January 11, 2018

Aradigm Reports Results of FDA Advisory Committee Meeting on Linhaliq

HAYWARD, Calif., Jan. 11, 2018 (GLOBE NEWSWIRE) -- **Aradigm Corporation** (NASDAQ:ARDM) (the "Company") today announces that the Antimicrobial Drugs Advisory Committee (ADAC) of the US Food and Drug Administration (FDA) did not recommend approval for Linhaliq™ as a treatment for non-cystic fibrosis bronchiectasis (NCFBE) patients with chronic lung *Pseudomonas aeruginosa* infections.

The Advisory Committee voted 12 "no" to 3 "yes", with 1 abstention, on the following question: "Has the applicant provided substantial evidence of the safety and efficacy of ciprofloxacin dispersion for inhalation in delaying the time to first exacerbation after starting treatment in non-cystic fibrosis bronchiectasis patients with chronic lung infections with *Pseudomonas aeruginosa?*"

The FDA is not bound by the Advisory Committee's guidance, but takes its advice into consideration when reviewing investigational medicines.

"While we are disappointed with the outcome of the ADAC vote, we remain confident in the efficacy, safety and tolerability of Linhaliq in NCFBE patients," said Igor Gonda, Ph.D., president and chief executive officer at Aradigm. "We will work closely with the FDA to address the issues discussed by the panel today as they complete their review of Linhaliq. We are committed to helping NCFBE patients, who presently have no available treatment options."

The FDA has set a PDUFA action date of January 26, 2018 for the completion of its review of Linhaliq. The clinical program for Linhaliq was developed with guidance from the FDA, who also granted Orphan Drug (June 2011), Qualified Infections Disease Product (June 2014), and Fast Track (August 2014) designations to Linhaliq.

The Linhaliq application was based on data from three clinical studies. Two Phase 3 studies, ORBIT-3 and ORBIT-4, were identically designed, multinational, randomized (2:1), double-blind and placebo controlled trials. Both were conducted concurrently in similar geographies over 48 weeks, with an additional 4 weeks of open-label treatment and a 30-day safety follow up. Together with the Phase 2b ORBIT-2 study, these trials provide evidence of the clinical benefit of Linhaliq for patients with NCFBE who have chronic lung infections with *P. aeruginosa*.

About Non-Cystic Fibrosis Bronchiectasis (NCFBE)

NCFBE 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. NCFBE represents an unmet medical need with high morbidity and mortality that affects more than 150,000 people in the U.S. and over 200,000 people in Europe. NCFBE patients who have chronic infections with *Pseudomonas aeruginosa* have a 6.5-fold increase in hospitalizations, three times higher mortality, and a worse quality of life compared with those without *P. aeruginosa* infections. 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 has completed two Phase 3 clinical trials with Linhaliq, an investigational proprietary formulation of ciprofloxacin for inhalation, for the treatment of NCFBE and submitted an NDA to the FDA for this indication. The PDUFA goal date for completion of the FDA review of the Linhaliq NDA is January 26, 2018. Aradigm's inhaled ciprofloxacin formulations, including Linhaliq, are also product candidates for treatment of patients with cystic fibrosis and non-tuberculous mycobacteria (NTM), and for the prevention and treatment of high threat and bioterrorism infections, such as inhaled tularemia, pneumonic plague, melioidosis, Q fever and inhaled anthrax.

Forward-Looking Statements

Except for the historical information contained herein, this news release contains forward-looking statements that involve risk and uncertainties, including the risk that Linhaliq may not receive regulatory approval or be successfully commercialized, 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.

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

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