MaxiVAX
activate your own defense

REQUEST FOR PROPOSAL

A PHASE Ia/Ib/II CLINICAL STUDY ASSESSING SAFETY AND TOLERABILITY OF MVX-ONCO-2 IN PATIENTS WITH SOLID TUMOR

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1 Purpose

MaxiVAX develops an active specific immunotherapy designed to trigger the patient's own natural immune response mechanism via proprietary technology in order to eliminate cancer cells. A big advantage of such approach is that it is tumor-agnostic, and it can lead to a cure rather than prolong life expectancy**,** like most existing cancer therapies.

A first-in-man phase 1 clinical study is currently being completed with MaxiVAX's first generation therapy, MVX-ONCO-1, targeting patients with a variety of solid tumors, including pancreas, colon, head and neck, chordoma, prostate and ovarian. A total of 31 patients, all having failed multiple standard therapies, were treated in the study so far. Results have shown no drug related side effects**,** in contrast to most current therapies, as well as encouraging efficacy data. The benign safety profile seen with MVX-ONCO-1 makes it a good candidate for combination therapies with other anti-tumor agents currently available or in development, such as immune checkpoint inhibitors (PD-1, PD-L1 or CTLA-4). MaxiVAX has now initiated a phase 2 clinical study in head and neck cancer with MVX-ONCO-1.

A second-generation therapy, MVX-ONCO-2, is under development. This request for proposal (RfP) aims at identifying a contract research organization (CRO) to support MaxiVAX in the set-up, conduct and reporting of the first clinical study with MVX-ONCO-2, of which MaxiVAX will be the sponsor. Further details on the project are provided in Section 3.

2 RfP instructions

2.1 General information

- MaxiVAX invites you as a service provider to submit one proposal covering the services described in Section 3.
- The issuance of this RfP in no way commits MaxiVAX to make an award. MaxiVAX is under no obligation to justify the reasons of its choice of service provider following the competitive bidding. MaxiVAX may choose not to justify its business decision to the participants of the RfP.
- MaxiVAX reserves the right to:
    - Reject any proposal without any obligation or liability to the potential service provider
    - Withdraw this RfP at any time before or after the submission of bids without any advance notice, explanation or reasons
    - Modify the evaluation procedure described in this RfP
    - Accept a proposal other than the one containing the lowest financial offer
    - Award a contract on the basis of initial proposals received without discussion of best and final offers
    - Award all services to only one supplier or allocate parts of them to different suppliers according to the needs of MaxiVAX.
- Proposals submitted after the deadline are subject to rejection.
- MaxiVAX reserves the right to request additional data, information, discussions or presentations to support each proposal. All bidders must be available to discuss details of their proposal during the RfP process.
- All offers must be submitted in an electronic format.
- Service providers are responsible for ensuring the accuracy of information provided in support of their proposal. MaxiVAX reserves the right to reject an awardee in the event of failure to

disclose any material information, or material changes or errors in any information on which the award decision was based.

- The proposed timelines below indicate the process MaxiVAX intends to follow. If there are changes to these timelines, MaxiVAX will notify you in writing.

2.2 Timelines

Process steps	Responsible party	Timelines
Launch RfP	MaxiVAX	**18 AUG 2020**
Send back the signed confidentiality disclosure agreement to MaxiVAX	Service provider	**31 AUG 2020**
Send the study synopsis to service provider	MaxiVAX	**7 SEP 2020**
Questions sent to MaxiVAX	Service provider	**14 SEP 2020**
Answers to questions sent to service providers	MaxiVAX	**21 SEP 2020**
Delivery of proposals to MaxiVAX	Service provider	**5 OCT 2020**
Notification to preselected bidders	MaxiVAX	**12 OCT 2020**
Bid-defence meetings	MaxiVAX / service provider	**W/C 19 OCT 2020**
Award notification	MaxiVAX	**2 NOV 2020**

2.3 RfP instructions and contact information

2.3.1 Confidentiality

Service providers interested in participating in this RfP are asked to email MaxiVAX's dedicated contact mentioned in Section 2.3.3 as soon as possible. MaxiVAX will then share a template Confidentiality Disclosure Agreement (CDA) for the service provider to complete (items highlighted in yellow), sign and return at the latest by the date mentioned in Section 2.2. Upon receipt of the duly signed document, MaxiVAX will share the study synopsis with the service provider.

All further discussions, meetings, information exchanges and subsequent negotiations related to this RfP that may occur are subject to the confidentiality terms and conditions of the CDA.

Please, note that the CDA is a standard document which MaxiVAX cannot afford negotiating due to project priorities, time and resources dedication. Following award of the selected service provider, a full contract negotiation process will be initiated, during which confidentiality clauses may be negotiated as appropriate.

2.3.2 Questions

All bidders may request further clarifications in regards of this current RfP, by addressing questions in writing to the dedicated contact identified in Section 2.3.3. These questions must be submitted to MaxiVAX by the date mentioned in Section 2.2, using the form provided in Section 5.

