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Aradigm Announces Australian Research Council Funding to Develop Nanotechnologies Targeting Bacterial and Fungal Biofilms

HAYWARD, Calif.--(BUSINESS WIRE)-- **Aradigm Corporation (NASDAQ:ARDM)** (the "Company") today announced that it entered into an agreement with the University of Sydney to collaborate on a joint program on the development of advanced nanotechnologies for targeting bacterial and fungal biofilms that are often present with concomitant infections in chronic diseases such as cystic fibrosis (CF) and non-CF bronchiectasis (non-CF BE). This agreement provides for funding of AUD$420,000 over a three-year period from the Australian Research Council through the Australian Linkage Project program.

"The adverse impact of bacterial and fungal biofilms in the medical field including medical devices, organ transplantation and many severe infections with organisms such as *Pseudomonas aeruginosa* and non-tuberculous mycobacteria, is a significant problem," said Professor Daniela Traini, Woolcock Institute, University of Sydney School of Medicine, and the Project Leader for this program. "Biofilms are not only ubiquitous, they exhibit a recalcitrance to control. According to the United States National Institutes of Health, more than 60% of all microbial infections are caused by biofilms. While acute infections involving motile bacteria are generally treatable with antibiotics and antifungals, once a biofilm is established the infection is often untreatable."

"We are grateful that the Australian government has chosen to fund this important collaborative program on biofilms which may lead to beneficial treatments for patients with severe lung infections. Our colleagues at the Woolcock Institute have world class expertise and equipment to study the effect of nanotechnologies on biofilms. These efforts build upon the body of knowledge that has already accumulated through Aradigm's development of inhaled liposomal ciprofloxacin formulations for treatment of severe lung infections," said David Cipolla, PhD, Vice President, Pre-Clinical R&D, Aradigm Corporation.

Aradigm recently announced the completion of the dosing of patients in the Phase 3 clinical program for Pulmaquin® in non-CF BE consisting of two worldwide, double-blind, placebo-controlled pivotal trials (ORBIT-3 and ORBIT-4) that were identical in design except for a pharmacokinetics sub-study that was conducted in one of the trials only. Each trial 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 received Pulmaquin (total treatment duration, including the double-blind period, of 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.

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 *P. 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.

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, world-wide 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 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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