

LIMITED SOURCES JUSTIFICATION

ORDER >\$150,000

FAR PART 8.405-6

Acquisition Plan Action ID: VA263-16-AP-11774

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: Karen McRae, 973-487-5922, 973-305-5200 fax

Mfgr/Contractor Address: 6 West Belt, Wayne, NJ 07470-6806

Dealer/Rep address/phone number: Karen McRae, 973-487-5922, 973-305-5200 fax

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

(1) AGENCY AND CONTRACTING ACTIVITY:

Department of Veterans Affairs
Network 23 Contracting Office (NCO 23)
City Scapes
474 45th St. S Suite 202
Fargo ND 58102
23

VISN:

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

Purchase of Xofigo (Radium 223) radiopharmaceutical

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

Radiopharmaceutical therapy for use in metastasized prostate cancer patients to the bone.

(b) ESTIMATED DOLLAR VALUE: \$432,000.00

(c) REQUIRED DELIVERY DATE: October 21, 2016

(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.

Currently Xofigo (Radium 223) is only manufactured and distributed by the vendor.

☐ 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.)

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

☐ 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.

☐ 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.

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

(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:

Only once source is available. This is therapy treatment for specific cancer patients.

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

After conducting an NDC search on va.gov/nac it was discovered that Bayer currently possess the only contract for Xofigo.

Based upon the above mentioned findings, because the VOSB rule of two could No generics exist

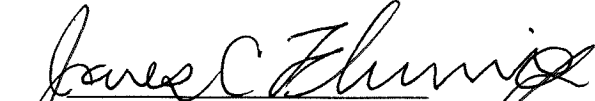
(7) ANY OTHER FACTS SUPPORTING THE JUSTIFICATION:

NONE

(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:

Should other distribution or generic versions of this radiopharmaceutical become available, this information will be included in the next contract when renewal is required.

(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.)*

		<u>August 17, 2016</u>
SIGNATURE		DATE
<u>Lisa L. Bickford</u>	<u>Administrative Officer, COR</u>	<u>Imaging Service Line</u>
NAME	TITLE	SERVICE LINE/SECTION
<u>Iowa City VA Health Care System</u>		
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.

SIGNATURE		DATE
Darryl W. Moon	Contracting Officer	NCO 23 - Commodities
NAME	TITLE	SERVICE LINE/SECTION
Fargo VA Health Care System		
FACILITY		

b. **Director of Contracting/DESIGNEE:** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief, and approve for other than full and open competition.

SIGNATURE	DATE
Scott J. Petrin	
NCO 23 Division Chief	