STATEMENT OF NEED (SON)

<u>Instructions:</u> This document should be used for the acquisition of PRODUCTS. Instructions for completion are in red, and should be excluded in the completed document.

1.0 TITLE

Lonza 4D nucleofector

2.0 BACKGROUND

Due to the ongoing clinical development of GPC3, GPC2 and mesothelin targeted CAR T cell therapies in the NIH Clinical Center, we urgently need to purchase a nucleofector for transfecting patient T cells with various optimized CAR constructs. The new instrument will allow us to quickly produce CAR T cells, which are reported to have high transfection efficiency, high cell viability, low non-specific T cell tonic signaling, and low exhaustion and improved functional/stemness of T cells. Additionally, it does not need the production of lentivirus, therefore avoiding the batch-to-batch variations of lentivirus titers and quality.

3.0 TYPE OF ORDER

This is a Firm Fixed-Price Purchase Order.

4.0 SPECIAL ORDER REQUIREMENTS

4.1 PRODUCT FEATURES/SALIENT CHARACTERISTICS

The CCR has approved the clinical trial using CAR T cells targeting GPC3 for treating liver cancer developed in our lab. We submitted an IND to the FDA in February 2021 with our clinical collaborator Tim Greten. The trial will likely start in 2021. In addition, the Cancer Moonshot Program and CCR Center for Cell-based Therapy approved our clinical trial proposals for CAR T cells targeting GPC2 and mesothelin for treating neuroblastoma and mesothelioma, respectively. We plan to submit an IND in 2021 with clinical collaborators Rosie Kaplan and Raffit Hassan. To this end, we hope to quickly test multiple engineered CAR plasmids for the humanization of Fv and the optimization of hinge/transmembrane domains. Using genome editing, we are also collaborating with CCR Genome Modification Core to compare off-the-shelf (allogenic) vs patient specific (autologous) CAR T cells for clinical development. In addition, we have established T cell stemness markers before and after transduction of our CAR constructs and hope to enrich for T cell stemness markers for more effective CAR T cell manufacturing. The Lonza 4D nucleofector will allow us to quickly produce CAR T cells using primary patient cells, which may have high transfection efficiency, high cell viability after transfection, low non-specific T cell tonic signaling, low exhaustion and improved function/stemness of T cells, without the need to produce lentivirus to avoid batch-to-batch variations of lentivirus titers and quality. We may also use this equipment to design new non-viral delivery (e.g., RNA) of CAR T or NK cells in the future. There is no equipment budget in any of our three CAR clinical development projects. Therefore, we are now requesting to purchase a Lonza 4D nucleofector. It is the only basic model that is comparable with an advanced GMP grade model (Maxcyte GT)

that is currently used in the product development core at the Center for Cellular Engineering for clinical trials at the NIH Clinical Center. The space has been identified in the current lab space Bldg 37 Room 5002. The equipment will be shared with all our collaborator labs including Hassan, Greten, Thiele, Kaplan, Pastan and Khan.

The following product features/characteristics are required for this requirement:

- Lonza 4D nucleofector

4.2 DELIVERY / INSTALLATION

POC: Jessica Hong (240-760-7851; bldg. 37 room 5002)
Delivery and installation Location: NIH, 37 Convent Dr. bldg. 37 room 5002, Bethesda MD 20892

4.3 TRAINING

Training will be provided upon installation for several key personnel in the lab (biologist, staff scientist, postdoc fellows)

5.0 PAYMENT

Payment shall be made once. Payment authorization requires submission and approval of invoices to the COR and NIH OFM, in accordance with the payment provisions listed below:

The following clause is applicable to all Purchase Orders, Task or Delivery Orders, and Blanket Purchase Agreement (BPA) Calls: PROMPT PAYMENT (JUL 2013) FAR 52.232-25. Highlights of this clause and NIH implementation requirements follow:

I INVOICE REQUIREMENTS

A. An invoice is the Contractor's bill or written request for payment under the contract for supplies delivered or services performed. A proper invoice is an "Original" which must include the items listed in subdivisions 1 through 12, below, in addition to the requirements of FAR 32.9. If the invoice does not comply with these requirements, the Contractor will be notified of the defect within 7 days after the date the designated billing office received the invoice (3 days for meat, meat food products, or fish, and 5 days for perishable agricultural commodities, dairy products, edible fats or oils) with a statement of the reasons why it is not a proper invoice. (See exceptions under II., below.) Untimely notification will be taken into account in the computation of any interest penalty owed the Contractor.

