LICENCE AGREEMENT

This Licence Agreement (the “Agreement”) is made as of 23 March 2017 (the “Effective Date”) by and between the Medicines Patent Pool Foundation, a non-profit foundation registered under the laws of Switzerland, and having a principal place of business at Rue de Varembe 7, Geneva 1202, Switzerland (“MPP”) and The Global Alliance for TB Drug Development, Inc. (“Licensee”), a not-for-profit corporation formed under the laws of Delaware, USA, having a principal place of business at 40 Wall Street, New York, New York, USA 10005. Each of MPP and Licensee is referred to in this Agreement as a Party. MPP and Licensee are collectively referred to in this Agreement as the Parties.

RECITALS

WHEREAS, MPP is a non-profit organization with a mission to improve the health of people living in the developing world by increasing access to quality, safe, efficacious and affordable HIV, HCV and tuberculosis medicines by facilitating access to intellectual property on these medicines;

WHEREAS, MPP and Johns Hopkins University entered into a License Agreement dated November 7, 2016 (the “JHU License”), in which MPP was granted certain rights to sublicense the Patents (as defined below) relating to the use of Compound (as defined below) in combination with other agents for the prevention and/or treatment of tuberculosis;

WHEREAS, the Licensee is a non-profit organization with a mission to discover and develop novel drug regimens for the treatment and prevention of tuberculosis (“TB”) and to make those drug regimens widely available to TB patients on an affordable basis, and desires to obtain a license from MPP in order to facilitate the Compound’s clinical development and ensure affordable access;

WHEREAS, MPP is willing to grant such a sublicense to the Licensee pursuant to the JHU License for the above-mentioned purposes;

NOW THEREFORE in consideration of the covenants and obligations expressed in this Agreement, and intending to be legally bound, the Parties agree as follows:

1. Definitions

1.1 Affiliate shall mean in relation to a Party, any corporation, firm, partnership or other entity which is directly or indirectly controlled by, in control of, or under common control of such Party. For the purposes of this definition “control” shall mean the ability of any corporation, firm, partnership or other entity, whether through ownership of shares or
otherwise, to procure that the affairs of a Party hereto are conducted in accordance with the wishes of such corporation, firm, partnership or other entity.

1.2 Agreement Quarter shall mean any period of three months ending on the last day of March or June or September or December.

1.3 Compound shall mean sutezolid, formerly known as PNU-100480.

1.4 Field of Use shall mean the prevention and/or treatment of TB.

1.5 Licensed Product(s) shall mean pharmaceutical combinations and compositions containing the Compound in combination with other active ingredients that, but for a license under this Agreement, would infringe a valid claim of a Patent granted and in force.

1.6 Patents shall mean those patents and patent applications as set forth in Exhibit A.

1.7 Territory shall mean those countries in which there are Patents issued or pending at the time of execution of this Agreement.

2. Scope of the Grant

2.1 Upon the terms and subject to the conditions set out in this Agreement and the JHU License, MPP hereby grants to the Licensee, and the Licensee hereby accepts, a non-exclusive, sublicensable, royalty-free, fully-paid license to develop, make, have made, use, file for regulatory approval, sell, offer to sell, import and export Licensed Products in the Field in the Territory. Any sublicense granted under this Agreement shall explicitly incorporate by reference the terms of this Agreement and will contain all of the benefits to the Johns Hopkins University stated herein, including the disclaimers, indemnification, and insurance requirements as described herein.

2.2 For avoidance of doubt, nothing in this Agreement shall be construed to prevent Licensee from engaging in any activities inside or outside the Territory where such activities would not infringe a valid claim of a Patent granted and in force.

2.3 Licensee agrees that in the event that MPP assumes, or obtains the option to assume, the responsibility for prosecuting and maintaining Patents, the Parties will discuss in good faith as to whether MPP may transfer partial or total such responsibility to Licensee.

