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NEWS RELEASE

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SEQUELLA LEAD DRUG COMPOUND SQ109 RECEIVES ORPHAN DRUG STATUS FROM THE US FDA AND ORPHAN MEDICINAL PRODUCT DESIGNATION FROM THE EUROPEAN MEDICINES AGENCY FOR THE TREATMENT OF TUBERCULOSIS

ROCKVILLE, MD -- Sequella, Inc., a clinical-stage biopharmaceutical company focused on commercializing products to treat diseases of epidemic potential, announced today that the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) independently reviewed Sequella lead drug compound, SQ109, and both agencies granted SQ109 orphan drug status for the treatment of tuberculosis. SQ109 shows excellent *in vitro* and *in vivo* activity against drug-susceptible and drug-resistant TB bacteria, including XDR-TB. Further, SQ109 synergizes with other TB drugs in experimental animal models of TB, and could result in new TB drug combinations that have much greater activity than the current standard of care.

“We are pleased that the FDA and the EMA awarded Sequella orphan drug and orphan medicinal product status for the use of SQ109 (N-adamantany1-N'-Geranyl-ehtylendiamine) for the treatment of tuberculosis (TB), a chronically debilitating and life-threatening infectious pulmonary and extrapulmonary disease,” said Dr. Carol Nacy. “With the resurgence of TB in a new drug-resistant form it is clear there is a need to readdress the treatment of this infectious and deadly disease. To accelerate our clinical programs, we will continue to work closely with the FDA’s Office of Orphan Products Development and the EMA’s Committee for Orphan Medicinal Products as we move through the clinical and regulatory process.”

The Orphan Drug Act (Public Law 97-414, enacted in 1983 and amended) provides for economic incentives to encourage pharmaceutical companies to develop drugs for rare diseases defined as those affecting fewer than 200,000 people in the United States. Orphan drug designation entitles Sequella, Inc. to seven years of market exclusivity for SQ109 for the treatment of patients with tuberculosis. Additional incentives for orphan drug development include tax credits related to certain development expenses, an exemption from the FDA user fee, and FDA assistance in clinical trial design. Importantly, the Orphan Drug Act facilitates a close working relationship between regulatory agencies and companies aimed at accelerating the drug development and approval processes for treatment of rare diseases. For further information, please visit: <http://www.fda.gov/orphan/oda.htm>.

The European Medicines Agency is the European Union body responsible for coordinating the existing scientific resources put at its disposal by Member States for the evaluation, supervision and pharmacovigilance of medicinal products. The Agency provides the Member States and the institutions of the EU the best-possible scientific advice on any question relating to the evaluation of the quality, safety and efficacy of medicinal products for human or veterinary use referred to it in accordance with the provisions of EU legislation relating to medicinal products.

In 2001, the EMA established the Committee for Orphan Medicinal Products (COMP), and charged it with reviewing designation applications from persons or companies who intend to develop medicines for rare diseases (so-called 'orphan drugs'). Orphan Medicinal drug products are intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition



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affecting no more than five in 10,000 persons in the European Union at the time of the submission of the designation application. Orphan Medical Product Designation of SQ109 for the treatment of tuberculosis entitles Sequella to incentives such as protocol assistance (scientific advice during the product-development phase), 10-year marketing exclusivity, certain fee reductions or exemptions, and national incentives detailed in an inventory made available by the European Union, including the ability to apply for EU grants. For more information, visit: <http://www.emea.europa.eu/pdfs/human/comp/29007207en.pdf>

“These US and European Union incentives will allow Sequella to move SQ109 through the product development process more quickly and efficiently,” said Dr. Nancy.

SQ 109 also received Fast Track Status from the FDA in January of 2007.

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About Tuberculosis (TB)

TB is a contagious infectious disease caused by the bacterium *Mycobacterium tuberculosis*. TB bacteria can be inhaled into lungs and are able to avoid destruction by certain white blood cells. Without containment by immune cells, the bacteria can spread throughout the body, multiply, survive and remain dormant for years. TB is the leading cause of global deaths that result from a single-agent infectious disease.

About Sequella, Inc.

Sequella is a clinical-stage biopharmaceutical company focused on commercializing improved treatment paradigms for diseases of epidemic potential. The company leverages its global influence, infectious disease expertise and diverse product portfolio to proactively address emerging health threats with significant market opportunity. For more information, please visit www.sequella.com.

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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