Sequoia Sciences Receives FDA Fast Track Designation for Vaccine for Urinary Tract Infections Caused by Multidrug-Resistant Bacteria

Non-Antibiotic Treatment Approach May Reduce the Development of Antibiotic Resistance and Promote Antibiotic Stewardship

ST. LOUIS (July 26, 2017) – Sequoia Sciences announced it has received Fast Track Designation from the U.S. Food and Drug Administration (FDA) for its novel, investigational vaccine designed to treat recurrent urinary tract infections (UTI) caused by multidrug-resistant bacteria. Fast Track Designation expedites the development and review of the vaccine through the U.S. regulatory process.

Sequoia’s vaccine is designed to create an immune response preventing bacteria from colonizing the urinary tract, and it recently completed its first clinical trial in women. Of the 67 women enrolled in this first study, 30 had a two-year documented history of recurrent UTI. The vaccine was well-tolerated and generated a strong immune response. Based on the results of this first study, initiation of additional studies is ongoing including evaluating Sequoia’s vaccine in patients requiring last-line of defense antibiotics. In granting Fast Track status, the FDA acknowledges that recurrent UTI caused by multidrug-resistant bacteria is a serious condition for which there is an unmet medical need.

“If approved, the vaccine could change the standard of care for recurrent UTI,” said Gary Eldridge, president and CEO, Sequoia Sciences. “Since UTI are a primary source of sepsis, decreasing recurrent UTI may ultimately drive down rates of hospitalization, sepsis and associated in-hospital mortality.”

Recurrent UTI Are Increasing Antibiotic Resistance

Antibiotics are the current standard of care for UTI patients, but repeated antibiotic use in this population contributes to the development of antibiotic resistance. Recurrent UTI patients frequently take daily antibiotics for one to four months or even longer. Each year, approximately 3 million patients in the U.S. and 10 million patients in North America, Europe and Japan experience recurrent UTI. It is estimated that about half of these patients have UTI caused by antibiotic-resistant bacteria.

In a 2010 survey, 83 percent of urologists reported having administered intravenous antibiotics to recurrent UTI patients who were resistant to all available oral antibiotics. Antibiotic resistance among UTI patients has continued to increase. The North American Emerging Infections Network reported that about 80 percent of responding infectious disease physicians had treated a UTI caused by the most resistant bacteria, carbapenem-resistant Enterobacteriaceae (CRE). Even more alarming, in 2016 CRE among patients in long-term care facilities was found to be more widespread than predicted. There are currently no FDA-approved therapies to specifically treat recurrent UTI.

“Many of my patients with multidrug-resistant recurrent urinary tract infections have tried multiple antibiotics for years without success,” said Liz D’Antonio, CRNP, director of clinical research Anne Arundel Urology. “A vaccine presents a new approach that could offer new hope for these patients. We eagerly await the results of the next studies as it hopefully moves toward approval.”
Antibiotic Resistance — A Global Health Threat
Leading health care organizations, including Centers for Disease Control and Prevention, European Centre for Disease Prevention and Control, World Health Organization and Infectious Diseases Society of America (IDSA), have declared that antibiotic resistance is one of the most serious health threats facing the world. New rules requiring antibiotic stewardship programs in hospitals emphasize the need to use fewer antibiotics. Sequoia’s investigational vaccine, if approved by the FDA, may help reduce the use of antibiotics and address this growing health threat.

About Sequoia Sciences
Sequoia Sciences is a pharmaceutical company discovering and developing new medicines targeting bacterial infections and cancers. Our pipeline includes a vaccine for the treatment and prevention of recurrent urinary tract infections and compounds targeting infection and cancer.

Forward-Looking Statements
Some statements in this news release are, or may be considered forward-looking statements for purposes of the Private Securities Litigation Reform Act of 1995. The words “believe,” “expect,” “anticipate,” “project” and similar expressions, among others, generally identify forward-looking statements. Sequoia Sciences cautions that these forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially from those indicated in the forward-looking statements. Such risks and uncertainties include, but are not limited to, challenges to intellectual property, competition from other products, difficulties inherent in the research and development process, adverse litigation or government action, and changes to laws and regulations applicable to our industry.

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1 Sequoia Sciences’ Annual Report 2016.
2 2014 National Disease and Therapeutic Index (NDTI, IMS Health, Plymouth Meeting, PA). ICD9: 595.0; 595.9; 599.0; 597.8.
4 Urologist UTI Survey. Sequoia Sciences, Inc. and HRA Research; 2010.
6 Han et al. Epidemiology of Carbapenem-Resistant Klebsiella Pneumoniae in a Network of Long-Term Acute Care Hospitals. Clinical Infectious Diseases. 2017;64(7):839-44.