3. Development and Registration

3.1 Development timelines. Licensee will (either directly or through one of its sublicensees) use commercially reasonable efforts to research, develop and commercialize Licensed Products in the Field, and will devote substantially equivalent efforts as it applies
to research, develop and commercialize its other products at a similar stage of development with similar medical potential. Licensee will be presumed to be in breach of its diligence obligations hereunder if it fails to reach the milestones at the time points as defined in Exhibit B unless Licensee can demonstrate that its failure to achieve a particular milestone was caused by unexpected scientific or clinical findings, delays caused by ethics committees or regulatory authorities or other similar unexpected events or delays. For avoidance of doubt, however, the failure of Licensee to raise the necessary funds to carry out the work necessary to complete a particular milestone will not be sufficient reason to rebut the presumption of a diligence breach. If it is determined that a failure of due diligence has occurred and is not cured or adequately rebutted within thirty (30) days of MPP’s written notice to Licensee of such failure, MPP will have the right to terminate the licenses granted to Licensee pursuant to Section 6.2 hereof.

3.2 Accessibility. Licensee and its sublicensees will commercialize Product(s) in a manner that facilitates its widespread availability, which commercially reasonable efforts shall include adequate manufacturing capacity, adequate supply of product meeting specifications, registration of Licensed Product(s) with applicable local and global health authorities, participation in local tenders and making available to local policy makers information regarding the Licensed Product(s). Licensee and its sublicensees will use commercially reasonable efforts to ensure that the Licensed Product(s) will be made available at Affordable Pricing as quickly as possible in sufficient quantities to meet the needs of TB patients throughout the world. “Affordable Pricing” as used herein with respect to all countries in the world listed as having high income economies by the World Bank other than Bulgaria, Estonia, Latvia, Lithuania and Russia (“Tier 1 countries”) shall mean a competitive price that facilitates adoption by the various procurement agencies in those countries and coverage for reimbursement by third party payors in those countries, where applicable. “Affordable Pricing” as used herein with respect to all countries in the world except Tier 1 Countries shall mean the lowest sustainable, competitive price for the Licensed Product(s) which covers the cost of raw materials, manufacturing, distribution and operational overheads, and includes a reasonable margin to help ensure the economic sustainability of the production and distribution of the Licensed Product(s). Notwithstanding the foregoing, nothing in this provision will prevent Licensee from requiring its sublicensees to implement accessibility policies that will result in prices for a Licensed Product being lower than what would be required by this Section 3.2 or a Licensed Product being more widely available than what would be required by this Section 3.2.

3.3 Quality. Licensee and its sublicensees will commercialize the Licensed Products in a manner consistent with MPP’s Quality Policy, as may be amended from time to time, but which requires, as of the Effective Date: (i) World Health Organization (“WHO”) pre-qualification standards; or (ii) the standards of any Stringent Regulatory Authority (“Stringent Regulatory Authority”), defined as regulatory authorities which are members, observers or associates of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use, as may be
updated from time to time. Where such approvals are not yet available, the Sublicensee(s) may obtain temporary approval through a WHO Expert Review Panel.

3.4 Most favored licensee. MPP agrees that it will not grant any other sublicense pursuant to the JHU License on terms that are more favorable to such sublicensee than that granted to Licensee under this Agreement, taking into account all relevant factors, such as the date on which a sublicense is granted and the purpose for which the sublicense is granted.

3.5 Stewardship. MPP and Licensee agree on the importance of facilitating proper development, stewardship and use of new TB drugs and regimens, and Licensee intends to develop and commercialize Licensed Products in a manner consistent with these goals. MPP and Licensee will confer, prior to the commercialization of any Licensed Products, in order to reach good faith agreement on terms governing the manufacture, use and sale of Licensed Products in a manner consistent with what is then recognized to be best practices for the proper stewardship of new drugs for TB, taking into account, for example, findings from the MPP’s work on TB drug stewardship.

3.6 Product Labeling. Licensee will cause that the labeling of all Licensed Products sold or offered for sale under this Agreement shall expressly state that the Licensed Product is manufactured under a license from the Medicines Patent Pool where local law permits.

