



FOR IMMEDIATE RELEASE

July 26, 2012

**Maxwell Biotech Venture Fund's Portfolio Company, Infectex, Receives Russian Regulator's Approval to Conduct Pivotal Clinical Trial for Sequella's Antibiotic, SQ109, for Tuberculosis**

**SQ109 will be evaluated for efficacy on multi-drug resistant patients**

Rockville, Md. — Sequella, a clinical-stage pharmaceutical company focused on commercializing novel antibiotics to treat life-threatening infectious diseases, licensed the late-stage development and commercialization of its lead antibiotic, SQ109, to a portfolio company of Maxwell Biotech Venture Fund Infectex in 2011. Infectex has recently received notification from the Russian Ministry of Health for approval to begin the pivotal clinical trial associated with a drug registration submission, and can now proceed with the clinical development of SQ109 for treatment of tuberculosis (TB) in the Russian Federation.

The pivotal clinical trial financed by Maxwell Biotech Venture Fund will be conducted in multi-drug resistant (MDR)-TB patients at TB centers in three major Russian cities (Moscow, Saint-Petersburg and Ekaterinburg) and will be managed by Infectex.

"We are extremely pleased that our corporate partner has achieved regulatory clearance to allow further study and potential commercialization of SQ109 in patients desperate for new therapeutic options," said Dr. Carol Nacy, CEO of Sequella. "We congratulate Infectex on this success, and we look forward to the future availability of SQ109 to improve the lives of patients suffering from MDR-TB."

According to the World Health Organization (WHO), Russia is one of the world's "high burden" TB countries, with over 150,000 cases of active TB reported each year and over 43,000 cases of MDR-TB. In parts of Russia and the CIS, TB infection rates are over 3 times that which the WHO considers epidemic, prompting the Russian government to make TB control a top priority. The Russian market for anti-tubercular drugs is well over \$150 million per year, with total TB control costs estimated to be well over \$1 billion.

"We are very glad to participate in this international project in close cooperation with our partners from Maxwell Biotech Venture Fund and Sequella and hope that a new drug candidate will strengthen the efficiency of the existing treatment regimens and will be able to improve Russian and global standards of care in the future", said Prof. Sergey Borisov, chief study coordinator, deputy director for science and clinical work at Moscow Research Center for TB control of the Moscow Department of Health.

###

## **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 one 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 XDR-TB strains. SQ109 also enhances the activity of 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 current 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 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 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 Infectex**

Infectex is a private Russian biotechnology company founded in 2011 with the goal to develop bring to the Russian market is an innovative drug for the multidrug-resistant tuberculosis (MDR-TB) treatment. Infectex is Skolkovo resident and takes part in a national Technology platform "Medicine of the Future". The Company has been financed by Maxwell Biotech Venture Fund established with the participation of RVC.

## **About Maxwell Biotech Venture Fund**

Maxwell Biotech Venture Fund (MBVF) formed with the participation of RVC provides investment capital and access to an established infrastructure for conducting high-quality clinical trials in Russia, and helps enable the rapid and cost-effective achievement of clinical objectives. The fund's unique business model can add value to our partners' pipelines and provide a commercialization path to one of the most lucrative emerging markets. MBVF relies on an experienced international team of managers and financial and industry experts and has offices in Moscow and Boston. MBVF is investing in product

development companies specializing in specific therapeutic areas or medical devices categories. To date, MBVF has invested in OncoMax (oncology), NeuroMax (CNS), MetaMax (oncology & metabolic diseases), Infectex (infectious diseases), CardioNova (cardiovascular diseases), Hepatera (liver diseases) and Photonics (novel lasers for medicine and dentistry). Products in these companies originated either from Russian scientists or were licensed from international biopharma companies.

### **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.

Sequella Media Contact: Alan S. Klein  
Executive Vice President, Corporate Development  
Telephone: 301-762-7776  
Email: [alanklein@sequella.com](mailto:alanklein@sequella.com)