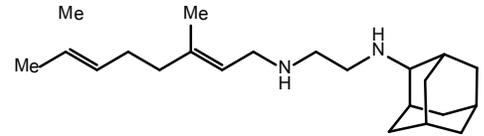


SQ109

A Broadly Active, Bactericidal, Small Molecule Antibiotic

SQ109 is an orally active antibiotic for treatment of pulmonary tuberculosis (TB), *Helicobacter pylori* related duodenal ulcers and carcinomas, and *Candida glabrata*. Currently in Phase 2 clinical trials, SQ109 could replace one or more drugs in the current first-line TB drug regimen, simplify therapy, and shorten the TB treatment regimen. Sequella filed a US IND in Oct 2010 to expand SQ109's therapeutic range to a second infectious disease, duodenal ulcers caused by *H. pylori*.



Overview

Infectious Disease Target	Research	Formulation	Pre-clinical	IND	Phase 1	Phase 2	Phase 3	NDA
Tuberculosis	SQ109							
Duodenal Ulcers/ Gastric Carcinomas	SQ109							
<i>Candida glabrata</i>	SQ109							

SQ109 is an oral NCE in Phase 2 clinical development for treatment of pulmonary TB. In January 2007, Sequella received Fast Track designation from the U.S. Food and Drug Administration (FDA) for SQ109. Fast Track designation for SQ109 is based on its potential to fulfill an unmet need in treating pulmonary TB, a serious, life-threatening medical condition. In October 2007, Sequella received Orphan Drug Status from the FDA, as well as the European Medicines Agency (EMA). SQ109 preclinical data thus far has demonstrated the potential to enhance the treatment of TB during the first two months of intensive therapy and to treat multi-drug resistant TB. In the Phase 1 clinical program, SQ109 was studied up to 300 mg doses, with an excellent safety profile and a half life of over 60 hours.

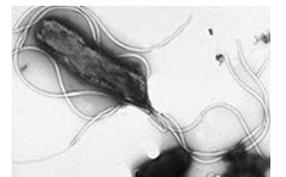
Market

Sequella is seeking partners worldwide for development and commercialization of SQ109. Based on several independent studies, the drug's worldwide TB market potential is approximately \$564m, with the majority of expected sales forecast from the Established Market Economies (EME); >\$650m for *H. pylori* related Duodenal Ulcer and Carcinoma markets; and \$350-400m for a new anti-fungal agent.

TB. The combined U.S. and EU market for treatment of TB and latent TB is estimated to be \$400m. In the U.S., there are an estimated 15 to 30 million suspected TB-infected people, with approximately 15,000 newly reported cases of active disease annually. Worldwide an estimated 2 billion people are latently infected with *M. tuberculosis* and 9+ million active cases of TB are diagnosed. Approximately 450,000 patients are treated or prophylaxed for TB annually in the U.S.



Duodenal Ulcers and Gastric Carcinomas. The U.S. market for a new and better drug to eradicate *H. pylori* is estimated to be >\$650 million annually. SQ109 has in vitro activity against *H. pylori*, an infectious agent that is the cause of more than 95% of duodenal ulcers, 85% of gastric ulcers, and most gastric carcinomas. SQ109 has potential to be used as monotherapy to completely eradicate *H. pylori* and reduce ulcer treatment time and cost.



Market

Candida glabrata Infections. The potential U.S. Market for a new antifungal drug is estimated to be \$350-\$400M. *Candida glabrata* infections account for a subset of this market. SQ109 has activity *in vitro* against common nosocomial fungal infections caused by *Candida glabrata*. *Candida* are commensal organisms that colonize the normal GI tract and sometimes the skin. Infections due to *Candida* account for about 70% of all major systemic fungal infections. *Candida* are the fourth most prevalent organisms found in bloodstream infections and the most common cause of fungal infections in immunocompromised people.

Regulatory and Development Background

Regulatory

- SQ109 is currently in Phase 2 clinical trials under a U.S. IND.
- SQ109 received FDA Fast Track designation in January 2007.
- Phase 2 clinical trials for *H. pylori* are anticipated to begin 1H 2011.

Development/Technical Background

Since 2000, Sequella has applied its scientific expertise in TB research to identify, characterize, and complete preclinical evaluation of SQ109. SQ109 was developed in partnership with the National Institutes of Health (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.

Sequella used combinatorial chemistry to generate a large library of diamine compounds. Working with NIH, Sequella developed a solid-phase method to synthesize hundreds of thousands of diamines and a high throughput screening assay to identify compounds that affect genes activated during cell membrane repair by the tuberculosis bacilli.

More than 63,000 compounds were synthesized and screened in 1999. SQ109 was selected as a lead compound. After a series of integrated studies designed to narrow the field of potential drug candidates, SQ109 completed preclinical toxicology and pharmacokinetic studies prior to entering clinical trials in 2006.

Peer-reviewed scientific articles are available; please contact us for details.

Manufacturing

Sequella has collaborated with leading active pharmaceutical ingredient (API) contract organizations to develop the chemical process for manufacture of SQ109. Chemical synthesis has been successfully scaled to commercial scale manufacturing. Three registration batches of SQ109 API have been manufactured using a robust, chemical synthesis that produces a highly pure (99.7%) API.



Intellectual Property

Sequella has 20 or more issued patents and additional patent filings, including a U.S. patent for compositions of matter and uses of diamine anti-infectives. These patents provide broad coverage for compositions, methods and use claims for treatment of tuberculosis, *H. pylori*-related ulcers, systemic fungal agents and other infectious pathogens. Sequella currently has issued and pending patents in the U.S., EU, Japan, EME, South Africa, China, Eurasia, and other key international markets.

Alliance Opportunity

SQ109 is available for partnering worldwide