3.7 Reports. During the period Licensee or its sublicensees are developing the Licensed Products, Licensee will provide MPP with an annual report describing (a) the status of development of each Licensed Product in development (b) the regulatory filing plan with the WHO Pre-qualification Programme and/or a Stringent Regulatory Authority anticipated for each Licensed Product in the upcoming calendar year, and (c) a list of countries for which regulatory approvals or authorizations have been obtained during the reporting period for any Licensed Product. Such annual report shall be provided to MPP within sixty (60) days of the end of each calendar year. Following regulatory approval for any Licensed Product by the WHO Pre-qualification Programme and/or a Stringent Regulatory Authority, Licensee will send (or cause its sublicensees to send) to MPP within thirty (30) days following the end of each Agreement Quarter a written report setting forth a list of countries for which regulatory approvals or authorizations have been obtained during the reporting period for any Licensed Product, as well a statement accounting for all Licensed Products (in terms of smallest units and patient packs for each formulation) sold or supplied by the Licensee under this Agreement during such Agreement Quarter. MPP agrees that information contained in these annual and quarterly reports shall be treated as Confidential Information.

4. Representations, Warranties and Covenants

4.1 MPP and Licensee each represent and warrant that, subject to the Negation
of Warranties and Disclaimers contained herein:

(a) it is duly organized, validly existing and in good standing under the laws of the jurisdiction of its incorporation and has full corporate power and authority to enter into this Agreement and to carry out the provisions hereof;

(b) this Agreement has been duly executed and delivered on behalf of such party, and constitutes a legal, valid, binding obligation, enforceable against it in accordance with the terms hereof; and

(c) the execution, delivery and performance of this Agreement by such party does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it is bound, nor violate any law or regulation of any court, governmental body or administrative or other agency having jurisdiction over such party.

4.2 Each of MPP and Licensee covenants and agrees that it shall perform all activities under this Agreement in accordance with all applicable laws and regulations.

4.3 Negation of Warranties. MPP provides Licensee the rights granted in this Agreement as is and with all faults. Except as specifically set forth in Sections 4.1 and 4.2 herein, MPP makes no representations and extends no warranties of any kind, either express or implied. Among other things, MPP disclaims any express or implied warranty of merchantability, safety, effectiveness, reliability, or fitness for a particular purpose.

4.4 No Representation of Patents. Licensee also acknowledges that MPP and JHU do not represent or warrant:

(a) the validity or scope of any Patents, or

(b) the commercial viability of Patents or Licensed Products, or

(c) that the exploitation of Patents will be successful, or

(d) that there are no third party claims or prior filed patents that would affect ownership of the Patents or freedom to operate.

4.5 No other Promises or Warranties. Other than the obligations specifically stated in this Agreement, MPP and JHU makes no promises, express or implied, regarding the Patents or any Licensed Product. Licensee agrees that no representation or statement by any MPP or JHU employee shall be deemed to be a statement or representation by MPP or JHU, and that Licensee was not induced to enter this Agreement based upon any statement or representation of MPP or JHU, or any employee of MPP or JHU. MPP and JHU are not responsible for any publications, experiments or results reported by any MPP or JHU employee, now or in the future, and it is the sole responsibility of Licensee to evaluate the Patents and the accuracy of any data or results.
5. **Indemnity and Insurance.**

5.1. **Indemnification.** Licensee agrees that it shall be responsible for injuries or losses to third parties arising from or related to its own acts or omissions, or caused by or arising from Licensee’s Licensed Products, or allegedly arising as a consequence of the exercise by Licensee of any rights granted in this Agreement. To that end, Licensee shall protect, indemnify, and hold harmless MPP and JHU, which shall include the Johns Hopkins Health System (“JHHS”), and JHU and JHHS respective present and former trustees, officers, inventors of the Patents, agents, faculty, employees and students (collectively the JHU Indemnitees), from any claims arising therefrom, including defending any action brought against MPP or the JHU Indemnitees with counsel reasonably acceptable to MPP and the JHU Indemnitees, and indemnifying MPP and the JHU Indemnitees, as against any judgments, fees, expenses, or other costs arising from or incidental to any product liability or other lawsuit, claim, demand or other action, whether or not MPP or a JHU Indemnitee is named as a party defendant in any such lawsuit and whether or not MPP or a JHU Indemnitee is alleged to be negligent or otherwise responsible for any injuries to persons or property.

Exercise of the rights granted in this Agreement by an Affiliate of Licensee or Sublicensee of Licensee or by a third party on behalf of or for the account of Licensee, shall be considered Licensee’s exercise of the rights granted in this Agreement for purposes of this Paragraph.

5.2. **Exclusions.**

(a) No indemnification will be provided for claims arising from the practice by MPP, the JHU Indemnitees, or any other Sublicensee of MPP of the Patents or exercise of rights retained by MPP under this Agreement.

