

Notice of Intent to Certify Sole Source

To: Interested Parties

From: Stacy Baldwin
Agency Procurement Officer

Date: May 16, 2016

Re: Sole Source Certification Number **SS5032** for Photrexa Viscous (riboflavin 5'-phosphate in 20% dextran ophthalmic solution) 0.146%, Photrexa (riboflavin 5'-phosphate ophthalmic solution) 0.146%, and the KXL system, (Photrexa KXL System, hereafter)

Contact Email Address: solesource@umc.edu

Sole Source Certification Award Details

Regarding UMMC Sole Source Certification Number SS5032 for Photrexa KXL System, please be advised that UMMC intends to award the purchase of the Photrexa KXL System to Avedro, Inc. as the sole source provider of the Photrexa KXL System UMMC issues this notice in accordance with Mississippi state law, policy, and procedures for sole source procurements.

Sole Source Criteria

1. Where the compatibility of equipment, accessories, or replacement parts is the paramount consideration (and manufacturer is the sole supplier).
2. Where a sole supplier's item is needed for trial use or testing.
3. Where a sole supplier's item is to be required when no other item will service the needs of UMMC.

Schedule

Task	Date
First Advertisement Date	May 16, 2016
Second Advertisement Date	May 23, 2016
Response Deadline from Objectors	May 31, 2016, at 3:00 p.m. Central Time
Notice of Award/No Award Posted	Not before June 27, 2016

Project Details

1. Describe the commodity that the agency is seeking to procure:

The University of Mississippi Medical Center (UMMC) seeks to purchase Photrexa Viscous (riboflavin 5'-phosphate in 20% dextran ophthalmic solution) 0.146%, Photrexa (riboflavin 5'-phosphate ophthalmic solution) 0.146%, and the KXL system (Avedro, Waltham, Massachusetts, USA). This system is the first and only FDA-approved therapeutic treatment for progressive keratoconus, a degenerative corneal condition with high prevalence in Mississippi, especially in rural areas and among African-American patient population. The KXL system provides an excellent non-invasive alternative to the treatment of this progressive disease.

2. Explain why the commodity is the only one (1) that can meet the needs of the agency:

Although cornea cross-linking technique has been in use for a few years to treat keratoconus overseas, Avedro's KXL system is the only FDA-approved such system in the U.S. Photrexa Viscous and Photrexa are photoenhancers indicated for use with the KXL System in corneal collagen cross-linking for the treatment of progressive keratoconus. Avedro's Photrexa Viscous, Photrexa and the KXL System represent a first-in-class therapeutic treatment for this sight threatening indication. Keratoconus is a progressive thinning and distortion of the cornea. It is the most common corneal dystrophy in the US, affecting approximately one in every 2,000 Americans or approximately 170,000 people in the US with high prevalence in the state of Mississippi. Keratoconus causes the cornea to bulge from its normal symmetric domelike smooth optical shape, creating an abnormal curvature that changes the cornea's optics, producing blurred and distorted vision that is difficult to correct with spectacle lenses. This progressive thinning and weakening can result in significant visual loss and may lead to corneal transplants. Corneal cross-linking provides patients a much-needed option to treat this debilitating disease. The KXL system represent an invaluable new treatment option for corneal surgeons in the treatment of keratoconus patients.

3. Explain why the source is the only person or entity that can provide the required commodity:

Avedro is the sole manufacturer and supplier of the KXL system with Photrexa Viscous (riboflavin 5'-phosphate in 20% dextran ophthalmic solution) 0.146%, Photrexa (riboflavin 5'-phosphate ophthalmic solution) 0.146%. This system is not available from any other distributor. See supporting letter from Avedro, Inc., Attachment A.

4. Explain why the amount to be expended for the commodity is reasonable:

The estimated amount to be expended is for the purchase of the KXL system with Photrexa Viscous (riboflavin 5'-phosphate in 20% dextran ophthalmic solution) 0.146%, Photrexa (riboflavin 5'-phosphate ophthalmic solution) 0.146% is \$245,000 based on potential candidates for this procedure. This amount is within the expected price range for these

products. UMMC was provided multi-level discounting on hardware, software, treatment kits and service.

5. Describe the efforts that the agency went through to obtain the best possible price for the commodity:

Through market intelligence, UMMC was able to negotiate best pricing for these products. All applicable discounts were explored and applied.

Submission Instructions and Format of Response from Objecting Parties

Interested parties who have reason to believe that the Photrex KXL system (hereafter, “Products”) should not be certified as a sole source should provide information in the Vendor Form for the State to use in determining whether or not to proceed with awarding the sole source to Avedro, Inc.. The Vendor Form may be found at <http://www.dfa.state.ms.us/Purchasing/documents/ObjectiontoSoleSourceDetermination.pdf>.

Objections must include the certification in Attachment B.

Comments will be accepted at any time prior to Tuesday, May 31, 2016, at 3:00 p.m. (Central Time) to solesource@umc.edu. Responses may be delivered via email to solesource@umc.edu. UMMC WILL NOT BE RESPONSIBLE FOR DELAYS IN THE DELIVERY OF RESPONSES. It is solely the responsibility of the Interested Parties that responses reach UMMC on time. Responses received after the deadline and responses that lack all required information will be rejected. UMMC reserves the right to inspect Interested Party’s commodity for comparison purposes.

If you have any questions concerning the information above or if we can be of further assistance, please contact solesource@umc.edu.

Attachment A: Vendor Correspondence

Attachment B: Objection Certification

Attachment A



Re: Sole Source Letter

Date: Friday, April 29th 2016

To Whom It May Concern:

We, Avedro Inc., hereby declare that we are the sole source provider of Photrexa Viscous, Photrexa and the KXL System for corneal cross-linking in the United States.

Sincerely,

A handwritten signature in black ink, appearing to read "John Frantzis", written over a horizontal line.

John Frantzis

VP, Global Sales

A handwritten date "5/1/16" in black ink, written over a horizontal line.

Date



Attachment B

**SUBMITTED IN RESPONSE TO
Sole Source Certification No. SS5032
Accepted until May 31, 2016, at 3:00 p.m.**

I certify that the information contained in this objection is true and accurate to the best of my knowledge. I understand that UMMC will investigate all statements made in this objection and that any false or misleading information provided may result in adverse action.

Objector Name
Objector's title

Date