



## **Aradigm Doses First Patient in Long-Term Phase 2 Study of a Novel Inhaled Ciprofloxacin Formulation for the Management of Respiratory Infections in Bronchiectasis**

### **Study Will Explore the Long-Term Safety and Efficacy of Inhaled Ciprofloxacin in a Severe Respiratory Disease with Unmet Medical Needs**

HAYWARD, Calif., Nov 16, 2009 (BUSINESS WIRE) -- Aradigm Corporation (OTCBB:ARDM) (the "Company") today announced that the first patient was dosed in a 6-month, multicenter, international Phase 2 clinical trial of a novel version of inhaled ciprofloxacin (ARD-3150) in 40 adult patients with non-cystic fibrosis bronchiectasis.

The randomized, double-blind, placebo-controlled trial will be conducted in Australia and New Zealand. Following a 14-day screening period, the patients will be treated once a day for 28 days with either the active drug, or placebo, followed by a 28-day off-treatment period. This on-off sequence will be repeated three times. The primary endpoint is defined as the mean change in *Pseudomonas aeruginosa* density in sputum (colony forming units - CFU - per gram) from baseline to day 28 of the active treatment group versus placebo. Safety and tolerability assessments of the treatment versus placebo group will be performed and secondary efficacy endpoints will include long-term microbiological responses, time to an exacerbation, severity of exacerbations, length of time to resolve exacerbations, and changes in spirometry and in quality-of-life measurements.

The study will explore whether the novel formulation ARD-3150, which has a different drug release profile than ARD-3100 (the formulation being studied under a U.S. IND in a separate 1-month dosing Phase 2b trial in a similar patient population), may have additional therapeutic benefits. The 6-month study will also generate valuable data on the long-term impact of once-daily inhaled ciprofloxacin in patients with severe bronchiectasis.

"Depending upon enrollment rates, the results of each of these trials are expected in the third quarter of 2010 and will provide us with an extensive data base of information, from which to select the optimum product and the most appropriate endpoints to test in Phase 3," said Paul Bruinenberg, MD, Medical Director, Aradigm Corporation.

#### **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. However, it is a condition 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](http://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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