

**For Immediate Release**

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## **Sequella Files IND and Receives FDA Go-ahead for Phase 2 Trial of SQ109 in *Helicobacter pylori*-associated Duodenal Ulcers**

*Company's Second IND Targets Entry into the \$24 Billion Gastrointestinal Market*

Rockville, MD -- Sequella, Inc., a clinical-stage company focused on commercializing novel drugs for treatment of infectious diseases, announced it has successfully filed an Investigational New Drug (IND) application with the U.S. Food & Drug Administration (FDA) to test SQ109 in patients suffering from *H. pylori*-related duodenal ulcers, and can now begin Phase 2 studies.

"*H. pylori* is a highly infectious pathogen that causes 95% of duodenal and 85% of gastric ulcers, and is implicated in most gastric cancers," said Dr. Carol A. Nancy, CEO of Sequella. "We are quite pleased with the clinical development of SQ109 as we progress through phase 2 trials for tuberculosis (TB) and look forward to achieving similar success against *H. pylori*."

SQ109 is currently in Phase 2 clinical assessment in patients with pulmonary TB. Based on Phase 1 results achieved under its TB IND, SQ109 will directly begin Phase 2 clinical studies in duodenal ulcers. Data from the laboratory of D. Scott Merrell at the Uniformed Services University of the Health Sciences, Bethesda, Maryland show both significant SQ109 antimicrobial activity against *H. pylori* and therapeutic potential.

In collaboration with Dr. David Y. Graham, a world expert in *H. pylori*, Sequella will conduct a phase 2A study to evaluate the safety, tolerability, and antimicrobial activity of SQ109 at the Baylor College of Medicine, Houston, Texas. "*H. pylori* is an important human pathogen and the cause of gastric cancer. Worldwide, increasing antibiotic resistance has resulted in a marked reduction in the ability to cure the infection, and new drugs are urgently needed," stated Dr. Graham.

According to the National Institutes of Health, approximately 14.5 million people in the United States are thought to suffer from ulcers. A new drug that simplifies the current 3-4 drug treatment regimen could result in a potential annual US market of more than \$500 million.

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### **About SQ109**

SQ109, identified as the lead drug candidate from among 63,000 compounds synthesized in a combinatorial chemistry program, is currently under US IND. SQ109 completed two phase 1 studies in the U.S. in December 2009. With a mechanism of action distinct from all other antibiotics used in TB therapy, SQ109 has excellent activity against both drug susceptible and drug resistant TB bacteria, including 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.

SQ109 also has excellent activity against *H. pylori*, and can kill 99.99% of these bacteria with concentrations easily achievable in stomach contents and tissues.

SQ109 was co-discovered by scientists at Sequella and the National Institute of Allergy and Infectious Diseases (NIAID), a part of the National Institutes of Health (NIH), under a Cooperative Research and Development Agreement.

### **About Helicobacter Pylori**

*H. pylori* is a spiral-shaped bacterium found in the gastric mucous layer or adherent to the epithelial lining of the stomach. *H. pylori* causes 95% of duodenal ulcers and up to 85% of gastric ulcers. According to the CDC, peptic ulcer disease has a large impact on the U.S. health care system. One out of ten Americans suffers from peptic ulcer disease during their lifetime. Ulcers cause an estimated 1 million hospitalizations and 6500 deaths per year. In the United States, annual health care costs of peptic ulcer disease have been estimated at nearly \$6 billion: \$3 billion in hospitalization costs, \$2 billion in physician office visits, and \$1 billion in decreased productivity and days lost from work. *H. pylori* is also implicated in gastric cancers, chronic gastritis, non-ulcer dyspepsia, and gastric MALT lymphoma.

### **About Sequella, Inc.**

Sequella, Inc., a clinical-stage company focused on commercializing novel drugs for treatment of life-threatening infectious diseases. The company leverages its global influence, R&D platforms, and 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. 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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