

# Vaccine Developed To Shield Newborn Calves From Deadly Rotavirus

Baylor College of Medicine  
The Ohio State University



After more than 20 years of basic research on the structure and biology of rotavirus, Dr. Mary Estes' and colleagues in her lab at Baylor College of Medicine and The Ohio State University, have contributed to the development of a vaccine that protect newborn calves from the life-threatening illness.

"When we started this research many years ago we were not planning on developing a vaccine," said Estes, Cullen Foundation Endowed Professor Chair of Human and Molecular Virology in molecular virology and microbiology at Baylor College of Medicine and emeritus founding director of the Texas Medical Center Digestive Diseases Center.

“Rotaviruses are the main cause of gastroenteritis in infants and children around the world; they cause more than 200,000 deaths annually.

Years of research opened a number of unforeseen possibilities. The research generated not only a better understanding of the viral proteins and the capsid structure and new basic science questions, but also resulted in a candidate viral vaccine product, virus-like particles. Their initial results were published by Baylor's Dr. Sue Crawford and their collaborative team in the *Journal of Virology* in 1994. Many collaborators at Baylor and other institutions were involved in demonstrating that rotavirus virus-like particles are candidate vaccines for animals and humans.

In addition to Crawford, key players included Dr. Margaret E. Conner, Dr. Sarah E. Blutt, and Dr. Max Ciarlet at Baylor, and Dr. Linda Saif at the Ohio State University in the Food and Animal Health Research Program.

"We used the particles for many basic science experiments initially and then we worked on a program for developing them as a virus-like particle vaccine," said Estes, who was recently named a fellow of the National Academy of Inventors. "Over a number of years, we determined the best immunization protocols, including the best route and use of different adjuvants, for virus-like particles to be highly immunogenic in a number of species. Our studies showed that these particles had clear potential as a vaccine for both humans and animals."

Although currently there are other human rotavirus vaccines available, their efficacy is limited. In developed countries the efficacy is about 90 percent, but in developing countries it drops to nearly 50 percent. There is still a need for alternative immunization protocols.

### **The road to commercialization**

The virus-like particles captured the interest of ImmuCell Corp., a growing animal health company that develops, manufactures and markets scientifically-proven products to improve health and productivity in the dairy and beef industries. One of ImmuCell's product lines aims to prevent pathogen-caused diarrhea, or scours, in newborn calves, a significant problem in these industries.

Rotaviruses, together with other pathogens such as coronaviruses and *E. coli* bacteria, are the most common causes of neonatal diarrhea in calves. This condition can be fatal from the loss of nutrients and dehydration. Survivors suffer the consequences of their neonatal condition through life; they are more susceptible to disease, gain less weight and produce less milk than calves that did not have scours.

The scientists at ImmuCell developed and field tested a vaccine of virus-like particles in cows. The cows responded to the vaccine by producing anti-rotavirus antibodies in the colostrum, which were tested for their ability to protect newborn cows from the virus. Successful field trials led to First Defense® Tri-Shield™, a new product approved by the US Food and Drug Administration in 2017 that combines the anti-*E. coli* and anti-coronavirus antibodies in ImmuCell's product First Defense® with anti-rotavirus antibodies.

In natural conditions, antibodies passed from the vaccinated dam to the calf through colostrum protect newborn calves from these pathogens. However, research suggests that many dams do not make sufficient levels of antibodies through this natural process, so a significant number of calves remain unprotected. The new product claims to overcome this situation by directly providing calves the amount of antibodies needed to confer protection against the pathogens in a large edible capsule.

“This is a very important achievement by our development and manufacturing teams after many years of challenging work,” commented Michael F. Brigham, president and CEO of ImmuCell. “Generating a consistent level of rotavirus antibodies through our proprietary hyper-immunization program is not easy. Our prior initiatives to achieve this result did not utilize the novel technology that we have exclusively licensed from Baylor College of Medicine in Houston.”

“We state in our grant proposals that our research is to help prevent or treat disease, but it is not very often that someone successfully achieves that goal,” Estes said. “I am delighted that we have a rotavirus vaccine that has been licensed and we hope will help improve the health of farm animals. I also hope that after the success in the cattle industry, health care officials will be encouraged to think about rotavirus vaccines based on virus-like particles for children.”

Michael Dilling, Director of the Baylor Licensing Group, agreed. “This is precisely the outcome that we want to see -- new products introduced to the market that incorporate important discoveries from the labs at Baylor.”

**Patent Number(s):** US 5,186,933, US 5,827,696, US 5,840,541, US 5,843,733, US 5,891,676

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