

**NEWS RELEASE**

**September 12, 2006**

**SEQUELLA LEAD DRUG CANDIDATE SQ109 TO BEGIN  
CLINICAL TESTING IN PHASE 1 TRIAL**

*A New Antibiotic for the Treatment of Pulmonary Tuberculosis, including XDR-TB*

ROCKVILLE, MD -- Sequella, Inc., a clinical-stage biopharmaceutical company focused on commercializing products to treat diseases of epidemic potential, announced today its intention to commence a Phase 1 clinical trial for SQ109, a new, orally-active diamine antibiotic for the treatment of Tuberculosis (TB) and other infectious diseases. The investigational new drug (IND) application was filed with the U.S. FDA on August 9, 2006. The Phase 1 dose-escalation study will enroll up to 48 healthy normal volunteers to assess the safety and pharmacokinetics of SQ109.

“The filing of our first IND is a significant milestone for the company,” said Dr. Carol Nacy, CEO of Sequella. “The initiation of SQ109 clinical development publicly validates our development strategy, proprietary discovery platforms, and diverse small molecule product portfolio, and underscores our core focus to commercialize improved treatment paradigms for diseases of epidemic potential.”

SQ109 could replace one or more of the current first-line anti-TB drugs, simplify therapy, and shorten the treatment regimen. With a mechanism of action distinct from other antibiotics used in TB therapy (including Isoniazid, Ethambutol and Ethionamide), SQ109 inhibits cell wall synthesis in a select group of microorganisms with excellent *in vitro* activity against both drug susceptible and drug resistant TB bacteria, including XDR-TB. SQ109 also enhances, both *in vitro* and *in vivo*, the activity of the anti-tubercular drugs Isoniazid and Rifampin, thereby shortening the time required to cure mice of experimental tuberculosis by 25%.

“SQ109 completes the company’s transition from diagnostic to therapeutic product development in the infectious disease market,” said Nacy. “In the case of TB, our strategy was to first commercialize an improved diagnostic product with greater sensitivity and specificity than the gold standard and then leverage the knowledge gained to develop an improved treatment regimen for all forms of the disease.”

Since 2000, Sequella has applied its scientific expertise in TB research and product development to identify, characterize, and complete preclinical evaluation of SQ109. 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.

Preliminary results of the Phase 1 trial are anticipated during the first quarter of 2007.

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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.



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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 agent. More than 8 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 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. For more information, please visit [www.sequella.com](http://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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**EDITOR'S NOTE: To obtain a statement from NIAID, please call 301-402-1663. This NIH News Release is available online at: <http://www.nih.gov/news/pr/sep2006/niaid-12.htm>**