

VHAPM Part 806.3 Other Than Full and Open Competition (OFOC) SOP
Attachment 2: Request for Sole Source Justification Format >\$150K

DEPARTMENT OF VETERANS AFFAIRS

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

Acquisition Plan Action ID: VA257-17-AP-10433 & VA257-18-AP-4190

1. **Contracting Activity:** Department of Veterans Affairs, Network Contracting Office 17 for the Nuclear Medicine Services at the San Antonio and Dallas VA Medical Center, 671-18-3-029-0047 and 549-18-1-068-0010.
2. **Nature and/or Description of the Action Being Processed:** The Nuclear Medicine Service at the Dallas VA Medical Center is requesting a long-term contract for the procurement of Xofigo on a sole source basis to Cardinal Health. Xofigo is manufactured by Bayer Healthcare Pharmaceutical; however, as of 2013, Cardinal Health is the sole authorized distributor for Xofigo. All commercial orders for Xofigo are distributed by Cardinal Health.
3. **Description of Supplies/Services Required to Meet the Agency's Needs:** Xofigo, also known as Radium (Ra) 223 dichloride, is a radiopharmaceutical, manufactured by Bayer Healthcare Pharmaceutical, that is utilized for treating patients with castration-resistant prostate cancer (CPRC), symptomatic bone metastases, and no known visceral metastatic disease. The Nuclear Medicine Service has a need for a contract vehicle to support the continued treatment of Veteran patients requiring Xofigo. The estimated contract value of this procurement is \$3,268,867.25.
4. **Statutory Authority Permitting Other than Full and Open Competition:**

(X) (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;
5. **Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires the Use of the Authority Cited Above (applicability of authority):** Per the Federal Drug Administration (FDA), Xofigo or Ra 223 dichloride, is the only FDA-approved radiopharmaceutical

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6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** To stimulate competition, a sources sought was posted to FBO under 36C25718Q9164 on March 12, 2018 with a closing date of March 26, 2018; however, no other party expressed, in writing, their interest in this acquisition.
7. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:** Market research revealed that Bayer Healthcare Pharmaceutical has a VA NAC Contract under V797P-2202D and IAW FAR 8.404(d), ordering activities are not required to make a separate determination of fair and reasonable pricing for supplies on schedule; however, as previously stated, all orders for Xofigo are processed through Cardinal Health as they are the sole distributor. Cardinal Health has provided, in writing, that they will honor the pricing listed on Bayer Healthcare Pharmaceutical's contract V797P-2202D. Before an award is made, the Contracting Officer will provide a separate determination for fair and reasonable pricing. Additionally, the Contracting Officer will seek any additional and available discounts.

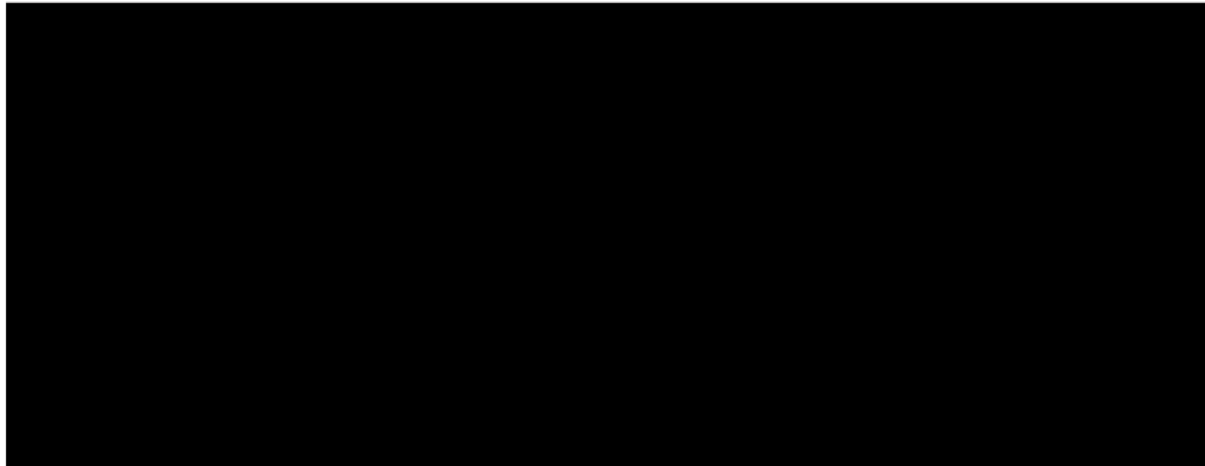
Furthermore, numerous Network Contracting Offices have awarded several contracts, on a sole source basis, to Cardinal Health for the procurement of Xofigo. Most recently, Network Contracting Office 19 awarded, on sole source basis, contract 36C25918P0185 on November 11/20/2017 for \$331,200.00 with a performance period of one year. The price unit dosage is \$77.40, which matches the price per dosage of this requirement. IAW FAR 13.106(a)(2)(II), price is fair and reasonable based on comparison of proposed prices with prices found reasonable on previous purchases.

