

Notice of Intent to Certify Sole Source

To: Interested Parties

From: Stacy Baldwin
Agency Procurement Officer

Date: April 18, 2016

Re: Sole Source Certification Number **SS5025** for **renewal of INOtherapy® Services Agreement for INOtherapy® Services**

Contact Email Address: solesource@umc.edu

Sole Source Certification Award Details

Regarding UMMC Sole Source Certification Number **SS5025** for **renewal of INOtherapy® Services Agreement for INOtherapy® Services**, please be advised that UMMC intends to award the **renewal of INOtherapy® Services Agreement for INOtherapy® Services** to **INO Therapeutics LLC dba IKARIA** as the sole source provider of the **nitric oxide-based inhalation therapy, INOtherapy®**.

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	April 18, 2016
Second Advertisement Date	April 25, 2016
Response Deadline from Objectors	May 5, 2016, at 3:00 p.m. Central Time
Notice of Award/No Award Posted	Not before September 16, 2016

Project Details

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

The University of Mississippi Medical Center is requesting the purchase of the INOtherapy® therapeutic system, which includes the pharmaceutical INOmax® from INO Therapeutics, LLC, an Ikaria company. This product and all accessory devices are needed for delivery of inhaled nitric oxide (INOtherapy® Systems). Inhaled nitric oxide is used extensively throughout critical care, perioperative, and emergency services within UMMC. Nitric oxide is delivered to the patient via mechanical ventilation after dilution with an oxygen/air mixture using an approved (CE-marked) nitric oxide delivery system. Inhaled nitric oxide causes vasodilation in the pulmonary vasculature.

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

INOtherapy® is an all-inclusive offering of drug product (INOMAX®), services and technologies. INOtherapy® includes FDA-approved pharmaceutical grade INOMAX® (nitric oxide) for inhalation, INOcal® calibration gases, use of Ikaria's proprietary drug-delivery system, distribution, emergency delivery, technical and clinical assistance, quality maintenance, in-service training and 24-hour technical service.

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

INO Therapeutics LLC, an Ikaria company, is the sole source provider of nitric oxide-based inhalation therapy, INOtherapy®, in the United States. INOtherapy® includes pharmaceutical, INOmax® (nitric oxide) for inhalation (NDC numbers 64693-002-01, 64693-001-01, 64693-002-02 and 64693-001-02). INOmax® is the only drug approved by the FDA to treat hypoxic respiratory failure (HRF) associated with pulmonary hypertension in term and near-term infants greater than 34 weeks gestational age. HRF is a serious condition in which blood vessels in the lungs constrict, making it difficult to oxygenate blood. INOmax® selectively relaxes pulmonary blood vessels, improves oxygenation and treats HRF in this fragile newborn population. Dr. Renate D. Savich is a Professor of Pediatrics and the Chief of Neonatology and Newborn Services Division at Blair E. Batson Hospital for Children. In Dr. Savich's expert medical opinion, Ikaria® is a unique and novel pharmaceutical agent and system, with no other product on the market capable of treating the pre-term neonatal population in need of such life-saving therapeutics. Dr. Savich further opines that not having INOmax® available at UMMC, a critical insufficiency in the standard of care would place many fragile patients at grave risk of adverse outcomes, including death.

INOmax® 400 parts per million (ppm) molecule (mol/mol) inhalation gas as it is known scientifically, used in conjunction with ventilator support and other appropriate active substances, is indicated:

1. Treatment of newborn infants \geq 34 weeks gestation with hypoxic respiratory failure associated with clinical or echocardiographic evidence of pulmonary hypertension, in order to improve oxygenation and to reduce the need for extracorporeal membrane oxygenation;

2. Treatment of perioperative pulmonary hypertension in adult clients and pediatric clients ages 0-17 years in conjunction with heart surgery, in order to selectively decrease pulmonary arterial pressure and improve right ventricular function and oxygenation.

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 **PRODUCT** is \$2,612,500/year; 12 monthly installments of \$217,708. This amount is within the expected price range for these products.

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 **renewal of INOtherapy® Services Agreement for INOtherapy® Services** (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 **Hologic Limited Partnership**.

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 Thursday, May 5, 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



February 29, 2016

Re: INO Therapeutics LLC - Sole Source Statement

Dear Valued Customer:

INO Therapeutics LLC, an Ikaria company, is the sole source provider of nitric oxide-based inhalation therapy, INOtherapy®, in the United States. INOtherapy includes our pharmaceutical, INOmax® (nitric oxide) for inhalation (NDC numbers 64693-002-01, 64693-001-01, 64693-002-02 and 64693-001-02).

Please feel free to call if you have questions or need additional information.

Best regards,

A handwritten signature in black ink that reads "Lori Donohue".

Lori Donohue
Contracts Manager
(908) 238-6668
critcare-contracts@mallinckrodt.com

Attachment B

**SUBMITTED IN RESPONSE TO
Sole Source Certification No. SS5025
Accepted until May 5, 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