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Sequella Acquires Exclusive Worldwide Rights to Pfizer’s Sutezolid, Currently in Clinical Development for Tuberculosis

Sequella Obtains Development and Commercialization Rights to Sutezolid for All Indications

Rockville, Md. — Sequella, a clinical-stage pharmaceutical company commercializing novel antibiotics to treat life-threatening infectious diseases, today announced that it has licensed Pfizer Inc’s exclusive worldwide rights to develop and commercialize sutezolid, a Phase 2 oxazolidinone antibiotic currently in development for the treatment of tuberculosis (TB).

Sutezolid demonstrated potent antibacterial activity against *Mycobacterium tuberculosis* in the laboratory and in animal models of TB, an aerosol-transmitted infection with a prevalence of over 2 billion people worldwide. It also demonstrated encouraging activity in a Phase 2a Early Bactericidal Activity (EBA) study in TB patients in South Africa. Under the terms of the parties’ exclusive license agreement, Sequella will be solely responsible for completing clinical development and commercializing the product globally. Financial terms of the transaction were not disclosed.

“We are delighted to bring in a second clinical-phase TB asset that may be paired with other TB drugs or with SQ109, our drug currently in Phase 2 studies for drug-sensitive TB in Africa and in a pivotal trial for multi-drug resistant (MDR) TB in Russia. These two drugs, SQ109 and sutezolid, could potentially anchor a totally new drug combination regimen to treat all forms of active TB disease,” said Dr. Carol Nacy, CEO of Sequella. “We will pursue development of sutezolid under its own NDA, and also plan for combination studies in subsequent clinical trials.”

“As Pfizer continues to concentrate our R&D resources where we believe we can have the greatest impact, we have evolved our internal infectious disease focus from treatment to prevention through our leading expertise in vaccine technology,” said Rod MacKenzie, PhD, Group Senior Vice President and Head of PharmaTherapeutics R&D at Pfizer. “Given the urgent patient need in TB, we sought a partner for sutezolid that would bring deep expertise and a strong commitment to TB patients. We believe Sequella meets these criteria and offers a portfolio with the important potential for combination studies.”

TB, whether drug sensitive or MDR, is always treated with three or more drugs to reduce emergence of drug resistance. Preclinical laboratory studies performed independently by both Sequella and Pfizer show SQ109 and sutezolid to each have activity as single agents, and promising additional activity when used in combination. A very low natural resistance rate of *M. tuberculosis* to either drug, demonstration that both drugs shorten treatment time in animal models of TB, and their distinct and complementary mechanisms of action on *M. tuberculosis*, all suggest that a regimen containing SQ109 and sutezolid could potentially improve existing therapies with regard to efficacy and containment of resistance.

Recent market reports estimate a $400-$500 million global peak sales market for a drug to treat MDR-TB, approximately 5% of TB worldwide and a rising global public health threat. Sequella intends to commercialize its TB assets for both drug sensitive and MDR-TB, if and when approved by applicable regulatory authorities. Sutezolid also has activity on several clinically important Gram positive bacteria.

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About Sutezolid

Pfizer had been developing an antimicrobial compound, sutezolid (PNU-100480 or U-480), as a promising new treatment for tuberculosis (TB). Sutezolid is currently in Phase 2 development and most recently completed a Phase 2a Early Bactericidal Activity (EBA) study in patients with TB in South Africa. Its potential indications include multi-drug and extensively drug resistant tuberculosis (M/XDR-TB), HIV-associated tuberculosis (HIV-TB), drug-sensitive tuberculosis (DS-TB), and suspected M/XDR latent *M. tuberculosis* infection (M/XDR-LTBI).

Sutezolid also shows promise for antibiotic-resistant Gram (+) bacterial infections, including methicillin-resistant *Staphylococcus aureus* (MRSA) and vancomycin-resistant *Enterococcus* (VRE).

About Sequella

Sequella 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 15 years and has drugs in Phase 2 clinical trials for gastritis (*Helicobacter pylori*) and TB (Phase 2) 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.

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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