

Date: 22 Apr 2024

Dear Sir/Madam,

Invitation To Tender for a Central Laboratory Services

You are invited to submit a tender to support Arbele Limited and its affiliates (**the Company**) to provide ADA, PK, PBMC analysis and biomarkers evaluation for Phase I MAD study.

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 take into account 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 Company's representatives named below. You should not contact other Arbele Ltd personnel unless directed to do so by Arbele Ltd representative. The Company 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, Dr. Alexis Che, Director of Clinical Operations will be considered during the pre-contact tender period.

As part of this tender process, Arbele Ltd 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,

Dr. Alexis Che – Director of Clinical Operations
Arbele Limited
E: Alexis.Che@arbelebio.com
T: +65 8503 6389

Ref: T-24-01



Invitation To Tender

ADA, PK Analysis and Biomarkers Assessment

A. Background

Arbele Limited, a biopharmaceutical company headquartered in Hong Kong Science & Technology Park, Hong Kong SAR, China, will conduct a MAD study in Australia, Hong Kong, US and China of its lead drug molecule, ARB202 (a humanized CDH17xCD3 bispecific antibody). The IND molecule is intended for treatment in advanced gastrointestinal cancers.

B. Project Summary

This is a multi-center, open label, MAD study, with approximately 30 patients from Australia, Hong Kong, US and China. We are now seeking a central laboratory located in Asia Pacific region and China to do ADA, PK assay and T-cell subset immunophenotyping and cytokines biomarkers analysis for patients in Australia/Hong Kong/US and China respectively.

List and scope of the sample analysis is described below. The assay will be done in GLP standard in accordance with the relevant guidelines and regulatory requirements, based on the recommendation by the central laboratory according to industry practices.

1. Pharmacokinetics
 - Completion of tech transfer and assay revalidation based on the analytical method and validation report
 - Batch sample collection and PK analysis, data transfer to sponsor reviews every 6-8 weeks
2. Anti-drug antibodies
 - Completion of tech transfer and assay revalidation based on the analytical method and validation report
 - Samples collected and analyzed by end of the study
3. Biomarker: Serum Cytokines
 - Samples collected and analyzed by end of the study
4. Biomarker: PBMC/T cell subset
 - Method development & validation
 - Sample collected per T&E schedule and shipped for PBMC isolation and analysis
 - T-cell subset immunophenotyping by flow cytometry
5. Biomarker: sCDH17
 - Completion of tech transfer and assay revalidation based on the analytical method and validation report
 - Samples collected and analyzed by end of the study

C. Respondent Instruction

For more information and inquires, interested parties and Service Providers may contact us at any office hours. Tenders should be submitted no later than 18:00 Hong Kong time on 31 May 2024. Submitted proposals will be reviewed immediately. Award notice will be issued in mid Jun 2024. Please deliver an electronic copy of the written proposal with pricing information to:

Dr. Alexis Che

Alexis.Che@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 Laboratory Practice (GLP) regulations with relevant Laboratory Accreditation
 - 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 able to provide consultation and guidance to effectively meet customer's requirements of specific program goals with robust assay development strategies

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 successful track record in immunoassay and biomarkers assay development, optimization and validation for early phases of Immuno-Oncology programs (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