May 11, 2016

# Two Presentations on Aradigm's Inhaled Liposomal Ciprofloxacin Programs at the American Thoracic Society 2016 International Conference

HAYWARD, Calif.--(BUSINESS WIRE)-- The first presentation is co-authored by an international team of investigators and employees of Aradigm Corporation (NASDAQ:ARDM) (the "Company"); it discusses the details of the design of the ongoing Phase 3 clinical trials ORBIT-3 and ORBIT-4 investigating the safety and efficacy of the Company's investigational drug product Pulmaquin® in non-cystic fibrosis bronchiectasis (NCFBE) patients chronically colonized with *Pseudomonas aeruginosa* (PA).

The second presentation from the Oregon State University, Corvallis (OSU) and the Company describes results of studies that demonstrated that Aradigm's investigational drug Lipoquin® inhibited the formation of microaggregates of *Mycobacterium Avium Subsp Hominissuis*; these microaggregates are the first step for biofilm formation of the non-tuberculous mycobacteria (NTM) formation in the human lungs.

The detailed description of this research and its findings will be presented at the following sessions:

**A51 - BRONCHIECTASIS: CLINICAL AND EPIDEMIOLOGIC STUDIES, 9:00 AM - 04:15 PM, 5/15/2016**

A1775 - ORBIT-3 and ORBIT-4: Design of a Phase 3 Program to Investigate Safety and Efficacy of Pulmaquin® in Non-Cystic Fibrosis Bronchiectasis (NCFBE) Patients Chronically Colonized with *Pseudomonas Aeruginosa* (PA) by A. E. O'Donnell, D. Serisier, A. Wanner, J. Froehlich, P. Bruinenberg and I. Gonda

Poster Board Number: P626

**B49 - NON-TUBERCULOUS MYCOBACTERIAL DISEASE AND CASE REPORTS, 9:00 AM - 04:15 PM, 5/16/2016**

A3734 - Liposome-Ciprofloxacin Inhibits *Mycobacterium avium subs hominissuis (*MAH) Microaggregate Formation in a Dose and Time Dependent Manner, by L. E. Bermudez, J. Blanchard, L. Babrak, and I. Gonda

Poster Board Number: P1234

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**About Pulmaquin and Lipoquin**

Pulmaquin is a dual release formulation composed of a mixture of liposome encapsulated and unencapsulated ciprofloxacin. Ciprofloxacin, available in oral and intravenous formulations, is a widely prescribed antibiotic. It is used to treat acute lung infections and is often preferred because of its broad-spectrum antibacterial activity against various bacteria, such as *Pseudomonas aeruginosa*. Pulmaquin is being evaluated in two ongoing Phase 3 studies to determine its safety and effectiveness as a once-a-day inhaled formulation for the chronic treatment of patients with non-CF BE who have chronic lung infections with *Pseudomonas aeruginosa*.

Following Phase 2a development of the liposomal portion of Pulmaquin (Lipoquin®) and Phase 1 development of Pulmaquin, the Phase 2b study ORBIT-2 with Pulmaquin was a 24-week multicenter, randomized, double-blind, placebo-controlled trial in 42 adult non-CF BE subjects. This study demonstrated a significant reduction in *P.aeruginosa* sputum activity (p=0.002) and a decrease in time to first exacerbation in the per protocol population (p=0.046) and the mITT (p=0.057) populations in the Pulmaquin treated subjects compared to placebo. Overall, the incidence of all treatment emergent adverse events was similar between groups. The most frequently reported treatment related adverse events (reported by ≥ 3 patients in either treatment group) included product taste abnormal and nausea in the Pulmaquin group and wheezing in the placebo group. No serious adverse events were considered treatment related. There were no deaths reported during ORBIT-2.

