JUSTIFICATION REVIEW DOCUMENT
FOR OTHER THAN FULL AND OPEN COMPETITION - FAR PART 6

Program/Equipment: In direct support of the U.S. Army Medical Materiel Development Activity (USAMMDA) Warfighter Protection and Acute Care (WPAC) Project Management Officer (PMO) product development effort, the Government is seeking to conduct postmarketing safety studies and clinical trials to assess possible serious risks associated with Artesunate for Injection (Artesunate).

Authority: 10 United States Code 2304(c)(1) as implemented in Federal Acquisition Regulation (FAR) 6.302-1 – Only One Responsible Source and No Other Supplies or Services will Satisfy Agency Requirement.

[redacted]

[redacted]

Prepared by:

[redacted]

Contracting Officer:

[redacted]

Technical Representative:

[redacted]

Requirements Representative:

[redacted]

Reviews

I have reviewed this justification and find it adequate to support other than full and open competition.

Legal Counsel

[redacted]

Chief, Services Group:

[redacted]

Alternate Command Advocate for Competition

[redacted]

Senior Contracting Official [redacted]

[redacted]

Justification and Approval
for Other than Full and Open Competition – FAR Part 6

1. Contracting Activity: The contracting activity responsible for this action is the U.S. Army Medical Research Acquisition Activity (USAMRAA), Fort Detrick, MD.

2. Description of Action: USAMMDA requests a new, Firm Fixed-Price contract with Amivas (US) LLC (Amivas), [redacted]

3. Description of Supplies/Services: This requirement is to conduct postmarketing safety studies and clinical trials to assess possible serious risks associated with Artesunate. Anticipated activities may include (but are not limited to):

a. Conduct a single-arm descriptive international study collecting data in women exposed to IV Artesunate during pregnancy to assess risk of pregnancy and maternal complications and adverse effects on the fetus, neonate, and infant. Infant outcomes will be assessed through at least the first year of life. The study will collect information for a minimum of seven (7) years.

b. Conduct a five (5)-year surveillance study to evaluate the potential development of resistance to Artesunate and dihydroartesisinin as obtained from ongoing resistance monitoring programs on antimalarials.

c. Conduct a female fertility study in rats that tests the adverse effects of intravenous Artesunate when administered prior to mating and continued through mating and implantation in accordance with International Council for Harmonisation S5(A) and 21 Code of Federal Regulation 58 Good Laboratory Practice for Nonclinical Laboratory Studies.

d. Conduct a descriptive five (5)-year study on the use of Artesunate in the U.S. to describe the patterns of disease occurrence in relation to several variables such as demographics, treatment location and date of treatment.

e. Conduct a multiple-dose safety, tolerability, pharmacokinetic study in pediatric patients with severe malaria from 0 to 12 months of age receiving Artesunate. The majority of pediatric patients in this age group is to be six (6) months of age and younger.

4. Authority Cited: The statutory authority permitting other than full and open competition is 10 United States Code 2304(c)(1) as implemented in FAR 6.302-1, Only

one responsible source and no other supplies or services will satisfy agency requirements.

5. Reason for Authority Cited: As described at FAR 6.302-1(a)(2), “when the supplies or services required by the agency are available only from one responsible source, or for DoD, NASA and the Coast Guard, from only one or a limited number of responsible sources, and no other types of supplies or services will satisfy agency requirements, full and open competition need not be provided for.”

6. Efforts to Obtain Competition: The sole source intent notice (W81XWH21R0043-NOI) was published on beta.SAM.gov from 19 March 2021 to 05 April 2021, and meets the requirement of FAR 5.201. No responses have been received to date.

a. *Effective competition.* No effective competition is anticipated for this requirement. No other vendors are directly required to conduct postmarketing studies and clinical trials by the FDA in response to the approved NDA for Artesunate.

b. *Subcontracting competition*. Subcontracting is anticipated to assist Amivas with completion of the postmarketing studies and clinical trials. All CONUS subcontracting will be required to comply with FAR 52.244-5 Competition in subcontracting, which will be included in the contract. All OCONUS subcontracting will adhere to the applicable provisions and clauses prescribed in FAR Part 25, supplemental instructions, and local policies.

7. Actions to Increase Competition: Due to the FDA requirements cited in Section 5, no actions are possible to increase competition for the instant requirement.

8. Market Research: USAMMDA and USAMRAA conducted market research activities from 24 February 2021 to 21 April 2021. USAMMDA's technical experts conducted FDA website, and other web-based searches, and found no other FDA licensed company for Artesunate. USAMRAA also queried Government databases; reviewed catalogs and literature published by service providers; reviewed other government contracts; and searched mandatory sources under FAR Part 8 including preferred sources and internal contracts. A search of the Small Business Administration Dynamic Small Business Search indicated >1,000 small businesses who perform similar types of services under the applicable North American Industry Classification System (NAICS) code for this requirement. The market research conducted supports the conclusion there are no other FDA licensed companies for Artesunate in the U.S. that can provide the required postmarketing studies and clinical trials. The Government also posted a Request for Information (RFI) on betaSAM (www.beta.sam.gov), as described in paragraph 9, which resulted in only one acceptable response.

9. Interested Sources: An RFI, PANMRA-21-P-2982, was posted on betaSam, in accordance with Procedures, Guidance and Information (PGI) 206.302-1, on 26 February 2021 and closed on 14 March 2021 (16 days) under NAICS 541715. The RFI requested contractor performance to conduct post-marketing safety studies and clinical trials to assess possible serious risks associated with the FDA approved Artesunate. One response was received from Amivas [redacted]; and one interested vendor was listed, US Federal Government Proposal Writer (FGPW) LLC [redacted] All responses were provided to the Requiring Activity (RA) subject matter expert (SME) on 17 March 2021. On 18 March 2021, the SME provided their review [redacted]

This RFI, posted in accordance with PGI 206.302-1, generated no information that would support effective competition. To date, no other sources have written to express an interest in response to the RFI.

