Planning

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

University Of Edinburgh

F01: Prior information notice
Reducing time limits for receipt of tenders
Notice identifier: 2025/S 000-043991
Procurement identifier (OCID): ocds-h6vhtk-056864
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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

jpike2@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

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

Reference number

EC1057

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

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

- Supplied 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.2.6) Estimated value

Value excluding VAT: £900,000

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

Duration in months

36

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

II.3) Estimated date of publication of contract notice

30 July 2025

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

Should operate processes in line with USA GMP.

Should have substantial prior experience of manufacturing lentiviral vectors with 10 years preferred, and substantial experience of achieving regulatory (FDA preferred) approvals of lentiviral vectors.

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.2.2) 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.1.8) Information about the Government Procurement Agreement (GPA)

The procurement is covered by the Government Procurement Agreement: Yes

IV.2) Administrative information

IV.2.5) Scheduled date for start of award procedures

31 July 2025

Section VI. Complementary information

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

This PIN is raised pre-emptively and a procurement is expected to follow shortly. In the event the procurement has to be re-started for any reason the University reserves the right to raise a new procurement in line with this PIN utilising shortened timescales if permitted by the Public Contract Regulations (Scotland) 2015

NOTE: To register your interest in this notice and obtain any additional information please visit the Public Contracts Scotland Web Site at https://www.publiccontractsscotland.gov.uk/Search/Search_Switch.aspx?ID=805717.

(SC Ref:805717)

VI.4) Procedures for review

VI.4.1) Review body

Edinburgh Sheriff Court

Edinburgh

Country

United Kingdom