



Aradigm Doses First Patient in Its Second Phase 2b Clinical Trial of Inhaled Liposomal Ciprofloxacin in Bronchiectasis Patients

HAYWARD, Calif., Feb 23, 2010 (BUSINESS WIRE) -- Aradigm Corporation (OTCBB:ARDM) (the "Company") today announced that it dosed the first patient in the U.S. as part of its ORBIT-1 (Once-daily Respiratory Bronchiectasis Inhalation Treatment) trial, an international, randomized, double-blind, placebo-controlled Phase 2b study designed to evaluate the Company's inhaled liposomal ciprofloxacin (ARD-3100) in patients with non-cystic fibrosis bronchiectasis (BE) under a U.S. IND. This orphan disease indication is a chronic, severe respiratory disease and there are currently no approved treatments for this disease in the U.S.

"The initiation of our ORBIT-1 trial, the second Phase 2b trial with our once-a-day inhaled liposomal ciprofloxacin formulations in BE patients, is another important milestone in developing new therapies for this underserved patient population. We have been fortunate to assemble an excellent international clinical investigators team for this trial. We expect to be able to report the results of this study in the second half of 2010," said Dr. Igor Gonda, the Company's CEO and President.

The ORBIT-1 trial, a Phase 2b study, will randomize 96 patients, who will receive for four weeks either one of two different once-daily inhaled doses (100 or 150 mg ciprofloxacin delivered by inhalation as 2 or 3 mL of liposomal dispersion, respectively) or once-daily inhaled placebo. The primary efficacy endpoint will be a standard measure of antibacterial activity - the change from baseline in sputum *Pseudomonas aeruginosa* colony forming units (CFUs). Secondary endpoints will include quality of life measurements and improvement of outcomes with respect to exacerbations. Lung function changes will be monitored for safety.

In a previously conducted Phase 2a study of ARD-3100 in BE patients, 150 mg or 300 mg ciprofloxacin delivered once-a-day by inhalation as 3 or 6 mL of liposomal dispersion, respectively, were administered in an open-label study for four weeks. The primary efficacy endpoint was the change from baseline to end of treatment in sputum *Pseudomonas aeruginosa* CFUs. Both doses of inhaled liposomal ciprofloxacin in the evaluable patient population demonstrated significant mean decreases against baseline in the *Pseudomonas aeruginosa* CFU of 3.5 log ($p < 0.001$) and 4.0 log ($p < 0.001$) units, respectively. With regard to safety, there were no statistically significant changes in lung function at the end of treatment as measured by the normalized forced expiratory volume in one second (FEV_1 % predicted). Inhaled liposomal ciprofloxacin was well tolerated.

The Company previously announced the initiation of a six-month Phase 2b study in BE patients in Australia and New Zealand, the ORBIT-2 trial, using another inhaled ciprofloxacin formulation (ARD-3150) that has a different drug release profile from ARD-3100. The results from each of these trials will produce an extensive data base of information from which to select the optimum product and the most appropriate endpoints to test in Phase 3.

About bronchiectasis

Bronchiectasis (BE) is a chronic condition characterized by abnormal dilatation of the bronchi and bronchioles associated with chronic respiratory infections. It is frequently observed in patients with cystic fibrosis. It is a condition, however, that affects about 110,000 people without cystic fibrosis (CF) in the United States and many more in other countries, and results from a cycle of inflammation, recurrent infection, and bronchial wall damage. There is currently no drug specifically approved for the treatment of this condition in the U.S.

About liposomal ciprofloxacin

Ciprofloxacin is a widely prescribed antibiotic to treat infections of the lung frequently experienced by CF and non-CF BE patients. It is often preferred because of its broad-spectrum anti-bacterial action. The available oral and intravenous formulations of ciprofloxacin are used to treat episodes of acute exacerbations of lung infections. The Company's once-a-day, novel inhaled formulations of ciprofloxacin (ARD-3100 and ARD-3150) are being tested for chronic maintenance therapy as they are expected to achieve higher antibiotic concentration at the site of infection and relatively low systemic antibiotic concentrations to minimize side-effects. The Company previously reported positive results in Phase 2a studies of 22 CF patients and 36 BE patients who received ARD-3100 once-a-day for 2 (CF) or 4 (BE) weeks, respectively. The Company is also developing these formulations as a potential treatment for the prevention and treatment of bioterrorism infections, such as inhaled anthrax.

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 Aradigm 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 the timing and results of clinical trials, as well as the other risks detailed from time to time in the Company's filings with the Securities and Exchange Commission (SEC), including the Company's Annual Report on Form 10-K for the year ended December 31, 2008 filed with the SEC on March 30, 2009, and the Company's Quarterly Reports on Form 10-Q.

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Aradigm Corporation
Nancy Pecota, Chief Financial Officer, 510-265-9370

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