

**LIMITED SOURCES JUSTIFICATION**

**ORDER >\$150,000  
FAR PART 8.405-6**

**Acquisition Plan Action ID: VA255-17-AP-5228**

This acquisition is conducted under the authority of the Multiple Award Schedule Program. The material or service listed in par. 3 below is sole source, therefore, consideration of the number of contractors required by FAR Subpart 8.4 – Federal Supply Schedules, is precluded for the reasons indicated below.

**Restricted to the following source:** Provide *original manufacturer's* name for material or contractor's name for service. (If a sole source manufacturer distributes via dealers, *ALSO* provide dealer information.)

Manufacturer/Contractor: BAYER HEALTHCARE PHARMACEUTICALS

Manufacturer/Contractor POC & phone number: [REDACTED]

Mfgr/Contractor Address: 100 Bayer Blvd Whippany, NJ 07981-0915

**(1) AGENCY AND CONTRACTING ACTIVITY:**

Department of Veterans Affairs  
Network Contracting Office (NCO) 15  
3450 S. 4th Street Trafficway  
Leavenworth, KS 66048

**VISN:**

15

**(2) NATURE AND/OR DESCRIPTION OF ACTION BEING APPROVED:**

Sole source award to Bayer Healthcare for Xofigo (radium Ra 223 dichloride) under VA797P-2202D.

**(3) (a) A DESCRIPTION OF THE SUPPLIES OR SERVICES REQUIRED TO MEET THE AGENCY'S NEED:**

Xofigo is an alpha-particle-emitting radioactive therapeutic agent for the treatment of patients with castration-resistant prostate cancer (CRPC), symptomatic bone metastases and no known visceral metastatic disease.

**(b) ESTIMATED DOLLAR VALUE:** [REDACTED]

**(c) REQUIRED DELIVERY DATE:** 7/1/2017

**(4) IDENTIFICATION OF THE JUSTIFICATION RATIONALE (SEE FAR 8.405-6), AND IF APPLICABLE, A DEMONSTRATION OF THE PROPOSED CONTRACTOR'S UNIQUE QUALIFICATIONS TO PROVIDE THE REQUIRED SUPPLY OR SERVICE. (CHECK ALL THAT APPLY AND COMPLETE)**

Specific characteristics of the material or service that limit the availability to a sole source (unique features, function of the item, etc.). Describe in detail why only this suggested source can furnish the requirements to the exclusion of other sources.

Bayer HealthCare and Cardinal Health today announced the signing of a 15-year agreement for the contract manufacturing of Xofigo (radium Ra 223 dichloride). Cardinal Health is the sole distributor of Xofigo in the U.S.

Xofigo is the only alpha radiation treatment for bone pain. Xofigo is the only drug that is known to treat the bone pain and reduce bone tumor size. This is the only treatment being prescribed by the VA doctors to treat this type of illness.

Chapter VI: Other Than Full and Open Competition (OFOC) SOP  
Attachment 2: Request for Limited Sources Justification Format >\$150K

A patent, copyright or proprietary data limits competition. The proprietary data is:  
(If FAR 8.405-6(a)(2)iii before posting. Do not include specific proprietary data. Only mention the  
type of equipment, procedure, etc. to show that proprietary supplies or services are being procured.)

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These are "direct replacements" parts/components for existing equipment.

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The material/service must be compatible in all aspects (form, fit and function) with existing systems presently installed/performing. Describe the equipment/function you have now and how the new item/service must coordinate, connect, or interface with the existing system.

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The new work is a logical follow-on to an original Federal Supply Schedule order provided that the original order was placed in accordance with the applicable Federal Supply Schedule ordering procedures. The original order must not have been previously issued under sole source or limited source procedures.

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An urgent and compelling need exists, and following the ordering procedures would result in unacceptable delays.

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**(5) DESCRIBE WHY YOU BELIEVE THE ORDER REPRESENTS THE BEST VALUE CONSISTENT WITH FAR 8.4 TO AID THE CONTRACTING OFFICER IN MAKING THIS BEST VALUE DETERMINATION:**

Price is consistent with NAC price and previous awards.

**(6) DESCRIBE THE MARKET RESEARCH CONDUCTED AMONG SCHEDULE HOLDERS AND THE RESULTS OR A STATEMENT OF THE REASON MARKET RESEARCH WAS NOT CONDUCTED:**

A search on the Vetbiz using the NAICS code 325412 showed 39 matches. A search on the NAC website using the keyword "xofigo" showed that the medication is on a NAC contract, V797P-2202D, with Bayer Healthcare Pharmaceutical which is a large business. A search on FPDS using the keyword "xofigo" showed 133 records with Bayer Healthcare Pharmaceutical from the Department of Veterans Affairs. Google search showed that "Cardinal Health is the sole distributor of Xofigo in the U.S.". An Intent to Sole Source was published on FBO and received zero response from vendors.

**(7) ANY OTHER FACTS SUPPORTING THE JUSTIFICATION:**

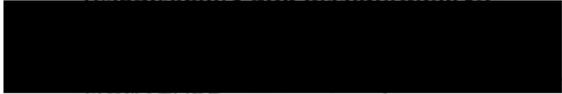
On 2/16/2017, V797P-2202D VA255-17-F-2381 589A72034 was awarded to Bayer Healthcare Pharmaceutical for the same medication for the Topeka VAMC.

**(8) A STATEMENT OF THE ACTIONS, IF ANY, THE AGENCY MAY TAKE TO REMOVE OR OVERCOME ANY BARRIERS THAT LED TO THE RESTRICTED CONSIDERATION BEFORE ANY SUBSEQUENT ACQUISITION FOR THE SUPPLIES OR SERVICES IS MADE:**

N/A

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**(9) 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. I understand that processing of this limited sources justification restricts consideration of Federal Supply Schedule contractors to fewer than the number required by FAR Subpart 8.4. *(This signature is the requestor's supervisor, fund control point official, chief of service or someone with responsibility and accountability.)*

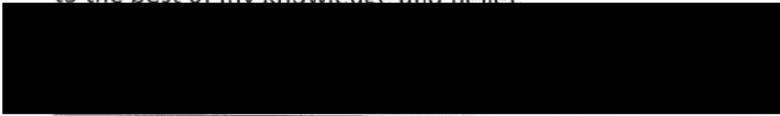
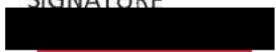
 \_\_\_\_\_ 6/28/17 \_\_\_\_\_  
SIGNATURE / DATE  
 \_\_\_\_\_ Radiology/Nuclear Medicine  
NAME TITLE SERVICE LINE/SECTION  
Eastern Kansas VAMC \_\_\_\_\_  
FACILITY

**(10) APPROVALS IN ACCORDANCE WITH THE VHAPM, Volume 6, Chapter VI: OFOC SOP:** *This part if filled out by Contracting Staff as part of the Justification*

**a. CONTRACTING OFFICER'S CERTIFICATION (required):** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

 \_\_\_\_\_ 6/28/2017 \_\_\_\_\_  
CONTRACTING OFFICER/DESIGNEE'S SIGNATURE DATE  
 \_\_\_\_\_ NCO 15  
NAME AND TITLE FACILITY

**b. Director of Contracting/DESIGNEE:** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

 \_\_\_\_\_  
SIGNATURE DATE  
 \_\_\_\_\_  
NAME Branch Chief