## FOR IMMEDIATE RELEASE

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# Sequella Awarded \$4.6 million in New NIH Grants to Expand Anti-Infectives Pipeline

*Company has \$4.8 million in non dilutive R&D funding for 2011 and \$3.3 million committed for 2012-2015* 

Rockville, Md. -- Sequella, Inc., a clinical-stage pharmaceutical company focused on commercializing novel antibiotics to treat life-threatening infectious diseases, today announced that it received a \$3.8 million 5-year R01 grant from the National Institutes of Health (NIH), National Institute of Allergy and Infectious Diseases (NIAID) to identify and develop new ethylenediamine-based antibiotics for *Clostridium difficile*, an emerging infectious pathogen causing life-threatening gastrointestinal disease.

Sequella chemists will collaborate with microbiologists at the University of Virginia to identify highly active chemical analogs of SQ109, an experimental drug in phase 2 clinical trials for a different indication, to improve SQ109 killing of *C. difficile*. The grant will support acquisition of all nonclinical data required to advance a lead drug candidate to IND-directed preclinical studies. *C. difficile* is responsible for more than 50% of hospital-acquired infections, with a total annual pharmacoeconomic cost of \$4 billion in the U.S. and nearly 700,000 patients infected. The potential U.S. market for a new drug to eradicate *C. difficile* is estimated at \$200-\$300M.

"There are few antibiotics currently available to treat *C. difficile* infections," said Dr. Carol Nacy, CEO of Sequella. "Hospital-based *C. difficile* infections have increased dramatically in both the U.S. and the E.U. in recent years. With documented high rates of relapse and drug resistance, new drugs to treat *C. difficile* are sorely needed."

Sequella also received two additional grants from NIAID at the NIH to plan Phase 3 clinical studies and develop clinical sites in Russia, the Commonwealth of Independent States, and Eastern Europe for evaluation of SQ109 in multi-drug resistant tuberculosis (MDR-TB) and to investigate a new drug target in *Mycobacterium tuberculosis*.

The three new grants, combined with other grants renewed for 2011, brings total non dilutive R&D funding for 2011 to \$4.8 million, with an additional \$3.3 million committed for future years. Given the significance of this non-dilutive grant support for earlier stage research, Sequella plans to raise an equity round this summer to support Phase 2 efficacy trials of SQ109 in *H. pylori*.

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## About SQ109

SQ109, identified as the lead drug candidate from among 63,000 diamine compounds synthesized in a combinatorial chemistry program, is currently under US IND. SQ109 completed three phase 1 studies in the U.S. and is currently being evaluated in Phase 2 efficacy studies in TB patients in Africa. With a mechanism of action distinct from all other antibiotics used in TB therapy, SQ109 has excellent activity against both drug susceptible and MDR TB bacteria, including extremely drug-resistant (XDR)-TB strains. SQ109 also enhances the activity of the anti-tubercular drugs Isoniazid and Rifampin and shortens by >30% the time required to cure mice of experimental TB. SQ109 could replace one or more of the current first-line antitubercular drugs, simplify therapy, and shorten the TB treatment regimen.

Sequella filed a second IND for SQ109 for treatment of *Helicobacter pylori* infections in 2010. SQ109 has excellent activity against *H. pylori*, killing 99.99% of these bacteria with concentrations easily achievable in stomach contents and tissues.

SQ109 was co-discovered by scientists at Sequella and the NIAID, a part of the NIH, under a Cooperative Research and Development Agreement.

## About Sequella

Sequella is a clinical stage pharmaceutical company focused on commercializing improved treatments for infectious diseases of epidemic potential. The company leverages its global influence, R&D platforms and infectious disease expertise to proactively address emerging health threats. Through focused execution, clear commercialization pathways, and strategic partnerships, Sequella intends to commercialize a broad product portfolio designed to treat global health threats with significant market opportunity.

## About the NIH and NIAID

NIH—The Nation's Medical Research Agency—includes 27 Institutes and Centers and is a component of the U. S. Department of Health and Human Services. It is the primary federal agency for conducting and supporting basic, clinical and translational medical research, and it investigates the causes, treatments and cures for both common and rare diseases. For more information about NIH and its programs, visit <u>http://www.nih.gov</u>.

NIAID conducts and supports research at NIH, throughout the United States, and worldwide to study the causes of infectious and immune-mediated diseases, and to develop better means of preventing, diagnosing and treating these illnesses. News releases, fact sheets and other NIAID-related materials are available on the NIAID Web site at <u>http://www.niaid.nih.gov</u>. For comments from the NIAID regarding this grant, please contact 301-402-1663.

## **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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Media Contact:	Alan S. Klein, Executive Vice President, Sequella, Inc.
	Phone: 301-762-7776
	Fax: 301-762-7778
	email: alanklein@sequella.com