

22 July 2013

Carol Nancy
Chairman of the Board of Directors and Chief Executive Officer
Sequella Inc.
9610 Medical Center Dr., Suite 200
Rockville, MD 20850

Open RE: Further research into sutezolid urgently needed for tuberculosis

Dear Dr. Nancy,

We are writing to congratulate Sequella for taking over the development of sutezolid (PNU-100480), a highly promising new treatment for tuberculosis (TB). We also urge you to pursue the rapid and collaborative development of this new drug, whose preliminary development was supported by Pfizer.

We encourage you to include in your development plans for sutezolid immediate collaborations with public, not-for-profit research consortia, so that the potential of this important new compound can be further explored in combination studies with other drugs.

TB—and in particular, drug-resistant TB—is a major public health threat around the world. Only a fraction of patients with drug-resistant TB access appropriate treatment, and only approximately 50% of those in treatment are cured. TB patients urgently need research into faster-acting, less toxic, and more effective potential treatment options such as sutezolid.

Since 2009, when Treatment Action Group (TAG) first started reporting on the development of sutezolid, the compound has made only modest advancement in clinical trials, with two phase 1 and one phase 2a clinical trials conducted by Pfizer. The U.S. National Institutes of Health-funded AIDS Clinical Trials Group (ACTG), the Centers for Disease Control and Prevention (CDC)-funded TB Trials Consortium (TBTC) and the TB Alliance have designed trials that would include sutezolid in novel regimens to shorten tuberculosis therapy and treat drug-resistant tuberculosis, but the drug has not been made available for these critical studies. We urge Sequella to be more proactive in developing sutezolid under its own New Drug Application, together with SQ109 and in concert with other drugs.

Developing novel treatments for drug-resistant TB requires not only combining sutezolid with your product SQ109, but also collaboration across research groups and product developers. Proposed studies – including the TB Alliance’s Nix-TB study evaluating a regimen of entirely new drugs given to people with pre-extensively drug-resistant TB and

extensively drug-resistant TB, and the ACTG's MARVEL study of five proposed treatment arms in people with MDR-TB— all depend on access to sutezolid. The ability to put together a treatment regimen that includes drugs from different classes is essential for treating patients with drug-resistant TB.

As Sequella prepares to take over the right to develop sutezolid from Pfizer, we ask that you ensure that this promising new drug is made available for key collaborations, including those proposed by the TB Alliance, the ACTG and the TBTC.

A strong commitment to advancing the drug rapidly and through collaboration with public sector research consortia will maximize the value of past and present investments in sutezolid.

We look forward to discussing these issues with you and the Sequella sutezolid team.

Best regards,

Mark Harrington, Treatment Action Group
Global TB Community Advisory Board
Community Research Advisors Group to the Tuberculosis Trials Consortium
Asia Pacific Network of People Living with HIV

CC: Leo Eink, Director and Chief Scientific Officer
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