name: Suitability to fulfil requirement / Weighting: 50

Cost criterion - Name: Total cost / Weighting: 50

II.2.6) Estimated value

Value excluding VAT: £900,000

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

Duration in months

36

This contract is subject to renewal

No

II.2.9) Information about the limits on the number of candidates to be invited

Envisaged minimum number: 3

Objective criteria for choosing the limited number of candidates:

Any tenderer who passes the SPD and fulfils the minimum technical criteria may complete their ITT

II.2.10) Information about variants

Variants will be accepted: No

II.2.11) Information about options

Options: Yes

Description of options

The time frame of the agreement – 3 years, reflects an initial delivery period expected to be no longer than 12 months post signature, and the option to buy additional deliveries for two years thereafter. The University may award additional deliveries to the awarded supplier via the Negotiated Procedure Without Prior Call for Competition.

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.1.1) Suitability to pursue the professional activity, including requirements relating to enrolment on professional or trade registers

List and brief description of conditions

Supplier must operate in a fashion compliant with USA GMP and be familiar with FDA approvals, having a significant prior record of successful lentiviral vector manufacture (10 years preferred) and regulatory (FDA preferred) approvals (50+ preferred).

III.1.2) Economic and financial standing

List and brief description of selection criteria

Should provide adequate confidence the supplier has required financial standing to fulfill the engagement.

Further requirement as set out in the procurement documentation

III.1.3) Technical and professional ability

Selection criteria as stated in the procurement documents

III.2) Conditions related to the contract

III.2.2) Contract performance conditions

Supplier shall be required to progress the contract in line with any agreed terms and quality criteria. Supplier to conduct themselves fully in line with the regulations and laws of their operational territory and in compliance with the laws of the State of California

Section IV. Procedure

IV.1) Description

IV.1.1) Type of procedure

Competitive procedure with negotiation

IV.1.4) Information about reduction of the number of solutions or tenders during negotiation or dialogue

Recourse to staged procedure to gradually reduce the number of solutions to be discussed or tenders to be negotiated

IV.1.5) Information about negotiation

The contracting authority reserves the right to award the contract on the basis of the initial tenders without conducting negotiations

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

1 September 2025

Local time

12:00pm

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

1 September 2025

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

English

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

Duration in months: 4 (from the date stated for receipt of tender)

Section VI. Complementary information

VI.1) Information about recurrence

This is a recurrent procurement: No

VI.2) Information about electronic workflows

Electronic ordering will be used

Electronic invoicing will be accepted

Electronic payment will be used

VI.3) Additional information

Any supplier who wishes to participate should enrol on PCST and complete their tender (including Qualification, Technical and Commercial) by the prescribed deadline).

We encourage all suppliers to carefully read the specification; consider their prior experience, and whether they can substantially meet the cost appetite set out prior to tendering.

In the event a supplier does not pass Qualification evaluation the University may elect to not review the rest of their bid.

The buyer is using PCS-Tender to conduct this ITT exercise. The Project code is 29817. For more information see:

<http://www.publiccontractsscotland.gov.uk/info/InfoCentre.aspx?ID=2343>

Community benefits are included in this requirement. For more information see:

<https://www.gov.scot/policies/public-sector-procurement/community-benefits-in-procurement/>

A summary of the expected community benefits has been provided as follows:

We encourage suppliers to make an offer however we recognise business norms differ by region and this may not always be possible. Suppliers who wish to consider social value as part of their tender may review options for doing so in Schedule 9B of the procurement documentation.

(SC Ref:805770)

VI.4) Procedures for review

VI.4.1) Review body

Edinburgh Sheriff Court

Edinburgh

Country

United Kingdom