Tulane University awarded up to $16 million to bring pneumonia nasal vaccine to clinical trials

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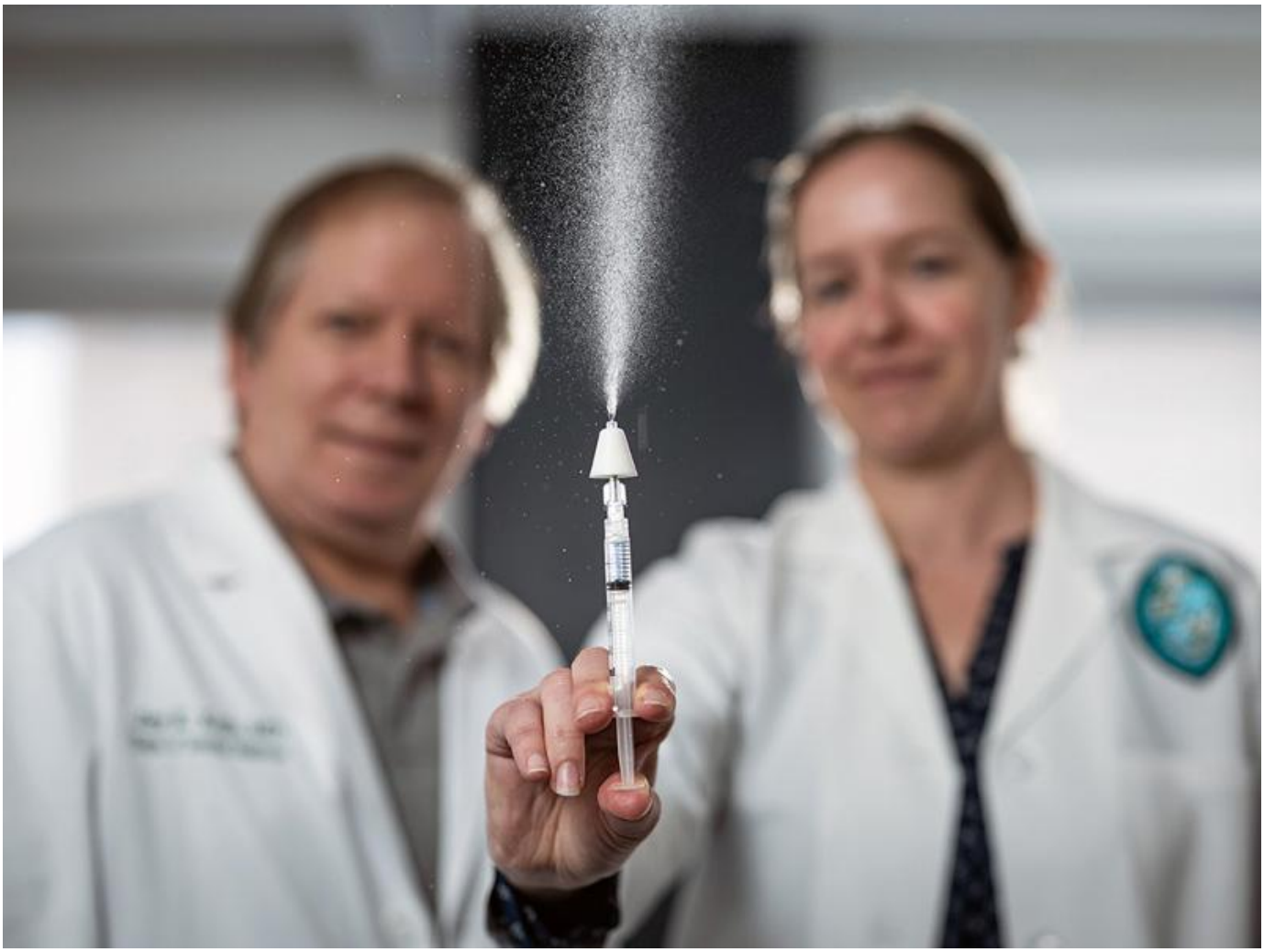


The new vaccine, called CladeVax, is a nasal spray designed to efficiently target mucosa in the nose, throat and lungs to protect the area most at risk for infection from the antibiotic-resistant Klebsiella pneumoniae bacteria, a leading cause of pneumonia. Photo by Rusty Costanza.

The National Institute of Allergy and Infectious Diseases awarded an up to $16 million contract to Tulane University to bring to phase one clinical trial a nasal spray vaccine university researchers invented to thwart antibiotic-resistant *Klebsiella*

pneumoniae, a leading cause of pneumonia.

Antibiotic-resistant bacteria are on the rise and are a significant cause of infections requiring hospitalization among children and the elderly. As doctors try to find new types of antibiotics to fight these so-called superbugs, Tulane University School of Medicine researchers Elizabeth Norton, PhD, and Jay Kolls, MD, inventors of the vaccine, are working to protect people before they are exposed to the pathogens in the first place.

“Multidrug-resistant bacteria are causing more severe infections and are a growing public health threat. Vaccines targeting these pathogens represent the most cost-effective option, particularly if you can use this vaccine to prevent or treat the infection in high-risk individuals,” said Norton, principal investigator and associate professor of microbiology and immunology. “Right now, there is no vaccine on the market that targets this type of pneumonia.”

Klebsiella pneumoniae is the third leading cause of hospital-acquired pneumonia and the second leading cause of bloodstream infections with the highest incidence of serious infections. It is also a major cause of childhood pneumonia in parts of Asia. The Tulane vaccine would target high-risk populations such as immunocompromised individuals, diabetics or organ transplant recipients.

