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

HAYWARD, Calif.--(BUSINESS WIRE)-- The National Institute of Allergy and Infectious Diseases (NIAID) and National Institutes of Health (NIH) awarded Aradigm Corporation (NASDAQ:ARDM) a Small Business Initiative Research (SBIR) grant to investigate the treatment of two pulmonary non-tuberculous mycobacteria (PNTM) infections, *Mycobacterium avium* and *Mycobacterium abscessus*, with Aradigm's inhaled liposomal ciprofloxacin products Linhaliq™ and Lipoquin®. The Principal Investigator is Dr. James D. Blanchard, Principal Scientist, Preclinical Development at Aradigm. Professor Luiz Bermudez at Oregon State University, Corvallis, will lead the laboratory research as a part of the consortium funded by this two year grant of approximately $972,000.

According to a report from NIH 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 per 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.

The Phase II SBIR grant builds upon the encouraging results demonstrated in the Phase I SBIR grant that found both Linhaliq and Lipoquin to have significant efficacy against *M. avium* complex and *M. abscessus* infection. The current standard of treatment of mycobacterial infections is the simultaneous use of multiple antibiotics, and the Phase II grant will focus on combination therapies. For *M. avium* complex infection, the efficacy of Linhaliq and Lipoquin will be tested in combination with clarithromycin, ethambutol, and amikacin using macrophage and biofilm test systems as well as a mouse lung infection. For *M. abscessus* infection, the efficacy of Linhaliq and Lipoquin will be tested in combination with linezolid and imipenem. The emergence of antibiotic resistance will be investigated.

"Pulmonary infections with non-tuberculous mycobacteria (NTM) have become a serious growing public health problem in the U.S. and many other countries as they can result in debilitating lung disease and are costly to treat. We have shown that lung-delivered liposomal ciprofloxacin is effective in *in vitro* and animal models of NTM without causing the emergence of resistant NTM. Patients with NTM at present typically have to use several antibiotics to avoid the emergence of resistance. This NIH grant is important as it enables us to compare the benefits of lung-delivered liposomal ciprofloxacin alone or in combination with other antibiotics," said Prof. Bermudez.

"Bronchiectasis and chronic lung infections with *Pseudomonas aeruginosa* and NTM are frequent co-morbidities. It is our goal to deliver a much needed new treatment for these patients with severe lung diseases," said Dr. Blanchard.

About Linhaliq

Linhaliq, formerly known as Pulmaquin®, is 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 often to treat acute lung infections because of its broad-spectrum antibacterial activity against various bacteria, such as *Pseudomonas aeruginosa*. Aradigm'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. Linhaliq is a dual release formulation that is a mixture of Lipoquin with unencapsulated ciprofloxacin. Aradigm completed two Phase 3 clinical trials with once daily inhaled Linhaliq in patients with non-cystic fibrosis bronchiectasis (NCFBE) with chronic lung infections with *Pseudomonas aeruginosa* and submitted a New Drug Application to the U.S. Food & Drug Administration for this product candidate in July 2017. Once daily inhaled Lipoquin was tested in Phase 1 and Phase 2 clinical trials in healthy subjects, cystic fibrosis patients and non-cystic fibrosis bronchiectasis 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 has completed Phase 3 development of Linhaliq (an investigational proprietary formulation of ciprofloxacin for inhalation) for the treatment of NCFBE. Aradigm's inhaled

ciprofloxacin formulations including Linhaliq 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.

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, 2016 filed with the SEC on March 30, 2017, and the Company's Quarterly Reports on Form 10-Q.

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