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## ImmuneWorks Names CEO; Plans Clinical Trials In IPF

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By Jennifer Boggs

Staff Writer

Founded less than two years ago to exploit a discovery by researchers at Indiana University on the role of Type V collagen in lung transplant rejection, start-up ImmuneWorks LLC is ready to start pushing its first program into the clinic aimed at idiopathic pulmonary fibrosis.

The company recently appointed industry veteran Wade Lange as president and CEO. As the first actual employee, Lange is charged with raising money and moving the firm's lead program through preclinical and toxicology work for submission of an investigational new drug application next spring.

ImmuneWorks was established in January 2006 by David Wilkes and Michael Klemsz, both researchers at IU's School of Medicine, along with Ronald Meeusen, who previously served as chief scientific officer at BioCrossroads, Indiana's life sciences initiative organization. The company's intellectual property, relating to work by Wilkes and Klemsz, covers the effects of Type V collagen in autoimmune and lung diseases and the development of therapeutics targeting that antigen.

That research initially began by "looking into an autoimmune basis for lung transplant rejection," Lange told *BioWorld Today*, adding that lung transplants have the "worst success rate of organ transplants." The researchers uncovered an apparent immune reaction to Type V collagen, which "becomes exposed during a lung transplant" and is attacked by the body's own immune system, leading to organ rejection.

However, because there are so few lung transplants performed every year - only about 1,500 in the U.S. and Canada - ImmuneWorks decided to focus its efforts first on idiopathic pulmonary fibrosis, a disease characterized by scarring of the lung causing fibrotic tissue in the lungs to thicken, reducing the tissue's ability to transfer oxygen to the bloodstream.

IPF affects about 200,000 in the U.S., and "about 60 percent of IPF patients have the autoimmune form," Lange said, meaning that treatment targeting Type V collagen might prove effective.

In addition to the therapeutic, ImmuneWorks plans to develop a companion diagnostic to determine whether IPF patients have the autoimmune form of the disease, he added. "Those that don't likely won't respond to Type V collagen treatment, so we'll need to be able to identify our patient population," as well as follow them in the course of the treatment to measure its effects.

Right now, the company is moving full speed ahead with its preclinical work, and expects to "enter toxicology studies later this year or early next year," Lange said.



The first drug candidate incorporates a purified Type 5 collagen to be administered orally in IPF patients. Since it's a natural product "it should enable us to get into trials quickly," he said.

In addition to appointing a CEO, ImmuneWorks signed agreements with Carmel, Ind.-based Anson Group for regulatory work, with Greenwood, Ind.-based Elona Biotechnologies for product development and with Indianapolis law firm Ice Miller LLP for legal services.

Looking into the future, Lange said ImmuneWorks likely will continue focusing on autoimmune diseases related to Type V collagen, and already has identified other lung diseases and "at least nonpulmonary disease" that could be treated by targeting the Type V collagen antigen. Beyond that, "we'll have an option to either go forward with an exclusive focus" on that target or possibly move more broadly into the autoimmune disease space, he added.

The company, which has been funded with about \$325,000 to date, is located in the Emerging Technologies Center at Indiana University. n