



Aradigm Receives FDA Clearance for Clinical Trial of Inhaled Liposomal Ciprofloxacin in Pediatric Patients With Cystic Fibrosis

HAYWARD, Calif., May 05, 2010 (BUSINESS WIRE) -- Aradigm Corporation (OTCBB:ARDM) (the "Company") today announced it received clearance from the U.S. Food and Drug Administration (FDA) for its inhaled liposomal ciprofloxacin Investigational New Drug (IND) application. The first trial planned under this IND is a Phase 1/2a, multicenter study designed to evaluate the pharmacokinetics, safety, and tolerability of once-daily administration of 150 mg (3 mL) of Ciprofloxacin for Inhalation (CFI, ARD-3100) in pediatric patients with cystic fibrosis (CF) who have a history of chronic *Pseudomonas aeruginosa* lung infection. Secondary endpoints will include quality of life measurements, lung function changes and improvement of outcomes with respect to exacerbations.

"We are very pleased to have an opportunity to investigate the utility of ARD-3100 in young CF patients and potentially provide another therapeutic option for the pediatric population," said Dr. Igor Gonda, president and CEO of the Company. "The IND approval follows Aradigm's previously reported encouraging results in adult patients with cystic fibrosis, and in patients with non-cystic fibrosis bronchiectasis."

"A once-a-day inhaled antibiotic, such as ARD-3100, would reduce the treatment burden for people with cystic fibrosis and be a welcome advance that could improve the lives of those with this disease," said Robert J. Beall, Ph.D., President and CEO of the Cystic Fibrosis Foundation.

Data analysis from a previously reported study with CFI in adult CF patients demonstrated that the *P. aeruginosa* Colony Forming Units (CFU) decreased by a mean 1.43 log over the 14-day treatment period ($p < 0.0001$). Evaluation one week after study treatment was discontinued showed that the *P. aeruginosa* bacterial density was still reduced by 1.02 log CFU from the baseline without additional antibiotic use. Pulmonary function testing as measured by the forced expiratory volume in one second (FEV_1) showed a significant mean increase of 6.9% from baseline after 14 days of treatment ($p = 0.04$). The study drug was well tolerated, and there were no serious adverse events reported during the trial. "Data from this new IND study will support inclusion of young CF patients in our future pivotal trials," said Dr. Paul Bruinenberg, the Company's Medical Director.

About cystic fibrosis

Cystic fibrosis is a life-threatening genetic disease that causes thick, sticky mucus to form in the lungs, pancreas and other organs. In the lungs, the mucus tends to block the airways, causing lung damage and making these patients highly susceptible to lung infections. According to the Cystic Fibrosis Foundation (CFF), CF affects roughly 30,000 children and adults in the United States (about 55 percent of the patients in the CFF Patient Registry are children), and roughly 70,000 children and adults worldwide. According to the American Lung Association, the direct medical care costs for an individual with CF are currently estimated to be in excess of \$40,000 per year. The Company was granted orphan drug designation in the US and EU for the management of CF with inhaled liposomal ciprofloxacin.

About liposomal ciprofloxacin

Ciprofloxacin is a widely prescribed antibiotic to treat infections of the lung frequently experienced by cystic fibrosis (CF) and non-cystic fibrosis bronchiectasis (BE) patients. It is often preferred because of its broad-spectrum anti-bacterial action. The available oral and intravenous formulations of the drug are used to treat episodes of acute exacerbations of lung infections in CF patients. The Company's once-a-day novel inhaled formulation of ciprofloxacin delivered in liposomes is to be used for chronic maintenance therapy as it is expected to achieve higher antibiotic concentration at the site of infection and relatively low systemic antibiotic concentrations to minimize side-effects. The Company previously announced initiation of two multinational Phase 2b clinical trials in subjects with BE, one using ARD-3100, ORBIT-2, (Once Daily Respiratory Bronchiectasis Inhalation Treatment) and another, ORBIT-1, using a formulation with a modified pharmacokinetic profile (ARD-3150). The results of these two trials are expected in the second half of 2010. The Company is also developing inhaled liposomal ciprofloxacin for the prevention and treatment of bioterrorism infections such as inhaled anthrax and tularemia.

About the Cystic Fibrosis Foundation

The Cystic Fibrosis Foundation (the "Foundation") is the world's leader in the search for a cure for cystic fibrosis. The Foundation funds more CF research than any other organization and nearly every CF drug available today was made possible because of Foundation support. Based in Bethesda, Md., the Foundation also supports and accredits a national care center

network that has been recognized by the National Institutes of Health as a model of care for a chronic disease. For more information, visit www.cff.org.

About Aradigm

Aradigm is an emerging specialty pharmaceutical company focused on the development and commercialization of a portfolio of drugs delivered by inhalation for the treatment of severe respiratory diseases by pulmonologists. The Company has product candidates addressing the treatment of cystic fibrosis, bronchiectasis, inhalation anthrax infections and smoking cessation.

More information about the Company can be found at www.aradigm.com.

Forward-Looking Statements

Except for the historical information contained herein, this news release contains forward-looking statements that involve risk and uncertainties, including dosing regimens and the advancement of product development, as well as the other risks detailed from time to time in Aradigm Corporation's Securities and Exchange Commission (SEC) Filings, including the Company's Annual Report on Form 10-K for the year ended December 31, 2009 filed with the SEC on March 24, 2010, and quarterly reports on Form 10-Q.

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