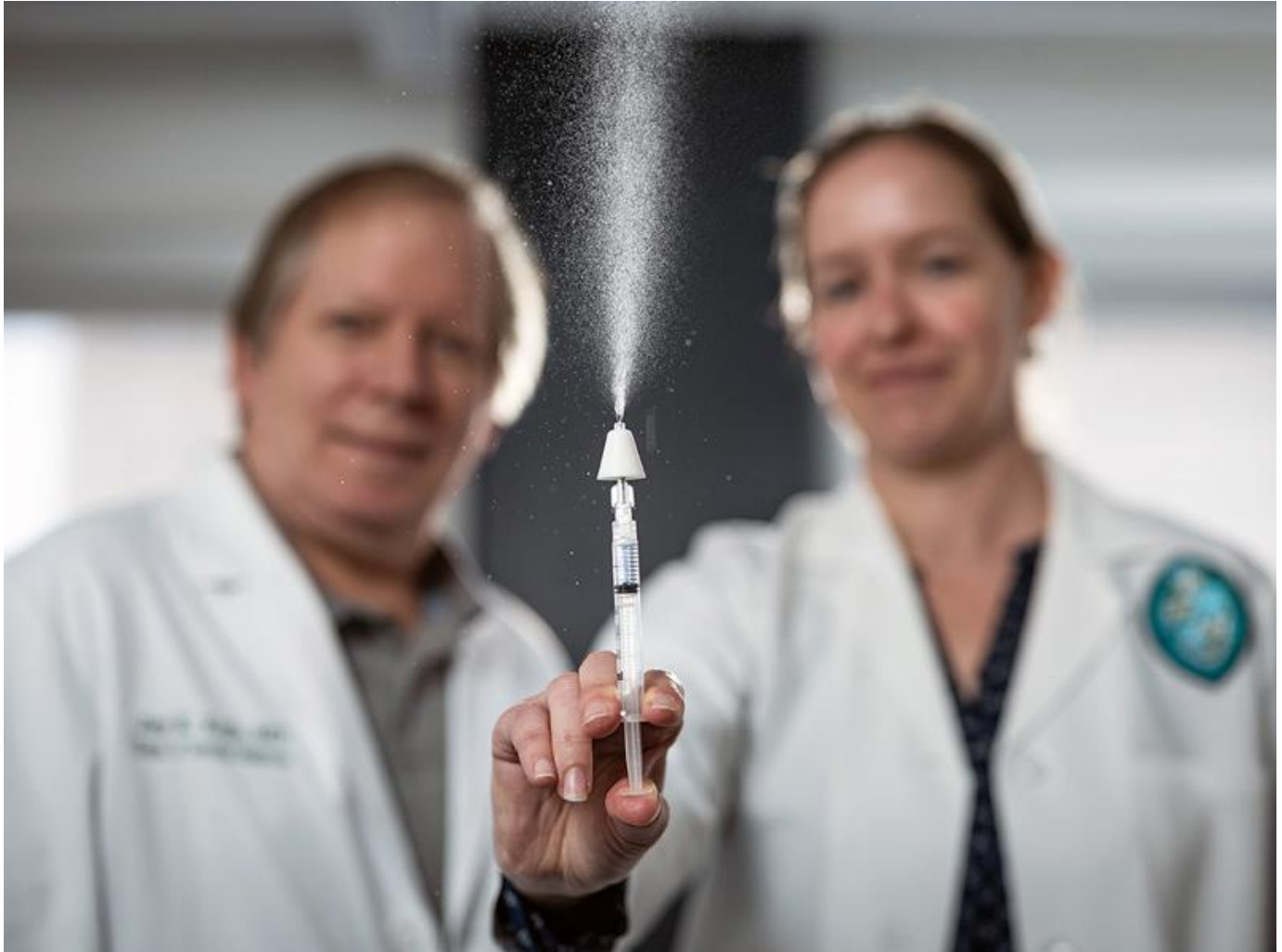


## **Tulane University awarded contract up to \$16 million to bring pneumonia nasal vaccine to clinical trials**

April 07, 2023 9:30 AM Keith Brannon  
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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 a contract worth up to \$16 million to Tulane University to bring a nasal spray pneumonia vaccine to

Phase One clinical trial. University researchers invented the experimental vaccine to thwart antibiotic-resistant *Klebsiella pneumoniae*, a leading cause of bacterial 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 experimental *Klebsiella pneumoniae* 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 the vaccine prevents or treats 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 be intended to help high-risk populations such as immunocompromised individuals, those with diabetes 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.