    1. Vendor/Contractor: Name, Address, Point of Contact for the invoice (Name, title, telephone number, e-mail and mailing address of point of contact).
    2. Remit-to address (Name and complete mailing address to send payment).
    3. Remittance name must match exactly with name on original order/contract. If the Remittance name differs from the Legal Business Name, then both names must appear on the invoice.
    4. Invoice date.
    5. Unique invoice #s for all invoices per vendor regardless of site.

6. NBS document number formats must be included for awards created in the NBS: Contract Number; Purchase Order Number; Task or Delivery Order Number and Source Award Number (e.g., Indefinite Delivery Contract number; General Services Administration number); or, BPA Call Number and BPA Parent Award Number.
7. Data Universal Numbering System (DUNS) or DUNS + 4 as registered in the Central Contractor Registration (CCR).
8. Federal Taxpayer Identification Number (TIN). In those exceptional cases where a contractor does not have a DUNS number or TIN, a Vendor Identification Number (VIN) must be referenced on the invoice. The VIN is the number that appears after the contractor's name on the face page of the award document.
9. Identify that payment is to be made using a three-way match.
10. Description of supplies/services that match the description on the award, by line billed.*
11. Freight or delivery charge must be billed as shown on the award. If it is included in the item price do not bill it separately. If identified in the award as a separate line item, it must be billed separately.
12. Quantity, Unit of Measure, Unit Price, Extended Price of supplies delivered or services performed, as applicable, and that match the line items specified in the award.*

* NOTE: If your invoice must differ from the line items on the award, please contact the Contracting Officer before submitting the invoice. A modification to the order or contract may be needed before the invoice can be submitted and paid.

B. Shipping costs will be reimbursed only if authorized by the Contract/Purchase Order. If authorized, shipping costs must be itemized. Where shipping costs exceed $100, the invoice must be supported by a bill of lading or a paid carrier's receipt.

C. Mail an original and 1 copy of the itemized invoice to:

National Institutes of Health
Office of Financial Management, Commercial Accounts
2115 East Jefferson Street, Room 4B-432, MSC 8500
Bethesda, MD 20892-8500

For inquiries regarding payment call: (301) 496-6088

In order to facilitate the prompt payment of invoices, it is recommended that the vendor submit a photocopy of the invoice to the "Consignee" designated for the acquisition in blocks 6A – 6E of the face page of the Order/Award document.

II. INVOICE PAYMENT

A. Except as indicated in paragraph B., below, the due date for making invoice payments by the designated payment office shall be the later of the following two events:

1. The 30th day after the designated billing office has received a proper invoice.
2. The 30th day after Government acceptance of supplies delivered or services performed.

B. The due date for making invoice payments for meat and meat food products, perishable agricultural commodities, dairy products, and edible fats or oils, shall be in accordance with the Prompt Payment Act, as amended.

III. INTEREST PENALTIES

A. An interest penalty shall be paid automatically, if payment is not made by the due date and the conditions listed below are met, if applicable.
   1. A proper invoice was received by the designated billing office.
   2. A receiving report or other Government documentation authorizing payment was processed and there was no disagreement over quantity, quality, or contractor compliance with a term or condition.
   3. In the case of a final invoice for any balance of funds due the contractor for supplies delivered or services performed, the amount was not subject to further settlement actions between the Government and the Contractor.

B. Determination of interest and penalties due will be made in accordance with the provisions of the Prompt Payment Act, as amended, the Contract Disputes Act, and regulations issued by the Office of Management and Budget.

IV. PROVIDING ACCELERATED PAYMENT TO SMALL BUSINESS SUBCONTRACTORS, FAR 52.232-40 (DEC 2013)

a) Upon receipt of accelerated payments from the Government, the Contractor shall make accelerated payments to its small business subcontractors under this contract, to the maximum extent practicable and prior to when such payment is otherwise required under the applicable contract or subcontract, after receipt of a proper invoice and all other required documentation from the small business subcontractor.
b) The acceleration of payments under this clause does not provide any new rights under the prompt Payment Act.

Include the substance of this clause, include this paragraph c, in all subcontracts with small business concerns, including subcontracts with small business concerns for the acquisition of commercial items.