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Emerging Company Profile

JDP: Emergency antihistamines

By Andrew Fisher
Staff Writer

JDP Therapeutics Inc. is hoping its injectable antihistamine can become standard of care for hospitalized patients suffering acute allergic reactions. By avoiding IV diphenhydramine's multiple doses and heavy sedative effects, the company is proposing its products will improve quality of care while producing cost savings for the healthcare system.

There are two main kinds of acute allergies: those suffered at home, such as reactions to nuts, shellfish or bee stings; and drug allergies, such as to penicillin.

Standard of care for acute allergies suffered at home is a self-administered intramuscular injection of epinephrine, followed by a trip to the emergency room, where patients receive IV diphenhydramine until their symptoms disappear.

Because diphenhydramine — better known by its brand name Benadryl — is a short-acting antihistamine, treatment usually involves several doses. Also, diphenhydramine is heavily sedative and results in longer hospital stays because patients who are sleeping or unable to drive safely can't be discharged.

In the case of hospitalized patients who are receiving regular doses of diphenhydramine to counter allergies to other drugs or to blood material following a transfusion, a non-sedative alternative would mean less monitoring of vital signs.

JDP Therapeutics Inc.

Lansdale, Pa.

Technology: Injectable formulation of an undisclosed marketed oral generic antihistamine

Disease focus: Allergy and immunology

Clinical status: Phase I

Founded: 2008 by Jie Du

University collaborators: None

Corporate partners: None

Number of employees: 3

Funds raised: Undisclosed

Investors: Private investors

CEO: Jie Du

Patents: None issued

CEO Jie Du said these patients are usually very sick, with pulse and breathing rates already below normal. Diphenhydramine can further lower these measures, making constant monitoring a necessity and increasing cost of care.

Phase I pharmacokinetic data show the company's lead product, JDP-205, could be given as a once-daily injection that is not sedating.

JDP-205 is an IV version of an oral generic antagonist of the histamine H1 receptor (HRH1). Du would not disclose the compound, but several oral generic rhinitis drugs, including loratidine (Claritin)

and cetirizine (Zyrtec), also target HRH1.

Phase II testing is slated to begin by March. Du said JDP is raising about \$15 million in a series A round, which should take the company through approval of the compound by YE14. She said the Phase II trial should take about 10 months, with another year and a half for Phase III testing.

JDP plans to submit an NDA for JDP-205 under section 505(b)(2) of the Food, Drug and Cosmetic Act, which allows sponsors to reference data on safety and efficacy from the scientific literature or from previously approved products.

The company also has completed Phase I testing of JDP-207, an intramuscular formulation of the same compound. The product could be used at home to stop milder reactions, or to slow more serious reactions before hospitalization.

For JDP-207, Du hopes to use an off-the-shelf auto-injector pen. The company hopes to receive approval of the compound by YE14.

Du hopes JDP will be acquired, but the company would hire a sales force to market its products "as a last resort."

JDP has filed five patent applications covering use of both formulations of the antihistamine to treat acute allergies.

Du said she is not aware of any similar treatments in development.

COMPANIES AND INSTITUTIONS MENTIONED

JDP Therapeutics Inc., Lansdale, Pa.

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