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Aradigm Announces Decision for Centralized Review of Pulmaquin by the European Medicines Agency

HAYWARD, Calif.--(BUSINESS WIRE)-- Aradigm Corporation (Nasdaq:ARDM) (the "Company") today announced that the European Medicines Agency (EMA) has approved its request to review Pulmaquin®, Aradigm's investigational inhaled liposomal ciprofloxacin product, under the Centralised Authorisation Procedure drug review process. This procedure results in a single marketing authorization that is valid in all 28 European Union countries, as well as three European Economic Area countries. Aradigm requested, and was granted, the centralized pathway on the basis that Pulmaquin represents a significant technical innovation for the potential treatment of non-cystic fibrosis bronchiectasis (non-CF BE) associated with chronic *Pseudomonas aeruginosa* (*P. aeruginosa*) infection.

"We are pleased that the EMA has agreed to review Pulmaquin through the centralized review process," said Dr. Juergen Froehlich, Aradigm's Chief Medical Officer. "This will enable us to streamline the process of gaining a license in all member states of Europe, with the opportunity of providing those living with non-CF BE and chronic lung infections with *P. aeruginosa* quicker access to Pulmaquin. Registration through the Centralized Procedure is typically reserved for products with significant therapeutic, scientific or technical innovation. This favorable decision reflects positively on the innovative approach we are taking investigating Pulmaquin for the treatment of this current unmet medical need in non-CF BE patients."

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.

About Pulmaquin

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 with chronic lung infections with *P. aeruginosa*. 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 *P.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.

More information about Aradigm can be found at www.aradigm.com.

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