

Date: September 22, 2023

Ref (T-23-03): Clinical grade cell electroporator

Dear Sir/Madam,

You are invited to submit a tender to provide a clinical grade electroporator to Arbele Limited, located at the Hong Kong Science & Technology Park.

By participating in this tender, you are indicating your acceptance to be bound by the guidelines set out in this letter and attachments. We provide below the key details of requirements, which you should consider in your response.

To simplify exchange of information regarding this invitation to Tender (ITT), please nominate a Bid Manager (together with their deputy) and relevant contact telephone, facsimile numbers, and email addresses.

Please direct any questions regarding the ITT content or process to the Arbele Limited representatives named below. You should not contact other Arbele Limited personnel unless directed to do so by Arbele Limited representative. Arbele Limited reserves the right to disqualify and reject proposals from suppliers who do not comply with these guidelines. All questions should be submitted in writing either by post or to the email address below.

Only communications made by your Bid Manager (or their deputy) to our named representatives, Kwong-Fai Wong, Chief Technology Officer will be considered during the pre-contract tender period.

As part of this tender process Arbele Limited makes no obligations in any way to:

- I. pay any vendor for any ITT response; or
- II. award the contract with the lowest or any bidder; or
- III. accept any ITT information received from vendors; or
- IV. include vendors responding to this ITT, in any future invitation; or
- V. any other commitment to vendors whatsoever.

I look forward to receiving your response.

Yours sincerely, Kwong-Fai Wong, PhD Chief Technology Officer Arbele Limited

E: tony@arbelebio.com

T: +852 3620 3002



Invitation To Tender

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A. Background

Arbele Limited is a biopharmaceutical company based in Hong Kong Science & Technology Park, Hong Kong SAR, China. Arbele is engaged in development and commercialisation of "first-in-class" immunotherapeutics, including cell-based therapies for treating advanced cancers that are highly prevalent and remain without effective cures.

B. System Requirements & Specifications

To facilitate our CAR therapy development project to meet clinical trial standard and regulatory requirements, we are seeking a clinical grade electroporation system. The specific requirements of the system are as follow:

- 1. The system needs to be a closed and cGMP compliant system with the capability of rapid transfection from 1×10^5 to 1×10^9 cells.
- 2. It should have capability of both flow and static electroporation.
- 3. It should be easy to operate and pre-installed with optimised protocols for various cell types.
- 4. GMP transfection solutions for cell and gene therapy should be included.
- 5. The system needs to be installed with 21 CFR Part 11 enabled software and it should support FDA master file.
- 6. Barcode reader need to be integrated to capture sample, reagent, and processing assembly information.
- 7. Installation, configuration, and maintenance service should be provided.
- The system should be compliant to CE or relevant regulatory (IEC 61326-1, EN 61000) requirements regarding conformity with health, safety, and environment protection standards (SPE 1000, EN 61010, CSA 61010-1) and be certified as ISO 9001 compliant.

C. Respondent Instruction

Tenders should be submitted no later than <u>9:00 Hong Kong time on the 5th of October 2023</u>. Please deliver an electronic copy of the written proposal with pricing information and payment terms to:

Kwong-Fai Wong

E: tony@arbelebio.com

Arbele Ltd reserves the right to disregard any response submitted after the deadline, and to modify the provisions of this ITT at any time prior to the scheduled date for written responses. Additional scope and requirements can be added. Notification of such changes will be provided to all vendors.

D. Evaluation Criteria

The equipment configuration must meet the requirements as stated in Section B. If met the system requirements and specifications, the proposal will be assessed using the following criteria and weightings:

- 1. The price should be competitive with reasonable payment terms (60%).
- 2. The service provider shows a successful track record of providing, distributing, and maintaining relevant cell electroporator or electroporator-related accessories (20%).
- 3. The timeline of the system delivery and installation on site (10%).
- 4. The technical supports, innovation, and added values as well as the strategic fit of the service provider will also be considered (10%).
- 5. The procurement contract will be awarded to the service provider with the highest assessment scores.