The Phase 3 clinical program for Pulmaquin in non-CF BE consists of two worldwide, double-blind, placebo-controlled pivotal trials (ORBIT-3 and ORBIT-4) that are identical in design except for a pharmacokinetics sub-study to be conducted in one of the trials. Each trial has enrolled patients (278 in ORBIT-3 and 304 in ORBIT-4) into a 48-week double-blind period consisting of 6 cycles of 28 days on treatment with Pulmaquin or placebo plus 28 days off treatment, followed by a 28 day open label extension in which all participants will receive Pulmaquin (total treatment duration approximately one year). The superiority of Pulmaquin vs. placebo during the double-blind period is being evaluated in terms of the time to first pulmonary exacerbation (primary endpoint), while key secondary endpoints include the reduction in the number of pulmonary exacerbations and improvements in the quality of life measures. Lung function is being monitored as a safety indicator.

Aradigm has been granted orphan drug designations for liposomal ciprofloxacin as well as for ciprofloxacin for inhalation for non-CF BE in the U.S. In addition, the U.S. Food and Drug Administration (FDA) has designated Pulmaquin as a Qualified Infectious Disease Product (QIDP). The QIDP designation is granted for treatment of non-CF BE patients with chronic lung infections with *Pseudomonas aeruginosa*. The QIDP designation made Pulmaquin eligible for Fast Track designation which was granted by the FDA in September 2014.

In 2013, Aradigm granted an exclusive, worldwide license for the Company's inhaled liposomal ciprofloxacin product candidates for the indication of non-CF BE and other indications to Grifols S.A. More information on the terms of this license may be found in the Company's Annual Report on Form 10-K for the year ended December 31, 2013 filed with the SEC on March 13, 2014.

**About Non-Cystic Fibrosis Bronchiectasis**

Non-CF BE is a severe, chronic and rare disease characterized by abnormal dilatation of the bronchi and bronchioles, frequently associated with chronic lung infections. It is often a consequence of a vicious cycle of inflammation, recurrent lung infections, and bronchial wall damage. Non-CF BE represents an unmet medical need with high morbidity and mortality that affects more than 110,000 people in the U.S. and over 200,000 people in Europe. There is currently no drug approved for the treatment of this condition.

**About Pulmonary Non-Tuberculous Mycobacteria (PNTM) Infections**

NTM is found almost everywhere - for example, in tap water and the soil. People with severe pulmonary diseases including cystic fibrosis, chronic obstructive pulmonary disease (COPD), and Alpha-1 Antitrypsin deficiency are particularly vulnerable to PNTM infections. PNTM symptoms include: fever, cough (including coughing up blood), weight loss/loss of appetite, fatigue and night sweats. Bronchiectasis is a frequent co-morbidity in these patients.

PNTM patients are treated with antibiotics. Some species of mycobacteria may be resistant to certain antibiotics and the antibiotics may cause side effects that require stopping the treatment. Treatment may last more than one year.

A publication from the National Institutes of Health based on U.S. Medicare data from 1997-2007 determined that the annual prevalence of patients infected with PNTM in the U.S. increased 8.2% per year from 20 cases/100,000 to 47 cases/100,000 in people over 65.

**About Aradigm**

Aradigm is an emerging specialty pharmaceutical company focused on the development and commercialization of drugs for the prevention and treatment of severe respiratory diseases. Aradigm is currently in Phase 3 development of Pulmaquin (an investigational proprietary formulation of ciprofloxacin for inhalation) for the treatment of non-cystic fibrosis bronchiectasis. Aradigm's inhaled ciprofloxacin formulations are also product candidates for treatment of patients with cystic fibrosis and non-tuberculous mycobacteria, and for the prevention and treatment of high threat and bioterrorism infections, such as inhaled tularemia, pneumonic plague, melioidosis, Q fever and inhaled anthrax. In addition, Aradigm has a pipeline composed of programs to prevent diseases in tobacco smokers through smoking cessation and a diagnostic program to detect aspirations of gastrointestinal fluid into the respiratory tract.

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 those related to the ORBIT-3 and ORBIT-4 clinical trials and the ability to continue successful product development of our potential product candidates, including Pulmaquin, 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, 2015 filed with the SEC on March 30, 2016, and the

Company's Quarterly Reports on Form 10-Q.



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

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