TBCAB
GLOBAL TB COMMUNITY ADVISORY BOARD

TAG
Treatment Action Group

President Ronald J. Daniels
Office of the President
242 Garland Hall
The Johns Hopkins University
3400 N. Charles Street
Baltimore, MD 21218

CC: Ms. Jill Uhl, Interim Executive Director, Johns Hopkins Technology Transfer
Dr. Heather Bakalyar, Senior Intellectual Property Manager, Johns Hopkins Technology Transfer
Dr. Susan Dorman, Associate Professor of Medicine, Division of Infectious Diseases, Johns Hopkins University School of Medicine
Dr. Eric Nuermberger, Associate Professor of Medicine, Division of Infectious Diseases, Johns Hopkins University School of Medicine

May 7, 2015

Dear President Daniels,

As advocates for and representatives of communities affected by tuberculosis (TB), we are eager to see the responsible and rapid development of sutezolid, an important potential new drug for TB. We are aware that Johns Hopkins is in discussions with Sequella about transferring its intellectual property rights to sutezolid. We urge you to take necessary steps to assure timely advancement of sutezolid—including in combination with other new medicines—through clinical trials, while simultaneously securing widespread and affordable postdevelopment access for patients and programs. Some of us are alumnae of Johns Hopkins institutions, and as such feel a special duty to encourage the university to act responsibly and with forethought at this critical juncture.

We therefore write to request that your institution:

1) encourage rapid development of sutezolid by creating firm deadlines that, if unmet, will require that intellectual property rights revert to the university;
2) ensure that any agreements made regarding intellectual property rights to sutezolid include specific and strong access provisions for collaborative research and for patients and programs; and
3) allow representatives of TB-affected communities to comment on the terms of the agreement.

We have been tracking the development of sutezolid for years and share the frustration of many in the TB field about its slow progress under the ownership first of Pfizer and now of Sequella. With so few clinical candidates in the TB pipeline, it is unacceptable to allow a promising compound to languish in early-stage research. We believe it is Johns Hopkins's responsibility to use its limited intellectual property rights to reverse this situation. We therefore respectfully request that Johns

Hopkins include clauses to hold Sequella accountable to clear, ambitious, and realistic timelines for the advancement of sutezolid through key milestones, by stipulating the reversion of intellectual property rights should these milestones not be met in a timely fashion.

At the same time, in order to achieve its full potential as a new TB drug candidate, sutezolid must be widely available for research in combination with other new and repurposed compounds. All TB drugs must be delivered as part of a multidrug regimen; in order to truly achieve the improved, safer, shorter, and more tolerable therapies that people with TB need, multiple new drugs are needed. Thus, any intellectual property transfer agreements must also come with specific conditions for collaboration and access for research for other drug and trial sponsors and research consortia that want to test sutezolid in well-designed combination studies. It is imperative that this research be done now.

Given the expertise within your academic community, preclinical and clinical experts at Johns Hopkins should have substantive input into the decisions about which trials can and should be immediately implemented. Participation in these studies should be an explicit, mandatory term of the agreement and not be left to the discretion of any single licensee.

Plans for posttrial access are also essential to include in any agreement; they should be made in accordance with the principles outlined in the *Good Participatory Practice Guidelines for TB Drug Trials*.[1] Plans should include provisions for both timely registration and affordable pricing in all countries with high burdens of TB and multidrug-resistant TB as well as compassionate use and other pre-approval access mechanisms following evidence of safety and efficacy in a phase IIb trial.

We also respectfully request that representatives of TB-affected communities, for example our group, the Global TB Community Advisory Board, be allowed to comment on the terms of any agreement before it is finalized. TB is a public health problem, and its potential solutions should not be hidden in private dealings.

We look forward to collaborating to ensure timely and responsible development of and access to sutezolid. Please direct any responses to Erica Lessem at erica.lessem@treatmentactiongroup.org or 1.212.253.7922.

Respectfully submitted,
Global TB Community Advisory Board
Treatment Action Group

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[1] Stakeholder and Community Engagement Workgroup of the Critical Path to TB Drug Regimens initiative. Good participatory practice guidelines for TB drug trials. 2012. Available from: http://www.cptrinitiative.org/downloads/resources/GPP-TB%20Oct1%202012%20FINAL.pdf. (Accessed 2015 May 6)