July 17, 2024

Dear Sir/Madam,

Invitation To Tender for Cell Line Development & Antibody Production Services

You are invited to submit a tender to provide cell line development and antibody production services to Arbele Limited.

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 the 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 Ltd representatives named below. You should not contact other Arbele Ltd personnel unless directed to do so by the Arbele Ltd representative. Arbele Ltd 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, Tony Wong Kwong-Fai, Chief Technology Officer will be considered during the pre-contract tender period.

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

1. pay any vendor for any ITT response; or
2. award the contract with the lowest or any bidder; or
3. accept any ITT information received from vendors; or
4. include vendors responding to this ITT, in any future invitation; or
5. any other commitment to vendors whatsoever.

I look forward to receiving your response.

Yours sincerely,

Tony Wong Kwong-Fai, PhD
Chief Technology Officer
Arbele Limited
E: tony@arbelebio.com
T: 852 3620 3002

Ref: T-24-02

Invitation To Tender

Cell Line Development & Antibody Production Services (Ref: T-24-02)

A. Background

Arbele Limited is a biopharmaceutical company based in Hong Kong Science & Technology Park engaging in development and commercialization of "first-in-class" humanized antibody biologics including antibody-drug conjugate (ADC) for treating advanced gastrointestinal cancers.

B. Project Summary

To proceed the project into IND filing and clinical trials of our lead ADC candidate, we are now seeking a proposal for cell line development and antibody production. The list and scope of each activity associated with the study is described below. The study should be designed and conducted in accordance with the guidelines of NMPA, EMA, FDA and other relevant regulatory agencies.

1. Development of antibody-producing CHO cell line

- Generation and isolation of single CHO cell clones with reasonable antibody production yield
- Master cell bank production with internal release and qualification
- Preparation of technical reports for submission to FDA, NMPA and other relevant agencies

2. Antibody production

- Cell culture and downstream process optimization
- Manufacture of antibody intermediate (non-GMP, 100-200L) for subsequent ADC production
- Reference standard preparation
- Development and validation of release tests
- Pilot formulation and stability studies
- Preparation of CMC data packages for submission to FDA, NMPA and other relevant agencies

C. Respondent Instruction

Tenders should be submitted no later than 18:00 Hong Kong time on the 27th of July 2024. Please deliver an electronic copy of the written proposal with pricing information to:

Tony 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

1. Fulfillment of regulatory compliance is compulsory. The service provider should:

- be able to conduct all testing in accordance with applicable Good Manufacturing Practice (cGMP) and Good Laboratory Practice (GLP) regulations
- have an outstanding track record in audits by US FDA, China NMPA, and other agencies
- demonstrate a body of Standard Operating Procedures and a documented training system which ensures all technical staff can capably perform their assigned procedures
- be equipped with a qualified lab record system, and demonstrate a quality assurance unit that routinely audit all aspects of lab operations

If the service providers pass criterion no. 1, the responses will be assessed using the following criteria and weightings:

2. The price should be competitive with reasonable payment terms (50%)

3. The service provider shows a record of successfully delivering CMC data of biologics drugs for filing of IND to FDA or to other agencies (30%)

4. The innovation and added value as well as the strategic fit of the service provider will also be considered (20%)

5. The procurement contract will be awarded to the service provider with the highest assessment scores