**PERFORMANCE WORK STATEMENT (PWS)**

Pylarify – Shreveport VA PET/CT Clinic

**Introduction:**

Overton Brooks VA Medical Center (OBVAMC) requires the manufacture and delivery of F18 Pifluflostat (PYLARIFY), a radioactive diagnostic agent indicated for Positron Emission Tomography (PET) imaging of prostate-specific membrane antigen (PSMA) positive lesions in male patients with prostate cancer. PYLARIFY is indicated for patients with suspected metastasis who are candidates for initial therapy and patients with suspected recurrence based on elevated serum prostate-specific antigen (PSA) level. Contractor agrees to provide all needed F18 Pifluflostat (PYLARIFY) as identified, to the OBVAMC Nuclear Medicine department, on a daily and/or as needed basis per this PWS.

Qualifications of Quoters: Quotes will only be considered from those who are regularly involved in the business called for, and who in the judgment of the Contracting Officer are financially responsible and able to show evidence of the reliability, ability, experience, equipment, facilities and personnel directly employed or supervised by them to render prompt and satisfactory service. PYLARIFY has been FDA approved for use in PET imaging of PSMA-positive lesions in men with prostate cancer.

1. Contractor must hold a current unrevoked license by the US Nuclear Regulatory Commission (USNRC), or a State with a formal Agreement with the USNRC that allows the State to regulate radioactive materials (Licensee) and be regularly established in the business of providing radiopharmaceuticals at the scale and frequency necessary to meet this requirement. The Radiopharmaceuticals must be shipped from the Licensee directly to OBVAMC Nuclear Medicine Service. Non-manufacturing waiver is not applicable to this solicitation.
2. Contractor/licensee shall meet all applicable Nuclear Regulatory Commission, VA/National Health Physics Program (NHPP), Department of Transportation, FDA, Joint Commission, OSHA, State, and Federal requirements, rules, and/or regulations related to the supply of Radiopharmaceuticals.

***Please note that the Offeror must provide copies of all relevant licenses, certifications, and/or partnering agreement(s), along with their proposal to the Contracting Officer.***

**Requested Services:**

1. Contractor/licensee must be able to provide the required PET radiopharmaceuticals to the Overton Brooks VAMC Nuclear Medicine Service PET/CT Clinic in Shreveport, Louisiana:

Overton Brooks VA Medical Center

Attn: Nuclear Medicine Service (115)

PET/CT Clinic, Bldg 1, 7th Floor, Room 7N9B

510 East Stoner Avenue

Shreveport, LA 71101

1. Delivery of F18 Pifluflostat (PYLARIFY) unit doses, necessary for the diagnostic PET/CT imaging of prostate-specific membrane antigen (PSMA) positive lesions in male patients with prostate cancer. Contractor/licensee shall have available an adequate supply of contracted products to meet the requirements of OBVAMC with proof of contingency supply chain to prevent disruption of clinical care. Doses will be ordered/scheduled with at least 24 hours advance notice to the vendor. Should the vendor’s ability to supply product from the applicable pharmacy be limited for any reason the vendor shall notify the Customer of any limitations on the delivery times and dates that may affect its ability to supply Product when requested.

*\*\*In the event local radiopharmacies are unable to provide delivery of PET radiopharmaceuticals, Contractor shall provide NMS a contingency plan for other locations to deliver doses with the least impact to patient care\*\**

**Deliverables & Acceptance Criteria:**

1. Contractor/licensee shall label all unit doses of delivered radiopharmaceutical with the amount, preparation time, expiration time, date, etc. It is preferable that Contractor has bar code compatibility with the OBVAMC Nuclear Medicine Information System (NMIS)
2. All packages containing radioactive material shall be labeled and shipped IAW Title 49, Code of Federal Regulations Part 172 and 173.

The label shall include the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL" and an identifier that ensures that the syringe, vial, or other container can be correlated with the information on the transport radiation shield label. Contractor/licensee shall label all unit doses of delivered radiopharmaceutical with the following details:

* *Amount of radiopharmaceutical at calibration/preparation date and time*
* *Radiopharmaceutical expiration date and time*
* *Radiopharmaceutical volume*
* *Label must be affixed to each unit dose*
  + *The label must include the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL" and an identifier that ensures that the syringe, vial, or other container can be correlated with the information on the transport radiation shield label.*

1. **Quality Control and Instructions**: Contractor/licensee shall perform all quality control procedures as required by Federal, and when applicable, State regulatory agencies. Quality Control (QC) results will be furnished to OBVAMC upon request. The objective of QC is to ensure that the radiopharmaceutical passes all required testing to ensure that it is a quality product and safe for patient use. The Contractor shall perform all QC’s IAW the manufacturer/governing body specifications, the approved QC instructions, and schedule. Using applicable manufacturer’s specifications, standard industry practices and this PWS, the Contractor shall test all products for Quality Control and only those products that pass quality control may be sent to the OBVAMC. This testing shall be performed at no cost to the VA. The contractor shall provide a detailed description of the test upon request. In the event that a quality control or material defect is suspected and/or detected by any OBVAMC staff Nuclear Medicine Technologist or staff Nuclear Medicine Physician, or qualified personnel from the OBVAMC Radiation Safety Office, the Contracting Officer Representative (COR) for this contract will notify the Contractor and request the Contractor to provide any consultation necessary to alleviate any said suspicion and/or defect by the following:

* Provide technical expertise in calibration.
* Provide professional examination of product; submit results and recommendations to the Contacting Officer.
* Make expedient replacement of any product suspected of being deficient.