(b) No indemnification will be provided for a claim against MPP for injuries allegedly caused solely and directly by negligent use or administration by MPP or another Sublicensee of MPP or a JHU Indemnitee of a Licensed Product, but any products liability or similar claim based upon Licensee’s Licensed Product made by or provided by Licensee or its Affiliates or its Sublicensees will be covered by this indemnification requirement.

5.3. **Rights and obligations of MPP and JHU.** MPP and JHU shall provide Licensee with prompt notice of any claims covered by Licensee’s obligation to indemnify, and will provide reasonable cooperation to Licensee in Licensee’s investigation and defense of such claims. MPP and JHU Indemnitees shall have the right to participate in such defense with counsel of its choice and at MPP’s and JHU Indemnitee’s own expense. MPP and JHU Indemnitees shall have the right to approve the settlement of any claim hereunder that imposes any liability or obligation on MPP or
JHU Indemnitees, or affects the Patents, other than the payment of money damages paid by Licensee or Licensee’s Sublicensees.

5.4. Insurance. Prior to initial human testing of any Licensed Product, Licensee will establish and maintain Comprehensive General Liability Insurance, including Clinical Trial Insurance, with a reputable and financially secure insurance carrier or through a self-insurance program acceptable to JHU to cover any liability of Licensee, JHU Indemnitees and MPP to third parties related to any Licensed Product, or otherwise arising from the activities of Licensee, or its Sublicensee(s). Prior to the first commercial sale of any Licensed Product, Licensee will or, in the event Licensee commercializes any Licensed Product through a Sublicensee, will cause its Sublicensee to establish and maintain Comprehensive General Liability Insurance, including Product Liability Insurance, with a reputable and financially secure insurance carrier or through a self-insurance program acceptable to JHU to cover any liability of Licensee, JHU Indemnitees and MPP to third parties related to any Licensed Product, or otherwise arising from the activities of Licensee, or its Sublicensee(s). The insurance policy shall provide minimum liability coverage of $5,000,000 per claim and $10,000,000 in the aggregate, and shall include MPP and JHU Indemnitees as additional insureds. Licensee will furnish a Certificate of Insurance or other evidence of compliance upon reasonable request. All insurance of Licensee will be primary coverage; other insurance of MPP and JHU Indemnitees will be excess and noncontributory.

5.5. MPP agrees that it shall be responsible for injuries or losses to third parties arising from or related to its own acts or omissions, or caused by or arising from Licensed Products of MPP or another MPP Sublicensee, or allegedly arising as a consequence of the exercise by MPP of any rights granted in this Agreement. To that end, MPP shall protect, indemnify, and hold harmless Licensee from any claims arising therefrom, including defending any action brought against Licensee with counsel reasonably acceptable to Licensee, and indemnifying Licensee, as against any judgments, fees, expenses, or other costs arising from or incidental to any product liability or other lawsuit, claim, demand or other action, whether or not Licensee is named as a party defendant in any such lawsuit and whether or not Licensee is alleged to be negligent or otherwise responsible for any injuries to persons or property.

Exercise of the rights granted in this Agreement by an Affiliate of MPP or another Sublicensee of MPP or by a third party on behalf of or for the account of MPP, shall be considered MPP's exercise of the rights granted in this Agreement for purposes of this Paragraph.

5.6. Exclusions.

(a) No indemnification will be provided for claims arising from the practice by Licensee or any Sublicensee of Licensee of the Patents or exercise of rights retained by Licensee under this Agreement.

(b) No indemnification will be provided for a claim against Licensee
for injuries allegedly caused solely and directly by negligent use or administration by Licensee or a Sublicensee of Licensee of a Licensed Product of Licensee or such Sublicensee, but any products liability or similar claim based upon a Licensed Product made by or provided by MPP or another Sublicensee of MPP will be covered by this indemnification requirement.

5.7. Rights and obligations of Licensee. Licensee shall provide MPP with prompt notice of any claims covered by MPP’s obligation to indemnify, and will provide reasonable cooperation to MPP in MPP’s investigation and defense of such claims. Licensee shall have the right to participate in such defense with counsel of its choice and at Licensee’s own expense. Licensee shall have the right to approve the settlement of any claim hereunder that imposes any liability or obligation on Licensee, or affects the Patents, other than the payment of money damages paid by MPP or another Sublicensee of MPP.

