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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

Published 29 July 2025, 4:23pm

### **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](mailto: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](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

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## **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

- 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.2.6) Estimated value**

Value excluding VAT: £900,000

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

Duration in months

### **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

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## **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

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## **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

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## **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](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