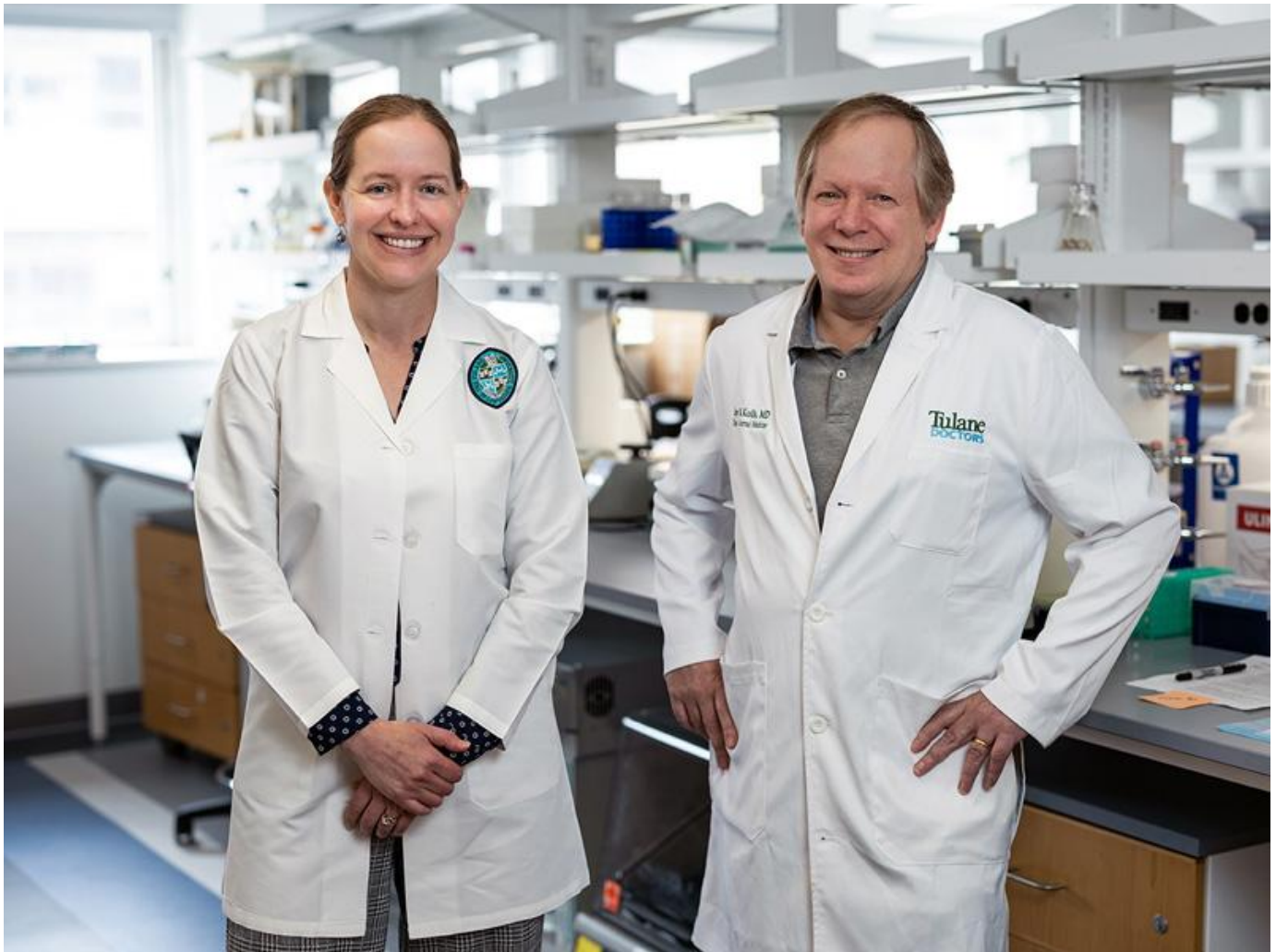
The nasal spray vaccine uses an adjuvant — a compound that stimulates the immune system — named LTA1 that Norton developed at Tulane. That adjuvant, which is made using a protein derived from the *E. coli* bacteria, will be combined with a series of proprietary antigens identified by the Kolls lab that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

"We believe this is a 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 bacterial 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 in 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 weapon in our 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."

This project has been funded in whole with Federal funds from the National Institute of Allergy and Infectious Diseases, National Institutes of Health, Department of Health and Human Services, under Contract No. 75N93022C00056. Tulane has received \$2.3 million for the initial base requirement activities, with up to \$14.2 million in additional funding if all options are exercised under the contract.



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

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