SUTEZOLID INDEPENDENT REVIEW COMMITTEE
AMENDED CHARTER
DATED: NOVEMBER 14, 2022

This Charter describes the roles and responsibilities of the Sutezolid Independent Review Committee (the "SIRC"). This committee has been formed by TB Alliance after consultation with multiple constituencies including the Bill & Melinda Gates Foundation (the “Foundation”) and the Medicines Patent Pool (the “MPP”) to support the accelerated development, registration, and launch of sutezolid for use as part of a universal regimen to treat drug sensitive as well as multi-drug resistant tuberculosis in furtherance of TB Alliance’s ultimate goal of facilitating the accessibility of future tuberculosis drug therapies to people most in need within developing countries at an affordable price (“Purpose”). The SIRC shall ensure that only scientifically appropriate research that furthers the Purpose is approved.

Whereas the SIRC was originally formed to facilitate the review and approval process for all submitted proposals requesting TB Alliance to: (a) supply quantities of sutezolid drug substance or drug product for future sutezolid studies; (b) make appropriate data related to the development of sutezolid available for future sutezolid studies and/or (c) provide a right of reference to TB Alliance’s regulatory filings related to the development of sutezolid for future sutezolid studies (“Sutezolid Request(s)”), and

Whereas, TB Alliance has previously shared sutezolid drug material, data or rights of reference with third parties in response to previous Sutezolid Requests and that as a condition of the SIRC approval for such request, such approved third parties (“Previous Requestor(s)”) have executed certain agreements (“Previous Sutezolid Agreements”) agreeing to grant TB Alliance certain rights to use the data generated by such Previous Requestor and to reference regulatory filings made by such Previous Requestor using such shared drug material, data or right of reference (“Access Rights”) and

Now Therefore,

(1) TB Alliance shall extend certain Access Rights granted to TB Alliance under the Previous Sutezolid Agreements to each member of the Sutezolid Consortium (as hereinafter defined);

(2) Any party making a future Sutezolid Request must, as a condition to receiving the SIRC’s approval of such request, agree to grant Access Rights to TB Alliance, all Previous Requestors and all parties making approved future Sutezolid Requests (“Future Requestor(s)” (TB Alliance together with the Previous Requestors and all Future Requestors shall be referred to herein as “Sutezolid Consortium Member(s)” and, collectively as the “Sutezolid Consortium”);

(3) Each Sutezolid Consortium Member must submit an additional request to the SIRC if it desires to use sutezolid drug material, rights of reference or sutezolid data (including the results of the studies or analyses that it conducted as a result of a previous Sutezolid Request) for any additional use;

(4) The SIRC’s Purpose is expanded to facilitate the review and approval process for all Sutezolid Requests made to any Sutezolid Consortium Member by another Sutezolid Consortium Member or by another third-party in accordance with the provisions of this Charter.

The SIRC will not review study protocols, regulatory submissions, clinical results, or other documents or

information submitted to the SIRC for the purpose of ensuring compliance with safety, regulatory or legal requirements. The requestor is solely responsible for determining and complying with all safety, regulatory and legal requirements.

The SIRC will not review any Sutezolid Request for (1) any data previously published by a Sutezolid Consortium Member or by any third party, or (2) any data planned to be published by a Sutezolid Consortium Member as long as the only restriction placed on the use of such data is that any unpublished data must be kept confidential until the earlier of (a) the date the data are published or (b) eighteen months from the date of the disclosure.

Membership of the Committee

Composition of the SIRC
The SIRC will be comprised of at least five members, of which one will serve as Chair who will facilitate the SIRC review process in accordance with this charter. The Chair will be elected by the SIRC for a three-year term. One member of the SIRC will represent TB Alliance, one will represent the Foundation and one will represent the MPP. Other members will be independent of the TB Alliance, the Foundation and the MPP. The independent members will be chosen based on qualifications listed below. At least two members independent of TB Alliance must participate in a review to have a quorum. To ensure adequate expertise is applied to each review, additional ad hoc nonvoting experts may be asked by the SIRC to participate in the review of a specific proposal.

Desired Qualifications of Independent SIRC Members

- Experience with the TB advocacy and patient community in high burden countries and familiarity with the global access objectives for a universal TB regimen
- Knowledge of TB drug Research and Development with particular emphasis on the oxazolidinone drug class
- Experience in drug development, preferably in the field of TB
- Drug regulatory affairs experience as relevant to evaluate the qualifications of the investigator team.

At each meeting of the SIRC, all members will provide disclosure of potential conflicts of interest that will be reviewed by the other SIRC members. If requested by any member, reimbursement will be provided for all incidental expenses (travel, lodging, etc) associated with the committee's work. No honoraria will be provided.

