

## News

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### Miller School Researchers Develop Revolutionary Anesthesia Formulation

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Ernesto A. Pretto, Jr., M.D.,  
M.P.H., left, with Christopher A.  
Fraker, Ph.D.

An innovative anesthesia formulation developed by a University of Miami Miller School of Medicine research team could dramatically improve surgical care around the world.

“If proven safe and effective in clinical trials, this new formulation could revolutionize the delivery of general anesthesia,” said Ernesto A. Pretto, Jr., M.D., M.P.H., professor and Chief of the Division of Solid Organ Transplant and Vascular Anesthesia in the Department of Anesthesiology.

Unlike conventional anesthesia systems that vaporize liquid anesthetics into gas and then deliver it to the bloodstream through the lungs, the new formulation would allow this class of anesthetic drugs to be injected directly into the bloodstream.

“This is potentially an easier, safer and faster way to deliver anesthesia in a low-cost, portable format, improving access to surgical care for patients in developing countries, soldiers on a battlefield or patients in traditional hospital settings,” said Christopher A. Fraker, Ph.D., a research assistant professor who developed the formulation in the Bioengineering Laboratory of the Diabetes Research Institute (DRI), whose support comes in large part from the Diabetes Research Institute Foundation.

U Innovation, which protects, transforms and guides the University of Miami’s intellectual property, recognized the potential of this breakthrough discovery. Its Wallace H. Coulter Center for Translational Research funded work on the technology and provided guidance toward commercialization.

On April 14, U Innovation’s Office of Technology Transfer signed a license agreement with The Medicines Company, a global provider of solutions for acute cardiovascular care, surgery and perioperative care, and serious infectious disease care. The agreement will allow The Medicines Company to develop and hopefully market the new formulation, said Pretto.

“This is a platform technology with many potential applications,” said Daniel J. Catron, senior licensing associate at the Office of Technology Transfer. “This innovative formulation is ideal for resource-limited medical settings. It could also be applied to veterinary medicine, providing potential benefits when sedating and treating large and small animals. The Medicines Company understands our vision and has the ability to take this development forward. This commercialization partnership can help patients on a global level, while also benefiting our University.”

The University is negotiating a Sponsored Research Agreement with a collaborative research team from the Department of Anesthesiology, the Diabetes Research Institute

and the College of Veterinary Medicine at the University of Florida. That team includes DRI Director Camillo Ricordi, M.D., Stacy Joy Goodman Professor of Surgery, Distinguished Professor of Medicine, Professor of Biomedical Engineering, Microbiology and Immunology, and Director of the DRI's Cell Transplant Center, Fernando Garcia-Pereira, D.V.M., from the University of Florida, and Behrouz Ashrafi, M.D., assistant professor of anesthesiology, as well as Pretto and Fraker. The agreement will help The Medicines Company advance the technology through additional pre-clinical testing needed to enable clinical trials, Pretto said.

“The University of Miami Miller School of Medicine is a world-class institution, and the opportunity to work with some of its most talented and innovative clinicians and scientists is an exciting, albeit humbling, opportunity,” said Jason Campagna, M.D. '96, Ph.D. '97, Vice President and Global Medical Lead for Surgery and Perioperative Medicine at The Medicines Company. “There are more than 300 million surgical procedures annually around the world, and the need for new anesthetics and ways to deliver anesthesia care safely has never been greater.”

Fraker said the anesthesia breakthrough originated with studies on how to protect insulin-producing pancreatic islet cells during transplantation to patients with life-threatening diabetes.

“I had studied fluorocarbon emulsions that carry oxygen to the blood, and was brought into an ongoing collaborative DRI/Department of Anesthesiology project by Dr. Antonello Pileggi,” Fraker said. “Dr. Pileggi was the initiator of many collaborative efforts and was adept at bringing in the right people to form teams that would accelerate and increase the chances of project success. We serendipitously found that mixing the anesthetic with a carefully developed emulsion could create an injectable that was safe and highly effective in sedating animals in the laboratory.”

This novel emulsion technology, made possible through the multi-year funding that Fraker and Pretto received from the Diabetes Research Institute Foundation, received a patent this year.

Looking ahead, Fraker said that injecting the anesthesia medication directly into the bloodstream has multiple benefits in clinical care.

“You can use a lower dosage to accomplish the same result, increasing the safety profile,” he said. “You can also bring patients out of anesthesia more quickly.”

The new anesthesia platform would also allow combat medics to sedate wounded soldiers, slowing the blood flow and the onset of shock while the patient is transported to a field hospital, as part of a regimen being called emergency preservation and resuscitation, Pretto said.

“Our team presented a prototype to the Defense Advanced Research Projects Agency, and it was well received. Because of its self-contained portability, this formulation could even be taken into space.”