Norton said that while the vaccine targets the *Klebsiella* bacteria, its unique design gives it the potential to be cross-reactive to other members of the Enterobacteriaceae family, the antibiotic resistant bacterial species behind many hospital-acquired infections, including *E. coli*.

The vaccine, called CladeVax, is designed to efficiently target mucosa in the nose, throat and lungs to protect the area most at risk for infection.

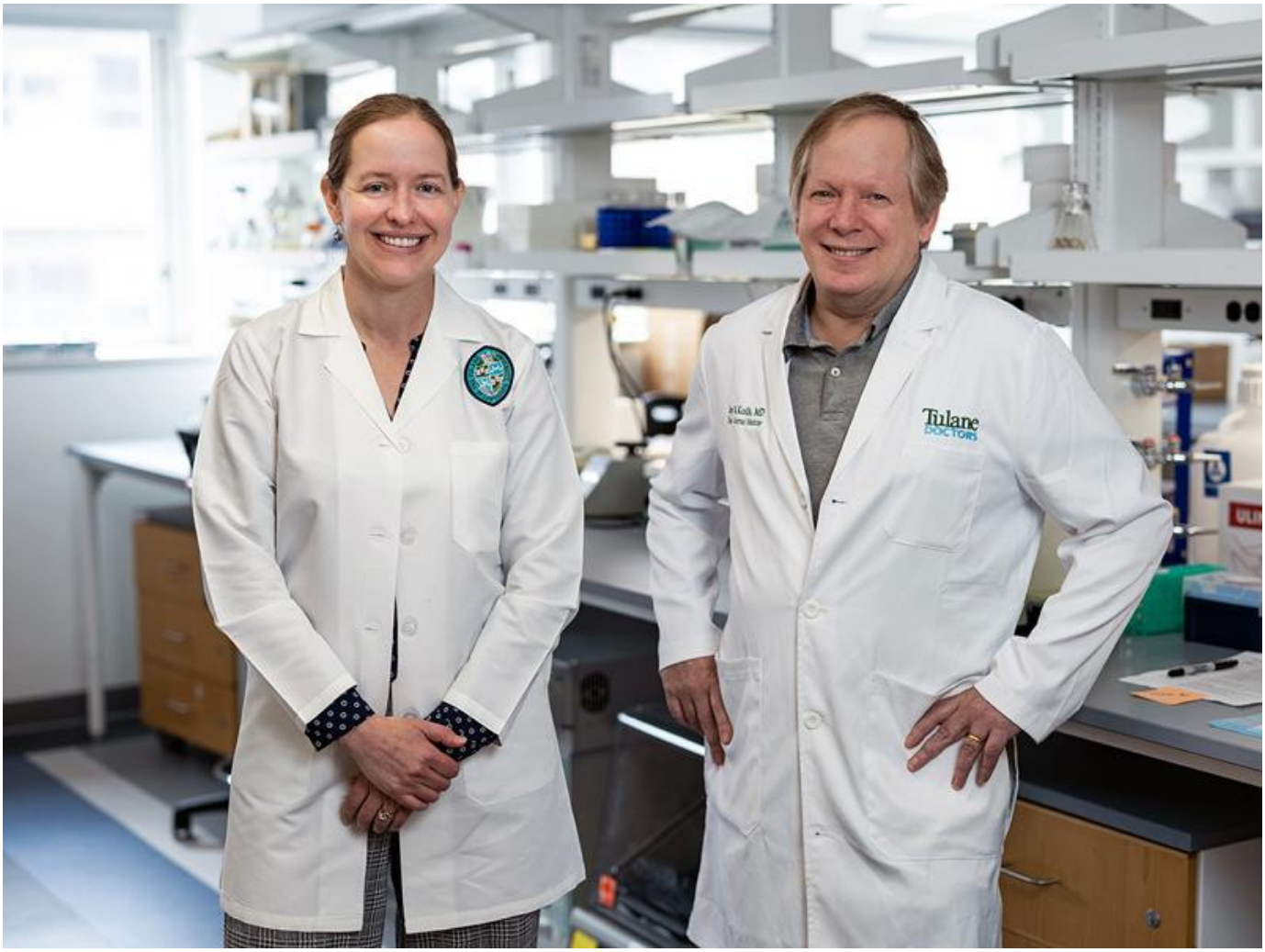
The nasal spray vaccine uses an adjuvant — a compound that stimulates the immune system — named LTA1 that Norton developed at Tulane. That adjuvant, which is made using a protein derived from the *E. coli* bacteria, will be combined with a series of proprietary antigens identified by the Kolls lab that include outer membrane proteins from the target bacteria.

“This is an entirely novel vaccine platform, from the use of the adjuvant to the needle-less route of administration,” said Kolls, co-principal investigator, and the John W. Deming Endowed Chair in Internal Medicine. “This represents an entirely

new class of vaccines for bacteria that elicits protection in two ways — both antibody and T-cell immunity. All current pneumonia vaccines only elicit antibodies against surface carbohydrates. Our platform has the potential advantage of providing a much broader protection against pneumonia.”

Tulane researchers will first test vaccine formulations in animal models and nonhuman primates for dosing and safety before advancing to clinical trials. The project will include collaborators at Tulane National Primate Research Center, the School of Public Health and Tropical Medicine, Tulane Clinical Translational Unit, and the University of North Carolina as well as contractors for GMP manufacturing.

“If this succeeds, we will have another arsenal for the growing number of antibiotic resistant sources of pneumonia or bloodstream infections,” Norton said. “And we can hopefully expand this nasal spray delivery platform to other infections, working on a single, combination vaccine that is needle-less and targets several organisms at once.”



The vaccine’s inventors Elizabeth Norton, PhD, and Jay Kolls, MD.

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