

NEWS RELEASE

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SEQUELLA RECEIVES FDA FAST TRACK STATUS FOR TB DRUG

ROCKVILLE, MD – Sequella, Inc., a clinical-stage biopharmaceutical company focused on commercializing improved treatment paradigms for diseases of epidemic potential, today announced it has received Fast Track designation from the U. S. Food and Drug Administration (FDA) for SQ109, the company's proprietary lead drug candidate for treatment of pulmonary tuberculosis (TB). With a mechanism of action distinct from other antibiotics used in TB therapy, SQ109 shows excellent *in vitro* activity against drug susceptible and drug resistant TB bacteria, including XDR-TB, as well as potent *in vivo* activity against pulmonary TB alone and with other TB drugs.

“This FDA Fast Track designation validates SQ109 as a potentially unique addition to the TB therapeutic armamentarium,” said Dr. Carol Nacy, CEO of Sequella. “This is an important regulatory milestone and recognition that SQ109 may address unmet needs in TB therapy to improve and shorten the current treatment regimen.”

According to a letter from the FDA, SQ109 received fast track designation based on the following: “SQ 109 has the potential to fulfill an unmet medical need, and the preclinical information available thus far demonstrates that SQ 109 has the potential to enhance the treatment of tuberculosis during the first two months of intensive therapy and to treat multi-drug resistant TB.” The FDA letter also stated that: “In 2002 the estimated number of active cases of tuberculosis was 9 million, with approximately 2 million deaths, worldwide.”

Mandated by the FDA Modernization Act of 1997, Fast Track designation expedites the development and review of a New Drug Application (NDA) for approval.

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About Tuberculosis (TB)

TB is a contagious infectious disease caused by the bacterium *Mycobacterium tuberculosis*. TB bacteria can be inhaled into lungs and are able to avoid destruction by certain white blood cells. Without containment by immune cells, the bacteria can spread throughout the body, multiply, survive and remain dormant for years. TB is the leading cause of global deaths that result from a single-agent infectious disease. Nine million new cases of active TB disease are reported every year. The World Health Organization (WHO) estimates that one-third of the world's population is infected with TB.

About SQ109

SQ109 is an orally active small molecule antibiotic that inhibits cell wall synthesis and acts on multiple cellular pathways in a select group of microorganisms, including *Mycobacterium tuberculosis*, the bacteria that cause TB. SQ109 enhances, both *in vitro* and *in vivo*, the activity of the anti-tubercular drugs isoniazid and rifampin, thereby shortening by 25% the time required to cure mice of experimental TB. SQ109 is currently in Phase I clinical trials under a US IND, and could replace one or more of the current first-line anti-TB drugs, simplify therapy, and shorten the treatment regimen. Since 2000, Sequella has applied its scientific expertise in TB research and product development to identify, characterize, and complete preclinical evaluation of SQ109.



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SQ109 was developed in partnership with the NIH, with several grants from the National Institute of Allergy and Infectious Diseases (NIAID) and the assistance of the NIAID and the National Cancer Institute Inter-Institute Program (NCI IIP) for IND-enabling studies.

About Sequella, Inc.

Sequella is a clinical-stage biopharmaceutical company focused on commercializing improved treatment paradigms for diseases of epidemic potential. The company leverages its global influence, infectious disease expertise, and diverse product portfolio to proactively address emerging health threats with significant market opportunity. The Company's lead drug candidate SQ109, a new orally-active diamine antibiotic for the treatment of tuberculosis (TB) and other infectious diseases, is presently in Phase I clinical studies. The company's lead diagnostic product candidate, the TB Patch, is completing several international clinical trials in anticipation of world-wide product registration. For more information, please visit www.sequella.com.

Forward-Looking Statement

This press release contains forward-looking statements that are subject to risks and uncertainties, and includes statements that are not historical facts. Actual results could differ significantly from results discussed. Sequella disclaims any intent or obligation to update forward-looking statements, except as required by law.

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