1. Contractor/supplier shall abide by Title 10, Code of Federal Regulation, which states: A Licensee may use for medical purposes only:

(a) By-product material or cyclotron produced materials manufactured, labeled, packaged, and distributed in accordance with a license issued pursuant to the regulations in Title 10, Code of Federal Regulations, Part 35 and/or the equivalent regulations of an Agreement State.

(b) Reagent kit that has been manufactured, labeled, packed, and distributed in accordance with approval by the Commission pursuant to Title 10 CFR 32.72 or an Agreement State under equivalent regulations for the preparation of radiopharmaceuticals for medical use.

1. Contractor will utilize only FDA approved products and sources for those products, unless otherwise mutually agreed upon in the context of compassionate care or IRB approved research.
2. Contractor/licensee will deliver radioisotope in an amount greater than or equal to the activity ordered with calibration for the specified appointment time so that patient administered quantity is within regulatory limits of the prescribed dose. All routine radiopharmaceutical dose deliveries must occur >30 minutes prior to the calibration time. In the event that Nuclear Medicine Service is unable to perform a patient scan due to a PYLARIFY dose arriving in an unusable form (e.g. too low activity and below the recommended range for diagnostic imaging radiopharmaceuticals, typically 10% to 20%), the vendor will not invoice for the dose.
3. Lead Shielding. Deliveries for OBVAMC Nuclear Medicine Service will incorporate sufficient lead or other high-density metal shielding to comply with all applicable federal and/or state standards and regulations relating to shipment of radioactive materials. Shipping containers shall comply with all federal and state regulations. This shall include Department of Transportation (DOT), Department of Energy (DOE), and Nuclear Regulatory Commission (NRC), and/or agreement state licensure. The level of non-fixed contamination on the external surfaces of each package shall be in accordance with 49 CFR 173.443 and shall not exceed the limits set forth in Table 9 of that standard.
4. Material Safety Data Sheets. The Contractor may be asked to provide current material safety data sheets (MSDS) and updates as necessary on all delivered products or the contractor must provide their website link where MSDS and package inserts for all radiopharmaceuticals can be accessed.
5. **Pricing and Radiopharmaceutical Returns for Credit:**

Pricing will be based upon a unit dose price per quantity of doses ordered with no other fees or surcharges. The Contractor shall accept returns for full credit toward future orders under the following conditions:

a. Product(s) ordered or shipped in error.

b. Product(s) damaged in shipment

c. Concealed shipping damages

d. Recalled product(s)

e. Outdated products in unopened, original container.

1. **Invoicing:** Contractor shall invoice at least once per month showing period covered, billing date, name of preparation, quantity, and amount, as well as the correct purchase order number. A mutually agreed upon method to track unused reimbursable doses must be established prior to contract initiation. Offeror that provides a volume driven tiered approach that results in discounting with increased quantity purchased, is preferred.
2. **Normal/Routine Ordering and Deliveries:** Routine PYLARIFY orders will be placed at least 24 hours in advance by authorized VA personnel during normal business hours throughout the workday (8:00am – 4:30pm).

* Deliveries should be made directly to the OBVAMC Nuclear Medicine Service PET/CT Clinic. After award, the Contractor/licensee will be furnished the name(s) of VA personnel that are authorized to place orders against the Contract and will provide appropriate personnel and contact information for staff receiving orders, able to offer technical or administrative support, as well as staff involved in radiopharmaceutical delivery in accordance with VA Radiation Safety Office requirements.
* Contractor/licensee will provide updated lists of delivery personnel who will sign in/sign out with OBVAMC/Nuclear Medicine Service staff upon each delivery of radiotracer and follow all relevant policies and procedures in place at OBVAMC facilities/Nuclear Medicine Service. Compliance with all applicable regulatory bodies, including FDA and LA/US DOT is requisite.
* Depending upon changing Medical Center/Facility patient care requirements, the Contractor/licensee may be required to provide routine delivery.
* Delivery orders, or the electronic ordering system, shall include the following information:
* Contract item(s) and quantity
* Time(s) of delivery
* Applicable VA purchase order number

1. Offeror with secure online ordering portal, or that utilizes a VA approved Information Security system that allows ordering which includes Protected Health Information (PHI) to better protect patient safety is preferred. Upon award, contractor will take necessary steps to ensure any needed infrastructure is in place prior to start of the contract.
2. It is incumbent upon the contractor to ensure delivery personnel are adequately familiar with each specific delivery location. Delivery personnel will park at the nearest secure location and proceed directly to the Nuclear Medicine Service site where they will be escorted to the radiopharmacy (Hot Lab) by OBVAMC staff.

