



**For immediate release**

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**Infectex Announces Positive Phase 2b-3 Clinical Trial Results of SQ109 for the Treatment of Multidrug-Resistant Pulmonary Tuberculosis**

Moscow, Russia and Rockville, MD, USA -- Infectex Ltd., a Russian portfolio company of Maxwell Biotech Venture Fund (MBVF), today announced positive results of a Phase 2b-3 clinical study of SQ109 added to the standard drug therapy regimen in patients with multidrug-resistant pulmonary tuberculosis (MDR-TB). SQ109 is a new small molecule drug discovered by scientists at Sequella, Inc. (USA) and the US National Institutes of Health.

A total of 140 patients were enrolled in a prospective, randomized, double-blind, placebo-controlled study conducted in 7 clinical centers in Russia. The main objective of the study was to assess efficacy, safety, and tolerability of SQ109 in combination with a standard regimen for MDR-TB treatment. Both the Intent to Treat (ITT) and Per Protocol (PP) patients treated with SQ109-containing regimens showed statistically significant improvement in clearance of lung bacteria.

"The sputum culture conversion rate (cessation of *Mycobacteria* excretion) of PP patients treated with SQ109 plus the standard regimen was 80%, significantly higher than patients treated with the standard regimen plus placebo (61%) by the end of 6 months of treatment," said Prof. Sergey Borisov, M.D., Deputy Director for Scientific and Clinical Work of Moscow City Research and Practical Center for Tuberculosis Control, principal study investigator, "Furthermore, SQ109 was both safe and well tolerated."

"We are delighted that Infectex has successfully completed this important study. SQ109 has the prospect of becoming both a part of a new tuberculosis regimen and a component of standard treatment", said Dr. Carol A. Nacy, CEO of Sequella.

"Now our goal is to bring the product to patients as soon as possible to increase the effectiveness of treatment and save thousands of lives of patients with tuberculosis not only in Russia, but also throughout the world", said Dmitry Popov, Managing Partner of MBVF.

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**About SQ109**

SQ109 is a novel 1,2-ethylene diamine small molecule drug with 3 unique mechanisms of action that are distinct from all other antibiotics used for the treatment of tuberculosis (TB). In laboratory studies, SQ109 demonstrated excellent activity against both drug susceptible and multidrug-resistant *M. tuberculosis*, including extensively drug-resistant TB strains. SQ109 also enhanced activity of anti-tuberculosis drugs isoniazid, rifampicin, and bedaquiline and shortened by >30% the time required to cure mice of experimental TB. SQ109 could replace one or more of the current TB drugs, simplify therapy, and shorten current treatment time. Infectex, Ltd, licensed the rights to develop and commercialize SQ109 in the Russian Federation and Commonwealth of Independent States from Sequella, Inc., in 2011. SQ109 is currently under Sequella's US IND and completed three Phase 1 studies in the U.S. and two Phase 2 studies in drug-sensitive TB patients in Africa in addition to the Phase 2b-3 study in Russia.

**About Infectex**

Infectex (Moscow, Russia) is a biotechnology company founded in 2011 with the goal to develop and bring to the Russian market drugs for MDR-TB treatment. Currently the company is developing two anti-TB drugs, SQ109 and Q203. Infectex is a resident company of Skolkovo Innovation Center. [www.infectex.com](http://www.infectex.com)

**About Sequella**

Sequella (Rockville, MD) is a privately-held clinical stage anti-infectives company focused on commercializing novel treatments for antibiotic-resistant infectious diseases. The company has been in operation for 19 years and has drugs in Phase 2 clinical trials for gastritis (*Helicobacter pylori*) and TB



and in IND-directed preclinical development for *Clostridium difficile* infections. Sequella 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. [www.sequella.com](http://www.sequella.com)

#### **About Maxwell Biotech Venture Fund**

Maxwell Biotech Venture Fund is the first Russian venture fund fully dedicated to investments in Life Sciences technologies. The fund has been created with participation of the Russian Venture Company. MBVF portfolio companies have nine innovative clinical stage drug candidates in development; four thereof are in late clinical stage of development. [www.maxwellbiotech.com](http://www.maxwellbiotech.com)

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