Date: 06 Jan 2023

Dear Sir/Madam,

Invitation To Tender for Regulatory Support Services

You are invited to submit a tender to support Tiberias Technology Limited and its affiliates (**the Company**) to prepare and submit CDRH pre-submission meeting, and file IDE for Phase I FIH 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 Tiberias Technology Ltd personnel unless directed to do so by Tiberias Technology 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, Tiberias Technology 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: +852 9657 2273

Ref: T23-01

Invitation To Tender

CDRH Pre-Submission meeting & IDE filing

A. Background

Tiberias Technology Limited, is a sister company with Arbele Limited and a wholly owned subsidiary of Arbele Investment Limited. The company focuses on research and development of a multicomponent biomarker platform in cancer. Through the collaboration with local university and hospital network, we are validating the clinical utility of CDH17 to detect gastrointestinal cancer and to co-develop a companion diagnostic (CDx) that is essential for safe and effective use of a corresponding therapeutic drug, ARB202 (a humanized CDH17xCD3 bispecific antibody).

B. Project Summary

A multi-center, open label, FIH MAD study, with approximately 40 patients from Australia, Hong Kong, Singapore and US will be started in 1H of 2023. The tissue diagnostics platform (the investigational medical device) will be used to detect the aberrant expression of CDH17 in GI cancer as the inclusion criteria for enrolling patients, who would be eligible to anti-CDH17 dosing finding therapy and treatment response in MAD study.

CRO with regulatory experience in IVD and CDx product development and market approval, will be appointed to conduct gap analysis of the company's product performance, and support us to prepare and submit CDRH pre-submission meeting and IDE filing in MAD study. In addition, CRO may be required to provide recommendation in our future regulatory, clinical and companion diagnostic co-development strategies in the next development stages, if needed.

List and scope of the regulatory support is described below.

1. CDRH pre-submission meeting
    - Conduct gap analysis and risk assessment on company documents and data
    - Provide guidance on requirements for IDE submission
    - Pre-submission preparation and submission to CDHR
    - Interaction with FDA as needed and provide communication support

2. IDE preparation and filing
    - IDE document preparation, review, QC and finalization
    - Submission to CDHR
    - Interaction with FDA as needed and provide communication support

C. Respondent Instruction

For more information and inquires, interested parties and CRO may contact us at any office hours. Tenders should be submitted ASAP, but no later than 18:00 Hong Kong time on 03 Feb 2023. Submitted proposals will be reviewed immediately. Award of notice will be issued in mid Feb 2023. Please deliver an electronic copy of the written proposal with pricing information to:

Dr. Alexis Che
Alexis.Che@arbelebio.com

Tiberias Technology Limited 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 and delivering high-quality submission is compulsory. The service provider should:
   - be able to conduct the submission in compliance with all relevant regulatory and statutory requirements
   - have an outstanding track record in audits by US FDA and other agencies
   - have in-depth regulatory knowledge and experienced in IVD and companion diagnostic product development and market approval
   - be able to provide consultation and guidance to effectively meet customer's requirements of specific program goals

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 preparation of CDHR pre-submission meeting and IDE filing, including interaction with FDA (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