In order to ensure a fair bidding process, questions on the substance of this RfP will only be answered in a document shared with all the bidders on the date indicated in Section 2.2.

2.3.3 Contact information

CDA, questions and proposals must be sent via email to:

Jessica Renaux, Senior Clinical Trial Manager at MaxiVAX

Email: jrenaux@maxivax.ch

Phone: +41 22552 2610

2.4 Format and content of the proposal

Responses to this RfP must be in English and must contain the following information:

- **A cover letter** including**:**
  - Name and address of the service provider
  - Name, title, phone number and email address of the person authorized to commit contractually the service provider
  - Name, title, phone number and email address of the person to be contacted in regards of the content of the proposal, if different from above
  - Signature of this letter done by a duly authorized representative of the company
  - Acceptance of the consultation principles as detailed in Section 2.1
- **A technical proposal**
  - Detailed proposal explaining how your company's approach will enable MaxiVAX's team to meet the project's deliverables both in terms of timelines and quality
- **A financial proposal**
  - The proposal must clearly outline individual costs for each activity listed in Section 3.2 (unit costs and total per activity), as well as total cost for the project
  - Currency in financial proposals must be either EUR or CHF
- **Administrative information**
  - Business company information: directors and officers, creation date, corporate headquarters, locations, business turnover of the past 3 years (global and in the field of service required), headcounts (global and in the field of service required), general services provided, customer's reference
  - Any other relevant information enabling MaxiVAX to assess the opportunity of contracting with your company

2.5 Conflict of interest

The service provider shall disclose any actual or potential conflicts of interest in the proposal.

3 Scope of work

3.1 General information on the project

The study synopsis will be shared with service providers after the CDA mentioned in Section 2.3.1 is returned to MaxiVAX duly signed.

3.2 Activities to be performed

- Clinical study management

    - Feasibility and Investigator sites selection, in consultation with MaxiVAX
    - Ethics Committee submissions
    - Development of recruitment plan and oversight of patient recruitment
    - Management of electronic trial master file (eTMF). As MaxiVAX does not currently possess its own eTMF, please include costs for two possible scenarios in proposal:
        - maintenance of sponsor's eTMF
        - creation and maintenance of eTMF with migration to sponsor at end of study
- Clinical trial monitoring
    - Development of monitoring plan
    - Set up and maintenance of investigator site files
    - Monitoring of study from sites from initiation through to sites close-out
- Data management
    - Development of data management plan
    - Electronic case report form (eCRF) design
    - Data cleaning
    - Provision of study data for interim Independent Review Committee (IRC)
    - Creation and maintenance of patient unique numbering system
- Biostatistics
    - Development of Statistical Analysis Plan (SAP)
    - Statistical analysis including tables, figures and listings
- Pharmacovigilance and medical monitoring
    - Development of safety management plan
    - Management of case reports
    - Medical monitoring for the trial
- Medical writing
    - Clinical study report (CSR)
- Reporting
    - Kick-off meeting with MaxiVAX (preferably face to face if possible)
    - Monthly meetings (teleconference) with MaxiVAX until end of services
    - Monthly study status reports until end of services
    - Quarterly financial reports until end of services
    - Transfer of study documents and data to MaxiVAX at the end of the study
    - Lessons learnt meeting at end of services

Sub-contractors for some activities listed above may be envisaged.

MaxiVAX will deliver:

- Clinical study synopsis and protocol
- Patient information sheet and informed consent forms (ICF)
- Operation manuals
- Pharmacy manuals, including IMP accountability forms
- Investigator Brochure (IB)
- Investigational Medicinal Product Dossier (IMPD)
- Management of IMP supply
- Global risk management plan

- Set up of IRC and IRC charter
- Global oversight of the study and of the CRO's performance

3.3 Timelines

Milestones	Draft timelines
Submission of clinical trial application to regulatory authority(ies) and ethics committees	FEB 2021
First site activated	APR 2021
First patient enrolled	APR/MAY 2021

Service providers should propose end of study timelines based on experience.

4 Evaluation criteria

The decision to award any contract as a result of this RfP process will be based on service providers' responses and any subsequent negotiations or discussions. The decision-making process will consider the ability of each service provider to fulfil MaxiVAX's requirements as outlined within this RfP and the cost of the offer.

Proposals will be assessed against criteria including but not limited to:

- Technical criteria
  - Facilities and license to perform the study in compliance with CFR part 11
  - Records of audits/inspections of the facilities/processes
- Capacity to deliver
  - Reasonable timelines including but not limited to related to regulatory and ethics submissions, patient recruitment, samples shipments, availability of reports. Please specify projected timelines in the proposal, including "best" and "worst" cases.
  - Project management capabilities and experience
  - Experience with similar work
  - Profile of staff involved (CVs)
- Financial criteria
  - Realistic costing of the proposal

5 Annex – questions and answers form

REQUEST FOR PROPOSAL FOR MVX-ONCO-2 CLINICALSTUDY
QUESTIONS AND ANSWERS

SERVICE PROVIDER'S QUESTIONS	MAXIVAX'S ANSWERS