6. Term and Termination

6.1 Term. This Agreement shall enter into force upon the Effective Date and, unless earlier terminated as provided herein, shall continue in force on a country-by-country basis until the expiration or abandonment of the last-to-expire Patent containing a valid claim in the Territory.

6.2 Termination for Material Breach. Subject to Licensee’s right to rebut a presumption that Licensee is in breach of its diligence obligations set forth in Section 3.1, a Party ("non-breaching party") shall have the right to terminate this Agreement in the event the other Party ("breaching party") is in material breach of any of its material obligations under this Agreement. The non-breaching party shall provide written notice to the breaching party. The breaching party shall have a period of 30 days after such written notice to cure such breach, or to provide a timeline to cure such breach to the satisfaction of the non-breaching party. If such breach is not cured within the 30 day period or in accordance with the timeline, this Agreement shall effectively terminate.

6.3 Effect of Termination. In the event that this Agreement is terminated other than under Section 6.1, all sublicenses will automatically be converted into direct licences between MPP and Licensee’s sublicensees, provided such sublicensees are not in material breach of the respective sublicense agreement.

6.4 Insolvency. Either Party may terminate this Agreement in the event that the other Party becomes insolvent, makes an assignment to the benefit of creditors, or has a petition in bankruptcy filed for or against it.

6.5 Waiver. The waiver by either Party of any breach of any term or condition of this Agreement shall not be deemed a waiver as to any subsequent or similar breach.
6.6 **Survival.** Sections 5, 6.3, 6.6, 6.7 and 7 shall survive termination or expiry of this Agreement.

6.7 **JHU License.** In the event the JHU License is terminated by Johns Hopkins University prior to the end of its term, this Agreement may automatically be converted into a direct license between Johns Hopkins University and Licensee pursuant to the applicable terms of the JHU License.

7. **Confidentiality and Publications**

7.1 **Confidential Information.** All technology, know-how, business information, (including the annual and quarterly reports required by Section 3.7 hereof) or any other confidential information disclosed by one party (the “Disclosing Party”) to the other party (the “Receiving Party”) hereunder (“Confidential Information”) shall be used solely and exclusively by Receiving Party in a manner consistent with the rights granted hereunder and the purposes of this Agreement as stated in the preamble and recitals hereto; maintained in confidence by the Receiving Party; and shall not be disclosed to any non-party or used for any purpose except to exercise its rights and perform its obligations under this Agreement without the prior written consent of the Disclosing Party, except to the extent that the Receiving Party can demonstrate by competent written evidence that such information: (a) is known by the Receiving Party at the time of its receipt and, not through a prior disclosure by the Disclosing Party, as documented by the Receiving Party’s business records; (b) is in the public domain other than as a result of any breach of this Agreement by the Receiving Party; (c) is subsequently disclosed to the Receiving Party on a non-confidential basis by a third party who may lawfully do so; or (d) is independently discovered or developed by the Receiving Party without the use of Confidential Information provided by the Disclosing Party, as documented by the Receiving Party’s business records. Within 30 days after any expiration or termination of this Agreement, Receiving Party shall destroy (and certify to the Disclosing Party such destruction) or return all Confidential Information provided by the Disclosing Party except as otherwise set forth in this Agreement. One copy of the Disclosing Party’s Confidential Information may be retained in the Receiving Party’s files solely for archival purposes as a means of determining any continuing or surviving obligations under this Agreement. The confidential obligations under this Agreement shall survive this Agreement for a period of 5 years.

7.2 **Publicity.** Each Party shall seek each other’s previous written approval of any initial press release or public announcement concerning the grant, scope or terms of this licence prior to such press release or other publication being made. Following an initial announcement, neither Party shall be required to seek the other Party’s consent to make public statements, by press release or otherwise, regarding the existence of this Agreement, the identity of the Parties, the terms, conditions and subject matter of this Agreement, or otherwise in reference to this Agreement, provided such statements are accurate and not misleading. It is understood and accepted by Licensee that MPP will publish the full
7.3 **Use of JHU Name.** Licensee shall not use the names, marks, logos, or trade dress of the Johns Hopkins University, Johns Hopkins Health System, or any employee, student, or trustee thereof without the express prior written permission of JHU.

