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## ***NEWS RELEASE***

### **FOR IMMEDIATE RELEASE**

#### **Sequella, Inc. Announces Positive Late Stage Clinical Trial Results for a Revolutionary TB Diagnostic**

ROCKVILLE, MD. January 31, 2002 -- Sequella, Inc., a biotechnology company dedicated to fighting infectious diseases, today announced positive late stage clinical trial results for its Transdermal Patch for Active Tuberculosis (TB). This revolutionary skin test will be the world's first diagnostic that can distinguish between active infectious TB, latent TB and prior TB vaccination. The Transdermal Patch is configured as a simple Band-Aid® applied to the forearm that delivers a soluble TB protein directly to the skin, a distinct advantage over the current nonspecific Mantoux skin test that must be administered by a needle and syringe.

Unlike the existing Mantoux TB skin test, the Transdermal Patch distinguishes active TB disease from latent TB infection or prior BCG vaccination. The Mantoux test is positive under all three situations. The distinction is important for physicians, since approximately 85% of infants born worldwide today are vaccinated with BCG, and an estimated one-third of the world's population has a latent TB infection. Sequella's Transdermal Patch addresses the critical need for a new test that quickly and effectively separates the two billion people with latent TB who do not need drug intervention from the eight million people who contract active TB each year and must be treated. Without adequate tools to distinguish between active TB, latent TB, and prior vaccination, TB cannot be effectively controlled.

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The late stage trials of the Transdermal Patch were performed by staff of the Japan BCG Laboratory, Sequella's partner in the development of this technology, at the Philippine General Hospital in Manila. These studies, published in the Scandinavian Journal of Infectious Disease, support positive findings of the first clinical trial (98% sensitivity, 100% specificity) and confirmed utility of this new diagnostic as a test for detection of active TB. In the expanded trial, the Transdermal Patch demonstrated a sensitivity of 88%, an efficacy of 93%, and a specificity of 100%. Also, 43 out of 49 patients with active TB had a positive reaction to the Patch, and there were no false positives in the control population (28 healthy staff people of the hospital). In contrast, all of the controls and active TB patients had positive Mantoux skin test results, since it does not distinguish between disease and prior exposure or vaccination. The Sequella trial also suggests that the Transdermal Patch for Active TB may be useful in monitoring the success of TB chemotherapy. A small number of patients successfully treated for TB reverted to a negative Patch test within six months after the completion of treatment, although their Mantoux tests remained positive.

“The continued success of the Transdermal Patch is a significant milestone for Sequella, as it brings us closer to launching a sensitive and specific TB diagnostic that will help prevent the spread of TB – a killer of over two million people annually,” said Carol A. Nancy, Ph.D., CEO of Sequella, Inc. “We chose to focus our efforts first on development of an accurate diagnostic for TB because we cannot effectively develop a drug for the treatment of TB without being able to easily and precisely diagnose this disease.”

Sequella, Inc. received grant funding from the National Institutes of Health for development of the Transdermal Patch and is partnering with the World Health Organization for a definitive prospective clinical trial of this diagnostic for testing on 900 volunteers suspected of having TB in South Africa. These studies will begin in Q2 2002, and the final results are expected before the end of the year. A successful demonstration of the Transdermal Patch's efficacy will lead to submission for regulatory approval in 2003. With 100 million people screened for TB every year, Sequella's addressable market for the Transdermal Patch is well over \$700 million.

## **About Sequella, Inc.**

Sequella, Inc. is a biotechnology company dedicated to commercializing therapeutics, vaccines, and diagnostics that can alleviate the global burden of infectious disease. The company, headquartered in Rockville, MD, is focusing its initial research efforts on products to address the growing TB problem worldwide. For more information about Sequella, Inc., please visit [www.sequella.com](http://www.sequella.com).

Some of the matters discussed in this press release are forward-looking, and are therefore subject to risks and uncertainties that could cause actual results to differ materially from those stated or implied in this report. These risks and uncertainties include but are not limited to those relating to new product development, uncertainties of the results of future clinical trials, and availability of financing and other sources of capital, as well as any risks discussed in Sequella's Business Plan and Private Placement documents.

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