

DEPARTMENT OF VETERANS AFFAIRS

**Justification and Approval (J&A)
For
Other Than Full and Open Competition (>\$150K)**

Acquisition Plan Action ID: VA259-17-AP-10194

1. Contracting and Organizational Activity:

Contracting Activity:

Department of Veterans Affairs
Network Contracting Office 19 (NCO19)
6162 South Willow Drive, Suite 300
Greenwood Village, CO 80111

Organizational Activity:

Department of Veterans Affairs
Oklahoma City VA Health Care System
921 N.E. 13th Street
Oklahoma City, OK 73104

2237: 635-18-1-229-0001

- 2. Nature and/or Description of the Action Being Processed:** A firm-fixed price, sole source purchase order for Xofigo Injection 6 ml/vial (aka: Radium Ra-223 Dichloride injection 6ml/vial), NDC 50419-0208-01) from Cardinal Health in the amount of _____ with an estimated period of performance of October 12th 2017 to October 11th 2018.

FAR13.5 Simplified Procedures for Certain Commercial Items: This procurement is for Xofigo Radiopharmaceuticals in accordance with FAR 13.5 Simplified Procedures for Certain Commercial Items and specifically FAR 13.501 Special Documentation Requirements, where acquisitions conducted under Simplified Acquisition Procedures are exempt from the requirements of FAR Part 6, but still require a justification using the format of FAR 6.303-2.

- 3. Description of Supplies/Services Required to Meet the Agency's Needs:** The Xofigo Injection 6ml/vial (aka: Radium Ra-223 Dichloride Injection 6 ml/vial) is a radioactive pharmaceutical used for the treatment of bone metastases in certain prostate cancer.

4. Statutory Authority Permitting Other than Full and Open Competition:

- (1) Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements per FAR 6.302-1;
 (2) Unusual and Compelling Urgency per FAR 6.302-2;
 (3) Industrial Mobilization, Engineering, Developmental or Research Capability or Expert Services per FAR 6.302-3;
 (4) International Agreement per FAR 6.302-4
 (5) Authorized or Required by Statute FAR 6.302-5;
 (6) National Security per FAR 6.302-6;
 (7) Public Interest per FAR 6.302-7;

FAR13.5 Simplified Procedures for Certain Commercial Items: The authority for applying the Simplified Procedures for Commercial Items of FAR 13.5 is 41 U.S.C. 1901 and is implemented by for restricting competition on this procurement via FAR 13.106-1(b)(2).

5. **Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires the Use of the Authority Cited Above (applicability of authority):** Bayer Healthcare Pharmaceuticals Inc. manufacturer of Xofigo Injection (aka: Radium Ra-223 Dichloride injection 6ml/vial). This radiopharmaceutical is only available from Cardinal Health, the sole distributor of Xofigo (see attached letter from Bayer Healthcare Pharmaceuticals).
6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** This justification will be posed on FBO.gov in accordance with FAR 6.305.
7. **Determination by the CO that the Anticipated Cost to the Government will be Fair and Reasonable:** The anticipated price is considered fair and reasonable, as Cardinal Health will continue to honor the established Federal Supply Schedule pricing under that is established under V797P-2202D. This contract is with Bayer HealthCare Pharmaceuticals, however Bayer will no longer accept orders against this contract.
8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** Bayer Healthcare Pharmaceuticals Inc. is the only vendor currently manufacturing Xofigo Injection (aka: Radium Ra-223 Dichloride injection 6ml/vial). This radiopharmaceutical is only available directly from Cardinal Health, the sole distributor for Bayer Healthcare Pharmaceuticals, Inc.. Market Research was conducted on the Vetbiz Registry, using the keyword "Xofigo", and no sources were identified.
9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** None
10. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:** The following firms(s) responded to an inquiry from the manufacturer Bayer:

Cardinal Health – Providing a letter from Bayer claiming they are the sole distributor of Xofigo.
11. **A Statement of the Actions, if any, the Agency May Take to Remove or Overcome any Barriers to Competition before Making subsequent acquisitions for the supplies or services required:** The VA will continue to monitor the commercial marketplace to determine if other sources are capable of providing a metastatic cancer treatment specific to the conditions of the selected patients. Once other sources enter the marketplace, future procurments may be competitive.
12. **Requirements Certification:** I certify that the requirement outlined in this justification is a Bona Fide Need of the Department of Veterans Affairs and that the supporting data under my cognizance, which are included in the justification, are accurate and complete to the best of my knowledge and belief.

Oklahoma City VAMC

13. Approvals in accordance with the VHAPM Part 806.3 OFOC SOP:

- a. **Contracting Officer or Designee's Certification (required):** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

Branch Chief, Supply 1 East
NCO19

- b. **One Level Above the Contracting Officer (Required over \$150K but not exceeding \$700K):** I certify the justification meets requirements for other than full and open competition.

Division Chief, Division II
NCO19