8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** Market research was conducted IAW FAR 10.002. It was found that this requirement is commercially available through the commercial marketplace. Pursuant to FAR 8.002 and FAR 8.003, it was found that this requirement could not be fulfilled using mandatory Government sources or other mandatory sources. Furthermore, key word searches were conducted on GSA Advantage and the VA NAC, it was found that this requirement could be fulfilled through V797P-2202D to Bayer Healthcare Pharmaceutical. A key word search of "radiopharmaceutical" was conducted on the SBA Dynamic Small Business Search Tool. This query returned 12 results. Phone calls were made to all 12 vendors; however, it was found that they would not be able to fulfill this requirement, Xofigo is proprietary to Bayer, and Cardinal Health is the only distributor for Xofigo.

A letter from Bayer is provided in the briefcase file that states that Cardinal Health is the sole distributor of Xofigo, and that as of 2013, all orders are to go through Cardinal Health. Cardinal Health will continue to honor VA FSS Federal Pricing against Bayer's FSS Contract V797P-2202D. To stimulate competition, a sources sought was posted to FBO under 36C25718Q0030 on October 11, 2017 with a closing date of October 27, 2017; however, no other party expressed, in writing, their

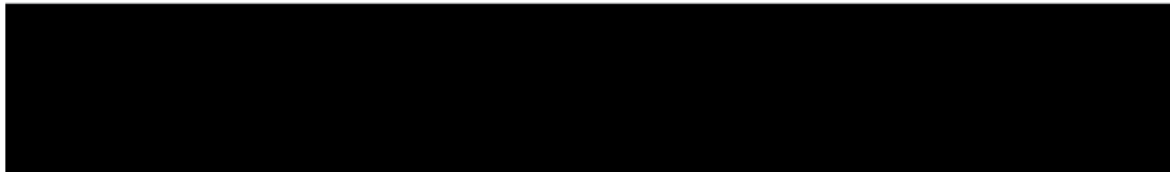
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9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** As previously stated, Cardinal Health is the sole authorized distributor for Xofigo and all commercial orders are placed through Cardinal Health.
10. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:** No other sources, other than the suggested source, expressed, in writing, their interest in this acquisition.
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:** Network Contracting Office 17 will work with the Dallas VA Medical Center Nuclear Medicine Service to continue monitoring the latest trends in radiopharmaceutical development
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.



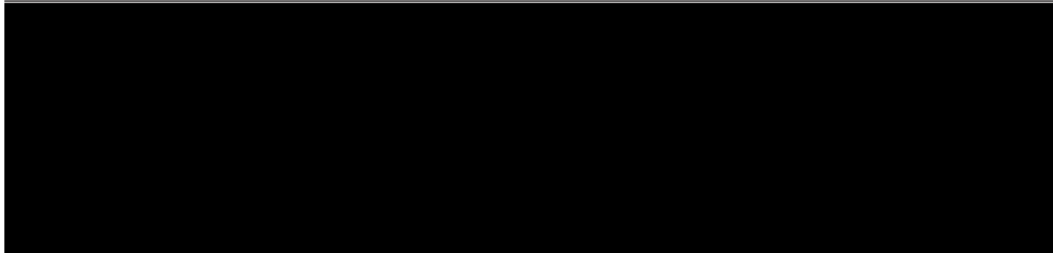
13. **Approvals in accordance with the VHAPM Part 806.3 OFOC SOP:**

- 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.



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- 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.



- c. VHA SAO HCA Review and Approval: I have reviewed the foregoing justification and find it to be complete and accurate to the best of my knowledge and belief and approve for other than full and open competition.

