August 1, 2013

Aradigm Awarded NIH Grant to Investigate the Treatment of Pulmonary Non-Tuberculous Mycobacterial (PNTM) Infections with Pulmaquin and Lipoquin

HAYWARD, Calif.--(BUSINESS WIRE)-- The National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH), awarded Aradigm Corporation (OTCBB:ARDM) a Small Business Initiative Research (SBIR) grant to investigate the treatment of pulmonary non-tuberculous mycobacteria infections with Aradigm's inhaled liposomal ciprofloxacin products Pulmaquin® and Lipoquin®. The Principal Investigator is Dr. James D. Blanchard, Principal Scientist, Preclinical Development at Aradigm. Dr. Luiz Bermudez at the Oregon State University, Corvallis, will lead the laboratory research as a part of the consortium funded by this grant of approximately $278,000.

According to a recent report from the National Institutes of Health based on an epidemiological study in U.S. adults aged 65 years or older, PNTM infections are an important cause of morbidity among older adults in the United States. From 1997 to 2007, the annual prevalence significantly increased from 20 to 47 cases/100,000 persons, or 8.2% per year. Forty-four percent of PNTM-affected people in the study had bronchiectasis compared to 1% in the non-PNTM cases pointing to an important co-morbidity. PNTM infections are common also in patients with other chronic lung conditions, such as cystic fibrosis and emphysema. In patients with AIDS, the infection is disseminated. The current clinical paradigm is to treat patients with lung or disseminated disease with combination therapy given orally or by IV. Unfortunately, these therapies often fail.

"I am very pleased that the National Institutes of Health recognized the potential of our therapeutic approach to become an effective tool to help patients with PNTM infections, a severe chronic respiratory condition that is a growing concern in the U.S. and other countries. I congratulate Drs. Bermudez and Blanchard on the award that will enable them to leverage the synergies of world class scientists from Oregon State University and Aradigm. We already have a substantial amount of safety information in animal models and humans, as well as efficacy in other infections for Pulmaquin and Lipoquin. This one-year consortium program is an essential prerequisite for entry into advanced human clinical trials in patients with PNTM," said Igor Gonda, President and CEO of Aradigm.

About inhaled ciprofloxacin (Pulmaquin and Lipoquin)

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 formulations of ciprofloxacin are encapsulated in liposomes, allowing for a sustained release of the drug within the lung and improving airway tolerability. The formulations are to be used 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. Lipoquin is a liposomal formulation of ciprofloxacin. Pulmaquin is a dual release formulation that is a mixture of Lipoquin with unencapsulated ciprofloxacin. Pulmaquin has been tested extensively in preclinical tests, as well as in the ORBIT-2 Phase 2b bronchiectasis study in which outstanding antimicrobial activity coupled with good safety and tolerability was found, and, most importantly, the positive impact on prevention of exacerbations compared to placebo was also observed. The Company previously reported positive results in Phase 2a studies of 22 CF patients and 36 BE patients who received Lipoquin once-a-day for 2 (CF) or 4 (BE) weeks, respectively. Currently, Aradigm is finalizing plans to initiate the Phase 3 clinical program in BE with Pulmaquin.

Additionally, Aradigm is developing these formulations as a potential medication for the prevention and treatment of high threat and bioterrorism infections, such as inhaled anthrax, tularemia and Q fever. Aradigm has been granted orphan drug designation for liposomal ciprofloxacin for cystic fibrosis in the U.S. and the E.U., and for the combination of liposomal ciprofloxacin and free ciprofloxacin for BE in the U.S.

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. The Company has product candidates addressing the treatment of bronchiectasis, cystic fibrosis, inhalation tularemia and 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 ability of animal results to predict efficacy in humans, 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, 2012 filed with the SEC on March 27, 2013, and the Company's Quarterly Reports on Form 10-Q.

Aradigm Corporation
Nancy Pecota, 510-265-8800
Chief Financial Officer

Source: Aradigm Corporation

News Provided by Acquire Media