Lead Antitubercular Drug Candidate SQ109 Begins New Multi-Arm, Multi-Stage (MAMS) Clinical Trial in Tanzania and South Africa

Trial goal is to identify a new drug regimen to shorten treatment time

Rockville, MD – March 14, 2014. Sequella, a privately held clinical-stage pharmaceutical company addressing the challenge of antibiotic-resistant bacterial diseases, announced today that the first patient was enrolled in a new Phase 2 clinical trial in drug-sensitive tuberculosis (TB) that includes the Sequella lead TB drug candidate, SQ109.

The trial is designed to identify new treatment regimens that may significantly shorten the duration of TB therapy from the current 6 months to less than 4 months by testing established drugs in combination with novel drugs like SQ109. Using the innovative MAMS approach, researchers will be able to rapidly test several potential treatments and select the best regimen to be used in a follow-on trial that will support drug approval.

"A major obstacle in the treatment of TB, in addition to drug resistance, is the duration of patient treatment time," said Dr. Carol Nacy, CEO of Sequella. "If we can develop a new drug regimen that can shorten treatment, we can make it easier for patients to complete their drug regimen and be cured, reducing TB transmission and moving towards eradication of the disease. We hope this trial brings about new and actionable information quickly."

The MAMS clinical trial is funded by the European Developing Country Clinical Trials Partnership (EDCTP), coordinated by the Ludwig Maximilian University (LMU), and carried out by the the Pan African Consortium for the Evaluation of Anti-tuberculosis Antibiotics (PanACEA). PanACEA members include TB experts from 6 European research institutions, 12 sub-Saharan Africa clinical trial sites, and 2 pharmaceutical companies, including Sequella.

SQ109 has a novel mechanism of action and reduces treatment time by 35% in murine models of TB. SQ109 is also effective against profoundly drug-resistant TB and exhibits synergistic activity with the first-line drugs rifampicin and isoniazid *in vitro* and *in vivo*. SQ109 is currently in a phase 2/3 pivotal trial in Russia with Sequella corporate partner, OOO Infectex, and a phase 2a clinical study for *Helicobacter pylori* infection in Texas funded by the National Institutes of Health.

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About Sequella:
Sequella is a privately held, clinical-stage pharmaceutical company addressing the challenge of antibiotic-resistant bacterial diseases through discovery, development and commercialization of first-in-class antibiotics with novel mechanisms of action. The company leverages strategic partnerships, R&D platforms, and infectious disease and anti-infectives expertise to proactively address emerging health threats. Through focused execution and clear commercialization pathways, Sequella intends to commercialize a broad product portfolio designed to treat global health threats with significant market opportunity.

Our current product portfolio addresses diseases with known or suspected infectious etiology: TB (*Mycobacterium tuberculosis*), gastritis, ulcers, and gastric carcinoma (*H. pylori*), CDI (*Clostridium difficile*), and Crohn's Disease (CD, *M. avium paratuberculosis*).

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