

BIOTECHNOLOGY

JDP Therapeutics Inc.

Aiming to improve treatment of acute allergic reactions

Plenty of people have seasonal allergies, and there are a number of good drugs to treat the symptoms that include stuffy noses, scratchy throats and itchy eyes. Indeed, there are so many excellent allergy drugs on the market already, including a slew of generic products, that lately some large companies have stopped investing in the area and allergy-oriented start-ups have been having a hard time attracting venture capital.

But there is one type of allergy whose symptoms could be better treated, says Jie Du, president and CEO of JDP Therapeutics Inc. The company she founded early in 2008 intends to develop a treatment for acute allergic reactions including anaphylaxis, the kind that can arise as a nearly immediate response to allergens like peanuts, shellfish, bee stings (venom), penicillin and other substances.

Du declines to name the generic compound her company has reformulated from a tablet to an injectable form, to treat anaphylaxis. But she says it was proven safe without any significant adverse events in a Phase I clinical study with 24 healthy human volunteers that concluded in July 2011. "The pharmacokinetic data were even better than expected," she adds. Du is confident the drug candidate dubbed JDP-205 will be valued in the market if and when it advances through Phase II and III human testing and receives FDA approval.

In the US each year, about three million people show up in hospital emergency rooms suffering from acute allergic reactions including anaphylaxis, Du says. That is the figure now, and reflects a steady rise owing in part to the fact that acute allergies in the US have been increasing by 8% each year for the past 10 years or so. A decade ago, only about 1.5 million Americans

went to the ER with acute allergies.

Epinephrine is the first-line treatment to open the airways and resolve the most dangerous symptom of acute allergy, including hypotension and broncho-constriction. But only about 20% of the cases that turn up at the hospital require an injection of that, Du explains. Sometimes the allergic reaction is not severe enough to be life-threatening and sometimes the patient has already received the drug – for instance via a simple injection device like an *EpiPen*, sold by prescription to people with known or suspected risk of acute allergic reaction.

Currently, the standard treatment for peripheral symptoms of acute allergic reaction is intravenous diphenhydramine, better known as *Benadryl*. Du says this antihistamine usually eliminates hives, swelling, redness and itching (aka urticaria, angioedema, erythema, and pruritus) within three to four hours. But *Benadryl* is known to be very sedating. So much so, Du says, that acute allergy patients end up staying in the ER another two to three hours longer because otherwise they are too drowsy to function.

Du believes JDP's drug candidate would have similar efficacy to diphenhydramine but be non-sedating, with a better side-effect profile. She says her company plans to test it in people who have not received epinephrine, and in that way position the drug candidate as a stand-alone treatment of acute allergic reactions and as an adjunct treatment to epinephrine.

Like so many other start-ups founded in the past few years, JDP Therapeutics is seeking funding from investors or a pharmaceutical partner to support a Phase II/III trial of JDP-205. Finding funding isn't the company's only challenge, however. The

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Business: Acute allergy treatment

Founded: March 2008

Founder: Jie Du

Employees: 3

Financing to Date: Undisclosed

Investors: Private investors

Board of Directors: Jie Du; Private investors

Medical Advisory Board: Robert M. Naclerio, MD (University of Chicago); William E. Berger, MD, PhD (Allergy and Asthma Associates of Southern California Medical Group); Michael S. Blaiss (University of Tennessee Health Sciences Center)

use of diphenhydramine as a treatment for acute allergy was "grandfathered" in; there were no clinical trials for it in this indication where it has now become standard. In fact, Du says, no one has ever conducted a clinical trial for acute allergy symptoms.

"We will have to figure out the dosing regimen from scratch," Du acknowledges, because even though JD-205 is based on "a molecule known to have a great safety profile," regulators will consider it a new product for a new indication. The start-up will also have to determine the best way of measuring symptom reduction. Would the best endpoint be swelling reduction? Reduction in the number or size of hives? Does the company need to measure JDP-205's effect on erythema? Can anticipated improvements in side effects be assessed by standardized measures, such as patient self-scoring on a drowsiness/alertness scale?

Du says she is undaunted by the challenges JDP Therapeutics faces, partly because of all the experience she gained in nearly 20 years of working in the pharmaceutical industry with companies including Abbott Laboratories Inc., Merck & Co.

Inc., and Mutual Pharmaceutical Co. Inc., a specialty pharma company in Philadelphia, where she bore primary responsibility for managing clinical trials. Du was also a co-founder in 2001 of Frontage Laboratories Inc., a pharmaceutical contract research or-

ganization that now serves clients in North America and Asia. Du has also had several of her own inventions patented. So she feels she has a lot to draw on. For her, as for so many start-up executives these days, the biggest question is how to get funding and

attract good people. Then JDP Therapeutics can continue its efforts to develop its new treatment for acute allergic reaction, based on a drug that is already trusted.

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— DEBORAH ERICKSON