

DEPARTMENT OF VETERANS AFFAIRS

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

Acquisition Plan Action ID: VA261-17-AP-10066

1. **Contracting Activity:** Department of Veterans Affairs, NCO 21 for VISN 21, VA Palo Alto Healthcare System (VAPAHCS) is requesting approval of a Justification for Other Than Full and Open Competition for the requirement specified in 2237 Number **640-18-1-053-0003**. The estimated dollar amount including options is : [REDACTED]
2. **Nature and/or Description of the Action Being Processed:** The VA Palo Alto Healthcare System (VAPAHCS) has a need for Radium 223 Dichloride (Xofigo) to continue treatment for patients with metastatic prostate cancer.
3. **Description of Supplies/Services Required to Meet the Agency's Needs:** 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.
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):**

a. **Only One Responsible Source (FAR 6.302-1)** – 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 Cardinal Health is the only authorized distributor for Xofigo. Furthermore, Xofigo is a proprietary product exclusively manufactured by Bayer Healthcare Pharmaceuticals.
6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** A market search was conducted by posting a Sources Sought Notice in both FBO and GSA eBuy. Market Research revealed Cardinal Health as the only source for Xofigo and the the only vendor for this particular radiopharmaceutical product.

7. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:** The Contracting Officer has determined that the anticipated price will be determined to be fair and reasonable. A FAR Part 13 Open Market Award Decision Documentation Form will detail how the Government has determined that the anticipated cost will be fair and reasonable. The basis of price reasonableness will be determined by 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:**

A Sources Sought Notice (RFQ1223447) was posted via GSA eBuy on 08/08/2017 and closed on 08/15/2016. It was issued to 46 vendors and zero quotes were received.

A Sources Sought Notice (VA261-17-N-0941) was also posted via FBO on 08/08/2017 and closed on 08/15/2017. Only Cardinal Health provided a quote for the exact product requested.

The notice included the salient characteristics and statement of work of the requirement. Any firm that believed it could provide the equipment listed were encouraged to submit written notification to the Contracting Specialist with requested information for consideration before the close of the Sources Sought Notice.

9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** N/A

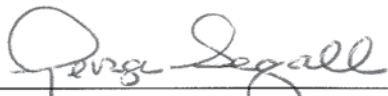
10. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:** The following firm(s) responded to the sources sought notice:

- Cardinal Health (Large) – Provided a quote with the exact product requested and claims it is 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:**

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.

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.


George Segall, MD, Nuclear Medicine Chief
VA Palo Alto Healthcare System (VAPAHCS)

9-11-17
Date

13. **Approvals in accordance with the VHAPM Part 806.3 OFOC SOP:** *This part if filled out by Contracting Staff as part of the Justification*

- 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.

Joleo B.
Dianala

Paul Griffin
1494727
Contracting Officer

Digitally signed by Joleo B.
Dianala 1494727
DN: dc=gov, dc=va, o=internal,
ou=people,
0.9.2342.19200300.100.1.1=jole
o.dianala@va.gov, cn=Joleo B.
Dianala 1494727
Date: 2017.09.22 14:08:27 -07'00'

Date

- 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.

Paul M. Griffin
635127

Samuel M. Harbin
Director of Contracting
NCO 21

Digitally signed by Paul M. Griffin 635127
DN: dc=gov, dc=va, o=internal, ou=people,
0.9.2342.19200300.100.1.1=paul.griffin4@va.gov,
v, cn=Paul M. Griffin 635127
Date: 2017.09.22 14:15:42 -07'00'

9/22/2017

Date