10. Other Facts:

a. Procurement history.

(1) Contract numbers and dates of all awarded.

W81XWH-09-C-0022 – Analytical and Characterization Studies of Organic Chemicals, Drugs and Drug Formulations. Period of Performance (POP) 22 October 2008 to 21 May 2014.

W81XWH-17-C-0004 – Design, formulate, test, and produce a currently Good Manufacturing Practice (cGMP) clinical lot of artesunic acid for intravenous injection and phosphate buffer (PB) used as its diluent. POP of 07 November 2016 to 03 August 2022.

(2) The competitive status of these actions.

W81XWH-09-C-0022 – The contract was awarded, on a competitive basis, to SRI International. Dalton Chemical Laboratories, Inc. (Dalton) was the subcontractor and manufacturer.

W81XWH-17-C-0004 – The contract was awarded, on a sole source basis, under FAR 6.302-2-Unusual and Compelling Urgency, to Dalton.

(3) Authority previously cited if less than full and open competition was used.

W81XWH-17-C-0004 – The previous contract was awarded, on a sole source basis to Dalton using the authority at 10 U.S.C. 2304(c)(2) as implemented in FAR 6.302-2, Unusual and Compelling Urgency.

(4) If a justification was prepared to support the procurement made before this one, a summary of the contents of paragraph 7 of the justification for that procurement and an explanation of the results.

Justification (JA16252) was prepared to support the previous procurement of Artesunate under contract W81XWH-17-C-0004, and was approved under the authority described in Section 10(a)(3). The award was made to Dalton for [redacted] and was approved by the USAMRAA Special Advocate for Competition. The contract expires in fiscal year 2022. The scope of the contract is to design, formulate, test, and produce a cGMP clinical lot of artesunic acid for intravenous injection and PB used as its diluent. Paragraph seven (7) of JA16252 states “this is a one-time action due to unusual and compelling urgency. Future procurements will be conducted using competitive procedures”.

Paragraph 7 of the justification relates to the manufacturing of Artesunate and does not pertain to the requirement for postmarketing studies and clinical trials imposed on Amivas by the FDA. No other company holds an approved NDA for Artesunate. Therefore, the efforts to increase competition described in paragraph 7 of JA16252 cannot be performed for this requirement.

(5) If any prior contract for this requirement was accomplished using full and open competition, include a detailed explanation of the changed circumstances causing this action to now limit the sources.

Between 2008 and 2009, the cGMP manufacture of Artesunate was transferred from WRAIR to USAMMDA’s WPAC product manager for medical product development and management. Contract W81XWH-09-C-0022 was awarded on a competitive basis for Analytical and Characterization Studies of Organic Chemicals, Drugs and Drug Formulations for WRAIR. Only one offer was received from SRI International.

Following the expiration of contract W81XWH-09-C-0022, [redacted] USAMMDA selected Amivas as the lead company to enter into a formal partnership. In 2016, USAMMDA entered into a Cooperative Research and Development Agreement (CRADA) with Amivas. This agreement transferred all development rights to Amivas, enabling the company to sponsor and file an NDA with the FDA for the development and manufacturing of Artesunate in the U.S. To date, Amivas is the co-development partner to the Surgeon General, Department of the Army for the development and registration of Artesunate in the U.S. During this period, the USAMMDA WPAC also issued contract W81XWH-17-C-0004 to Dalton as described in Section 10(a)(4).

Inventory of Artesunate was supplied by SRI International (prime contractor) and Dalton (subcontractor) through contract W81XWH-09-C-0022. [redacted] This depletion reduced stocks to such an extent that the USAMMDA FHP could not meet the treatment protocol and have enough on hand in case of another deployment to an endemic area. [redacted]

(6) An explanation of any unusual patterns that may be revealed by the history, e.g., several consecutive, urgent buys. None.

(7) If a justification was prepared to support the procurement made before this one, briefly describe the circumstances justifying the procurement and whether there have been any significant changes.

The circumstances justifying the procurement made before this one is described in Section 10(a)(5), paragraph 3. Amivas received FDA marketing authorization on 26 May 2020 for Artesunate under section 505(b)(2) of the FD&C Act. This is determined to be a significant change following the award of contract W81XWH-17-C-0004. As part of acceptance of the FDA marketing authorization Amivas has agreed to provide further research data to the FDA, agreeing to the postmarketing requirements and commitments. [redacted]

b. Other facts. Provide any other facts. None.

11. Technical Certification:

I certify 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.

[redacted]

12. Requirements Certification:

I certify 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.

[redacted]

13. Fair and Reasonable Cost Determination:

I hereby determine that the anticipated cost to the Government for this contract action will be fair and reasonable. This determination will be made using cost and price analysis. The estimated cost of the contract action is over the threshold for certified cost or pricing data of $2 million as required by DoD Class Deviation 2018-O0015; and does not fall under any exemptions described in FAR 15.403-1. Certified cost and pricing data will be required.

[redacted]

14. Contracting Officer Certification:

I certify that this justification is accurate and complete to the best of my knowledge and belief.

[redacted]

Approval

Based on the foregoing justification, I hereby approve the procurement of Artesunate for Injection Postmarketing Studies and Clinical Trials [redacted], on an other than full and open competition basis pursuant to the authority of 10 United States Code 2304(c)(1) as implemented in Federal Acquisition Regulation 6.302-1(a)(2), Only one responsible source and no other supplies or services will satisfy agency requirements, subject to availability of funds, and provided that the services and property herein described have otherwise been authorized for acquisition.

[redacted]