

LIMITED SOURCES JUSTIFICATION

ORDER >SAT

FAR PART 8.405-6

Acquisition Plan Action ID: 626-20-1-2518-0012

- 1. Contracting Activity:** Department of Veterans Affairs, Network Contracting Office (NCO) 9, Nashville VA Medical Center, 1310 24th Avenue, South, Nashville, TN 37212. The purchase requires (2237) number for this requirement is 626-20-1-2518-0012.
- 2. Description of Action:** This acquisition is a new requirement for the drug Tisagenlecleucel trade name Kymriah.
- 3. Order against:** ☒ FSS Contract Number: V797D-30268

Name of Proposed Contractor: Curascript Inc. dba Priority Healthcare Distribution Inc.
(authorized distributor for Novartis)

Street Address: 255 Technology Park

City, State, Zip: Lake Mary, FL 32746-6216

Phone: 866-844-0148

4. Description of Supplies or Services:

The estimated value of the proposed action is \$284,904.00

Novartis will manufacture and commercialize the drug KYMRIAH, tisagenlecleucel suspension for CAR-T Therapy which has been approved by the U.S. Food and Drug Administration ("FDA") pursuant to a Biologics License Application for the treatment of patients up to 25 years of age with B-cell precursor acute lymphoblastic leukemia that is refractory or in second or later relapse.

Manufacture of the drug by Novartis requires the apheresis (e.g., recovery, collection, processing, testing, cryopreservation) and release packaging, labeling, storage and delivery of patient cells from a patient who is prescribed CAR-T Cell treatment and who may receive the drug as a patient-specific treatment.

AUTHORITY AND SUPPORTING RATIONALE: (see 8.405-6(a)(1)(i)(A), (B), and (C) or 8.405-6(b))

- ☐ An urgent and compelling need exists and following the ordering procedures would result in unacceptable delays.
- ☒ Only one source is capable of providing the supplies or services required at the level of quality required because the supplies or services are unique or highly specialized;

The drug KYMRIA, tisagenlecleucel is patient specific and the FDA has approved only one source as the manufacturer of the drug. In addition, the VA Medical Center in Nashville, TN is the only authorized facility in the nation to provide treatment with this drug to veteran patients.

- ☐ In the interest of economy and efficiency, 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.

- ☐ Items peculiar to one manufacturer:

☐ 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.

(5) DESCRIBE WHY YOU BELIEVE THE ORDER REPRESENTS THE BEST VALUE CONSISTENT WITH FAR 8.404(d) TO AID THE CONTRACTING OFFICER IN MAKING THIS BEST VALUE DETERMINATION:

All other possible treatment options have been eliminated, and this is the only remaining treatment option for the patient. The rates are set by contract and policy.

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

Market research was conducted by querying Vendor Information Pages (VIP) with no results and by querying the National Acquisition Center which resulted in one vendor which is listed above.

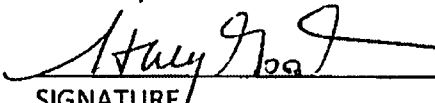
(7) ANY OTHER FACTS SUPPORTING THE JUSTIFICATION:

The drug manufacturing process is time sensitive as it is manufactured from the cells of each specific patient. The manufacturing process takes 22 days and the cells must be received by the manufacturer in a timely manner.

(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:

Until the FDA approves more vendors there are no actions the VA can take at this time.

(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.


SIGNATURE

10/17/19
DATE

Stacey Goodman, M.D.
NAME

Program Medical Director
TITLE

Stem Cell Transplant Program
SERVICE LINE/SECTION

VA TVHS, Nashville TN
FACILITY

(10) APPROVALS IN ACCORDANCE WITH THE VHAPM Part 806.3 OFOC SOP:

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

Dana M.

Digitally signed by Dana M.

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Dixon 235460

Date: 2019.10.17 14:07:28
-05'00'

10-17-19

DANA DIXON

DATE

CONTRACTING OFFICER, NCO 9

b. One Level Above the Contracting Officer (Required over the SAT but not exceeding \$700K): I certify the justification meets requirements for other than full and open competition.

Digitally signed by Carol

Carol L. Franklin

L. Franklin 236163

236163

Date: 2019.10.17

14:18:21 -05'00'

10-17-19

CAROL FRANKLIN

DATE

BRANCH CHIEF, NCO 9