8. **Miscellaneous**

8.1 **Agency.** Neither Party is, nor will be deemed to be, an employee, agent or representative of the other Party for any purpose. Each Party is an independent contractor, not an employee or partner of the other Party. Neither Party shall have the authority to speak for, represent or obligate the other party in any way without prior written authority from the other Party.

8.2 **Entire Understanding.** This Agreement embodies the entire understanding of the Parties with respect to the subject matter hereof and supersedes all previous communications, representations or understandings, and agreements, whether oral or written, between the parties relating to the subject matter hereof.

8.3 **Severability.** The Parties hereby expressly state that it is not their intention to violate any applicable rule, law or regulation. If any of the provisions of this Agreement are held to be void or unenforceable with regard to any particular country by a court of competent jurisdiction, then, to the extent possible, such void or unenforceable provision shall be replaced by a valid and enforceable provision which will achieve as far as possible the economic business intentions of the Parties. The provisions held to be void or unenforceable shall remain, however, in full force and effect with regard to all other countries. All other provisions of this Agreement shall remain in full force and effect.

8.4 **Notices**

(a) Any notice or other communication to be given under this Agreement, unless otherwise specified, shall be in writing and shall be deemed to have been provided when delivered to the addressee at the address listed below (i) on the date of delivery if delivered in person or (ii) one day after receipt if sent by a reputable international courier service:

In the case of Licensee:

The Global Alliance for TB Drug Development, Inc.  
24th Floor  
40 Wall Street  
New York, New York 10005  
Attention: Melvin Spigelman, CEO
Email: Melvin.spigelman@tballiance.org

In the case of MPP:

Medicines Patent Pool
Chemin Louis-Dunant 17
Geneva 1202
Switzerland

Attention: General Counsel
Email: office@medicinespatentpool.org

(b) Either party may change its address for communications by a notice in writing to the other party in accordance with this Section.

8.5 Language; Governing Law. This Agreement shall be construed, and legal relations between the parties hereto shall be determined, in accordance with the laws of the State of New York applicable to contracts executed and wholly to be performed within the State of New York without giving effect to the principles of conflicts of laws. Any disputes between the parties to the Agreement including the applicability of any Patent, shall be brought in the state or federal courts located in New York, New York. Both parties agree to waive their right to a jury trial and to consent to jurisdiction in such courts.

8.6 Dispute resolution. The parties agree that in the event of a dispute they shall first attempt in good faith to resolve such dispute. In the even that such dispute is not resolved on an informal basis, either Party may refer the dispute to the Executive Director of the MPP, and to Licensee’s CEO (together, the Designated Officers). If such dispute is not resolved by the Designated Officers within 30 days, either party may commence court proceedings.

8.7 Assignment. Neither Party may assign all or part of this License Agreement without the other Party’s prior written consent.

8.8 Amendment. No amendment or modification hereof shall be valid or binding upon the parties unless made in writing and signed by both parties.

[signatures appear on following page]
IN WITNESS WHEREOF, the parties hereto have executed this Licence Agreement as of the Effective Date.

**MPP:**

**Medicines Patent Pool Foundation**

[Signature]

By [Name]

Title: **Executive Director**

**LICENSEE:**

The Global Alliance for TB Drug Development, Inc.

[Signature]

By [Name]

Title: **President & CEO**
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**Exhibit B**

**Development Milestones***

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<th>Milestone Description</th>
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<tr>
<td>Initiate Phase 1 Single-ascending Dose and Multi-ascending Dose Study</td>
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<td>Initiate Phase 2 Study</td>
<td>March 1, 2019</td>
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<td>Initiate Phase 3 Study**</td>
<td>January 1, 2021</td>
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<td>SRA Approval</td>
<td>December 1, 2024</td>
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* MPP and Licensee will negotiate in good faith an appropriate advance in the Development Milestones in the event that already existing pre-clinical and clinical data on sutezolid becomes available for use by Licensee.

**Assumes data from TB Alliance’s linezolid optimization study provides sufficient clinical evidence to move a sutezolid containing regimen directly into a small Phase 3 salvage trial.