MEMORANDUM OF UNDERSTANDING
BETWEEN THE MEDICINE PATENT POOL FOUNDATION
AND THE GLOBAL ALLIANCE FOR TB DRUG DEVELOPMENT

This Memorandum of Understanding ("MOU") is made as of 26 October 2017 by and between the Medicines Patent Pool Foundation ("MPP"), a not-for-profit corporation organised under the laws of Switzerland, whose business headquarters is located at Rue de Varembe 7, Geneva 1202, Switzerland, and The Global Alliance for TB Drug Development, Inc. ("TB ALLIANCE") a New York-based not-for-profit product development partnership with a principal address at 40 Wall Street, 24th Floor, New York, N.Y. 10005, USA. TB ALLIANCE and the MPP together the "Parties":

Background:

Tuberculosis ("TB") is a contagious disease of global proportions, killing someone every twenty seconds. Today's TB drugs are more than 40 years old and must be taken for 6-9 months for drug sensitive TB. Long, demanding treatment schedules prove too much for many patients, and the resulting erratic or inconsistent treatment breeds drug resistance. New drugs are desperately needed to save millions of lives needlessly lost to TB. Mounting resistance to today's drugs, including multi and extensively drug-resistant TB (MDR-TB and XDR-TB), coupled with a growing number of patients co-infected with TB and HIV, are making the pandemic more threatening and more deadly.

TB ALLIANCE is a not-for-profit, product development partnership accelerating the discovery and development of new TB drugs and regimens that will shorten treatment, be effective against susceptible and resistant strains, be compatible with antiretroviral therapies for those HIV-TB patients currently on such therapies, and improve treatment of latent infection.

MPP is a non-profit organization with a mission to improve the health of people living in low- and middle-income countries by increasing access to quality, safe, efficacious and affordable medicines by facilitating access to intellectual property to allow for the rapid development and manufacturing of these medicines.

TB ALLIANCE and MPP entered into a Licence Agreement dated 23 March 2017 whereby MPP granted to TB ALLIANCE a non-exclusive license to certain patents covering the use of investigational compound, sutezolid, in combination with other active ingredients. TB ALLIANCE is actively investigating the use of sutezolid and is currently conducting a Phase 1 clinical trial of the compound.

TB ALLIANCE and MPP share an interest in having the knowledge and data around sutezolid and its optimal use in TB treatment be treated as a global public good, made available to
all interested parties. The Parties also share an interest in facilitating the development work of third parties who share in the Parties’ goal of making sutezolid-containing TB regimens equitably available to all those in need of TB treatment.

To that end, TB ALLIANCE and MPP have agreed upon a framework of collaboration (the “Collaboration”) as follows:

(1) **Description of the Collaboration.** The Parties wish to accomplish the following objectives through this Collaboration:

   a) In order to make sutezolid drug product manufactured on behalf of TB ALLIANCE available to interested third party investigators, TB ALLIANCE will establish an Independent Review Committee to review the third parties’ intended study protocol. TB ALLIANCE will invite MPP to designate an individual to serve on the Independent Review Committee. As and when necessary, MPP will provide input and support relating to any material transfer agreements that TB ALLIANCE may enter into in making the sutezolid drug product available to third parties.

   b) TB ALLIANCE commits to making the data on sutezolid (including from pre-clinical and clinical studies) that it generates available to any third party that has a bona fide scientific or other interest in the development of sutezolid for the treatment of TB, directly or through a third party data repository, provided that the recipient of the data also commits to similar data sharing commitments. As and when necessary, MPP will provide input and support in evaluating a third party’s data sharing commitments.

(2) **Press Release and Other Communications.** The signature of the present MOU may be announced through a press release agreed to by the Parties. TB ALLIANCE acknowledges that this MOU, in accordance with MPP policy, will be made publicly available on MPP’s website and by other appropriate means.

(3) **Confidentiality.**

   a) During the term of this MOU, the Parties may make available to each other certain Confidential Information (as hereinafter defined) or one party may otherwise learn of Confidential Information belonging to the other party. For purposes of this Section, "Confidential Information" means any and all confidential or proprietary information regarding a party or its business, including, without limitation, all products, patents, trademarks, copyrights, trade secrets, processes, techniques, scientific information, computer programs, databases, software, services, research, development, inventions, financial, purchasing, accounting, marketing, fundraising and other information, whenever conceived, originated, discovered or developed, concerning any aspect of its business, whether or not in written or tangible form; provided, however, that the term
"Confidential Information" shall not include information (i) which is or becomes generally available to the public on a non-confidential basis, including from a third party provided that such third party is not in breach of an obligation of confidentiality with respect to such information, (ii) which was independently developed by a party not otherwise in violation or breach of this Agreement or any other obligation of one party to the other, or (iii) which was rightfully known to a party prior to entering into this Agreement.

b) The Parties shall hold in strictest confidence any of the other party’s Confidential Information; and shall not distribute, disclose or convey Confidential Information to any third party and shall not make use of any Confidential Information for its own benefit or for the benefit of any third party. The foregoing to the contrary notwithstanding, the Parties shall not be in violation of this subsection in the event that a party is legally compelled to disclose any of the Confidential Information.

c) Any legally-binding documentation entered into by the Parties in relation to this MOU and the Collaboration shall contain relevant clauses referring to or incorporating the provisions of this Section 3 relating to the treatment of confidential information.

d) The obligations of this Section 3 shall continue for a period of five (5) years after the termination of this MOU.

(4) Status of MOU. The Parties agree to be bound by the provisions of Sections 3 and 4 hereof and agree that the remaining Sections of this MOU are not intended to be legally binding, and represent the framework for future discussions between the Parties in relation to the Collaboration.

(5) Effective Date, Term and Termination. This MOU shall become effective on the date of last signature and continues for five (5) years. It may be modified by mutual written consent of the signature Parties. This MOU may be terminated by any Party upon a sixty (60) days advance written notice to the other Party.

The memorandum of understanding can be renewed by written amendment signed by both Parties, such amendment setting forth the terms and conditions of the renewal.
THE MEDICINES PATENT POOL FOUNDATION

By: 

Name: Chan Park
Title: General Counsel
Date: 6 October 2017

THE GLOBAL ALLIANCE FOR TB DRUG DEVELOPMENT, INC.

By: Dr. Melvin Spigelman

Name: Dr. Melvin Spigelman
Title: President & CEO
Date: October 26, 2017 | 7:08:15 PM PDT