Nuclear Medicine Service normal business hours are considered Monday through Friday: 7:00 am – 4:30 pm, except Federal Holidays.

The following are Federal Holidays:

New Year’s Day

Birthday of Martin Luther King, Jr. (day of observance)

Washington’s Birthday

Memorial Day

Juneteenth

Independence Day

Labor Day

Columbus Day

Veteran’s Day

Thanksgiving Day

Christmas Day

(Any other day designated as a National Holiday by the President of the United States.)

1. Contractor will provide OBVAMC Nuclear Medicine Service (NMS) personnel access to relevant online and/or live Initial, as well as Continuing, Education at no cost to OBVAMC to ensure staff are trained and remain current in this product as well as safe receipt and handling of radioactive materials/radiopharmaceuticals, correct use of infrastructure applications such as an online ordering portal/NMIS, as well as any related regulatory requirements (Example: DOT).
2. Ordering Contact Information: Contractor/licensee shall provide contact information for the placement of orders for items listed in the “Schedule of Supplies and Services” Section.

POC Name:

Address:

City/State/Zip Code:

Ordering Phone Number:

Ordering Fax Number:

Ordering E-Mail Address:

1. DELIVERY COMMITMENT: Time of delivery specified or mutually agreed to at the time of receipt of telephone/electronic order(s) shall become mandatory upon the Contractor's/licensee’s acceptance to commitment. Delivery of supplies by the scheduled time will be complete except as otherwise authorized by the Ordering Personnel. Failure to perform in accordance with the delivery commitment may be grounds for termination of contract in accordance with the provisions for default. The Government may terminate this contract in whole or in part if the contractor fails to meet the required delivery schedule. The contractor/licensee shall not be charged with damages when the delay in delivery arises out of causes beyond their control and without the fault or negligence of the contractor/licensee.
2. DELIVERY LOCATION:

Overton Brooks VA Medical Center

Attn: Nuclear Medicine Service (115)

PET/CT Clinic, Bldg 1,

7th Floor, Room 7N9B

510 East Stoner Avenue

Shreveport, LA 71101

All orders shall be placed by authorized VA personnel during VA normal business hours throughout the workday. The Contractor will be furnished the name(s) of VA personnel that are authorized to place orders against the Contract and will provide appropriate personnel and contact information for staff receiving orders, able to offer technical or administrative support, as well as staff involved in radiopharmaceutical delivery in accordance with VA Radiation Safety Office requirements. Orders shall only be placed by authorized OBVAMC Nuclear Medicine Service personnel via telephone, fax, e-mail, or via an approved, secure, online ordering system. For electronic ordering systems, a closed-loop communication process such as confirmation e-mails is preferred.

The Contractor shall understand the limitations of the Nuclear Medicine Service at OBVAMC due to Radiation Safety with regards to storage and making radioactive kits for multiple use: Deliveries shall only contain unit dose or specific isotope bulk orders placed by authorized VA personnel.

Access to the OBVAMC PET/CT Clinic radiopharmacy (Hot Lab), during non-business hours, shall be obtained by contacting designated on-call Nuclear Medicine personnel. VA Police Service may be called to assist with escort in certain circumstances; however, the primary point of contact will be Nuclear Medicine staff. Delivery personnel must be always escorted within facility ‘Controlled areas’/Nuclear Medicine Service, as per TJC and NRC/regulatory requirements.

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| a. | **Common Nomenclature** (commercial description): | F18 PSMA injection (PYLARIFY) |
| b. | **Kind of material** (i.e., type, grade, alternatives, etc.): | Radioactive dose |
| c. | **Electrical Data** (i.e., 110 v, 60 Hz, 3 Ph, etc.): | N/A |
| d. | **Dimensions, size, capacity**: | Unit dose measured in millicuries |
| e. | **Principles of operation**: | Injection for patient imaging |
| f. | **Restrictive environmental conditions**: | Store in secure, designated hot lab |
| g. | **Intended use:** | Patient injection for diagnostic imaging |
| h. | **Equipment with which the item is used with**  **(N/A if not applicable):** | PET/CT scanner for imaging post patient injection |
| i. | **End item application**: | N/A |
| j. | **Original equipment manufacturer part number**: | N/A |
| k. | **Other pertinent information that describes the item, material or service required:** | Radioactive dose |

**Term of Contract**

The period of performance will be a base year:

* Base year: 01 Apr 2025 through 31 Mar 2026

1. **Schedule of Supply and Services\*\***

Contractor agrees to provide all needed F18 Pifluflostat (PYLARIFY) as identified, to the Overton Brooks VA Medical Center Nuclear Medicine department, on a daily and/or as needed basis per this PWS.

It is anticipated that a Firm-Fixed Price, single award contract shall be made based on the best value to the Government. The VA intends to award a contract to a single contractor.

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| **Item #** | **Vendor/Description/Part Number** | **12-month estimated Qty** |
| 1 | F18 Pifluflostat (PYLARIFY) Radiopharmaceutical Injection | 200 |
| 2 | Delivery | 200 |
| 3 | Unused Doses | 10 |

**C&A requirements do not apply and a Security Accreditation Package is not required.**