Proposal Submission

TB Alliance will manage Sutezolid Requests for the Sutezolid Consortium and will designate an email address or set up an online portal for receiving requests for the use of sutezolid drug substance, drug product, data or regulatory filings. Alternatively, TB Alliance may, at its election, designate a third party to receive requests and to collect, hold and facilitate the exchange of documents provided by a requestor or by a Sutezolid Consortium Member in response to such request or otherwise in furtherance of the Purpose. The requestor must provide the following information to TB Alliance or its designee:

- Title of proposed research

- Proposal summary indicating how the proposed research advances sutezolid drug development and access in the context of the ultimate goal of a universal TB drug regimen.
- A detailed research protocol at the minimum outlining the following:
    - Study hypotheses, objectives, design, endpoints and timelines
    - Experimental methods (study population, entry criteria, interventions, etc.), and
    - Analytical methods (key measurements, statistics, etc.)
- Ability to submit and manage an IND or CTA for ex-US studies cross-referencing the TB Alliance IND if the clinical study is to be conducted under an IND or ex-US equivalent (if clinical)
- Ability to comply with all relevant GxP requirements, if applicable
- Publication plan including agreement to Open Access principles as defined in the application
- Qualifications and experience of the research team (include Curricula Vitae)
- Quantity and form of sutezolid needed for study (if drug substance or drug product is requested)
- Either source of funding or plan to obtain the funding to enable the research and to comply with the requestor's obligations under the Required Agreement as defined below (drug product will not be supplied until funding covering all aspects of the proposed work is secured)
- A statement indicating that the requestor's proposal is in furtherance of TB Alliance's goal of facilitating the accessibility of future tuberculosis drug therapies to people most in need within developing countries at an affordable price.

The templates for the relevant material transfer and data sharing agreements (Required Agreement) will be made available to the requestor for review. The requestor will be required to acknowledge review and agreement to the material terms and provisions contained in the relevant Required Agreement as a condition to the SIRC's approval.

An acknowledgement of receipt of the above listed information will be sent within 5 business days.

Review Process

TB Alliance will appoint a coordinator for the SIRC. The coordinator will review each application received for completeness. If there are missing components, the coordinator will inform the requestor and ask them to update or modify their application. Once an application is complete, the review process will be conducted as follows:

- The coordinator will notify the members of the SIRC of an active application for review and provide the documents through attachments to email or through a shared link to a secure cloud storage. Members with any perceived conflict of interest should notify the coordinator detailing the conflict. The SIRC will decide whether the Committee member is eligible to participate in the review of the application.
- An *ad hoc* teleconference will be scheduled to discuss the application. The review of the protocol by the SIRC should preferably occur within 20 business days of the completion of the application. If the application cannot be reviewed within the one teleconference, another teleconference may be scheduled within an additional 20 business days. If additional expertise is required, the Chair, in consultation with other SIRC members, as needed, will invite one or

more experts to participate in the review. The SIRC may, at its sole discretion, invite individuals submitting an application to participate in parts of the SIRC meeting.

- Decisions reached by the SIRC will be considered final unless new relevant information is provided to the SIRC that mandate further review.
- The coordinator will document, via formal written minutes, the meetings of the SIRC including their recommendation and feedback on the proposal. The coordinator will then communicate both the recommendation and feedback to the requestor. If a request is not approved or requires revisions, a detailed explanation of the issues to be resolved with the application in its current form will be provided to the requestor by the coordinator on behalf of the SIRC.
- All documentation and correspondence related to requests and review of proposals by the SIRC will be kept in a secure location that will be made available to relevant constituencies upon request.

Review Criteria

The goal of the SIRC is to expedite the development path of sutezolid such that approved proposals contribute to the timely, accurate and quality evaluation of sutezolid as part of future tuberculosis therapies in furtherance of the Purpose. The SIRC may request additional information or clarification that may be needed to adequately review a proposal. The SIRC will not review study protocols, regulatory submissions, clinical results, or other documents or information submitted to the SIRC for the purpose of ensuring compliance with safety, regulatory or legal requirements.

After review the SIRC will make one of the following recommendations:

- Not approved: The proposal is deemed as not meeting the criteria as stated.
- Approved: The proposal is approved as submitted.
- Revise and resubmit: The proposal holds scientific merit; however, there are issues the SIRC will require to be resolved before the proposal can be approved.

The SIRC will strive to reach a consensus with respect to each application but if a consensus cannot be reached, the majority view shall control. In all decisions, the SIRC will endeavor to provide detailed feedback to the investigator within the scope of the review. The feedback is provided solely as courtesy and will not modify the requestor's obligations to determine on its own and comply with all safety, regulatory and legal requirements in the conduct of its work. The SIRC and its members and their respective organizations will have no liability as to any errors, mistakes or inaccuracies contained in any feedback. Revised proposals will be re-evaluated by the SIRC to determine final disposition.

Approved Proposals

If approval is granted to the requestor and funding is available to enable the research and to comply with the requestor's obligations under the relevant Required Agreement, TB Alliance and the requestor will execute the Required Agreement. Reasonable efforts will be made to satisfy the request in a timely manner.

This Charter may be amended or revised from time to time. Approved November 14, 2022.