

**LIMITED SOURCES JUSTIFICATION**

ORDER >\$150,000

FAR PART 8.405-6

Acquisition Plan Action ID: VA261-16-AP-5290, 640-17-1-053-0004 Xofigo (RA-223) Dichloride Injection

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: Thomas Bobsein, 862-404-5312

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

Dealer/Rep address/phone number/e-mail address: thomas.bobsein@bayer.com

The requested material or service represents the minimum requirements of the Government.

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

Department of Veterans Affairs

Network Contracting Office (NCO) 21

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

The VA Palo Alto Health Care System (VAPAHCS) has a need for Radium 223 Dichloride (Xofigo) to continue treatment for patients with metastatic prostate cancer

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

Xofigo (radium Ra 223 dichloride) injection is used to treat prostate cancer that is resistant to medical or surgical treatments that lower testosterone and has spread to the bones. The medical term for this condition is metastatic castration-resistant prostate cancer, or mCRPC.

**(b) ESTIMATED DOLLAR VALUE:** \$ 201,230.00

**(c) REQUIRED DELIVERY DATE:** As needed after receipt of order through 09/30/2017

**(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.

The VAPAHCS must have the capability to order Xofigo to continue treatment of select patients with metastatic prostate cancer. Xofigo is manufactured by Bayer Healthcare Pharmaceuticals and is

available under FSS NAC V797P-2202D through Bayer Healthcare Pharmaceuticals. Cardinal Health 414 is the only authorized distributor for Xofigo and every order placed through Bayer is prepared/delivered from Cardinal.

A patent, copyright or proprietary data limits competition. The proprietary data is: Xofigo is a proprietary product exclusively manufactured by Bayer Healthcare Pharmaceuticals. (If FAR

**(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:**

The fixed prices for supplies and services listed under FSS Contract V797P-2202D have been determined to be fair and reasonable by GSA. Therefore, ordering activities are not required to make a separate determination of fair and reasonable pricing. The prices listed under FSS Contract V797P-2202D represent the best value (as defined in FAR 2.101) and results in the lowest overall cost alternative (considering pricing, special features, administrative costs, etc.) to meet the Government's needs

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

A market search was conducted on Xofigo in National Acquisition Center's Pharmaceutical Catalog. Market Research revealed Bayer Health as the only source for Xofigo and the only vendor with an FSS contract for this particular radiopharmaceutical product.

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

N/A

**(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:**

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 procurements may be competitive.

**(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.)*

George Segall 7.27.16  
SIGNATURE DATE  
George Segall Chief 115  
NAME TITLE  
VA Palo Alto Health Care system (VAPAHCS) Nuclear Medicine  
FACILITY SERVICE LINE/SECTION

