

**DEPARTMENT OF VETERANS AFFAIRS**

**Justification and Approval**

**For**

**Other Than Full and Open Competition**

1. **Contracting Activity:** Justification for other than Full and Open Competition

**Agency:** Department of Veterans Affairs  
NCO 23 - Fargo  
474 45<sup>th</sup> St S, STE 202  
Fargo, ND 58102  
**VISN:** 23  
**2237 #:** 437-14-3-030-0855

2. **Nature and/or Description of the Action Being Processed:** Award a firm-fixed-price purchase order on a sole source basis for Imbruvica (Ibrutinib) 140mg capsule 120 count bottle.
3. **Description of Supplies/Services Required to Meet the Agency's Needs:** Imbruvica (Ibrutinib) is used to treat Mantle Cell Lymphoma (MCL) and Chronic Lymphocytic Leukemia (CLL). Ibrutinib is an inhibitor of Bruton's tyrosine kinase (BTK). It is a white to off-white solid with the empirical formula C<sub>25</sub>H<sub>24</sub>N<sub>6</sub>O<sub>2</sub> and a molecular weight 440.50. Ibrutinib is freely soluble in dimethyl sulfoxide, soluble in methanol and practically insoluble in water.

Required: 4 bottle (120 count) of Imbruvica (Ibrutinib) 140mg capsule

**ESTIMATED DOLLAR VALUE:** \$32,572.56

**REQUIRED DELIVERY DATE:** 06/27/2014

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):** Imbruvica is produced and distributed solely by Pharmacyclics. Imbruvica has been shown to have lesser side effects than other CLL therapies and has worked as a "last ditch" effort in the treatment of MCL and CLL.
6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** None.
7. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:** The price paid for this order will be compared to previous purchases of the same or similar medications to determine the price to be fair and reasonable.
8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** Market research was not conducted. See email from NAC about ordering procedures.
9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** None
10. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:**  
Pharmacyclics  
995 E. Arques Ave.  
Sunnydale, CA 94085
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:** The NAC is currently in the process of adding this drug the PBM to be ordered through the pharmacy prime vendor process.
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.

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Debbie Schmidt  
Pharmacy Technician  
 Fargo VA Health Care System

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Date

**13. Approvals in accordance with FAR 6.304**

- a. **Contracting Officer'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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Christopher Volk  
Contracting Officer  
NCO 23 - Fargo

\_\_\_\_\_  
Date

- b. **NCM/PLCM (Required \$3K and above)**: I certify the justification meets requirements for other than full and open competition and I approve this other than full and open award.

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Scott Petrin  
Contract Manager  
NCO 23 - Fargo

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Date