



September 25, 2017

## Aradigm Announces FDA Acceptance of NDA for Linhaliq with Priority Review Status

HAYWARD, Calif.--(BUSINESS WIRE)-- **Aradigm Corporation (NASDAQ: ARDM)** (the "Company") today announced that the U.S. Food and Drug Administration (FDA) has accepted for filing with Priority Review its New Drug Application (NDA) for Linhaliq™ for the treatment of non-cystic fibrosis bronchiectasis (NCFBE) patients with chronic infections with *Pseudomonas aeruginosa* (*P. aeruginosa*).

The granting of Priority Review for the Linhaliq NDA accelerates the timing of the FDA review of the application compared to a standard review. The PDUFA (Prescription Drug User Fee Act) goal date for completion of the FDA review of the Linhaliq NDA is January 26, 2018.

"We are pleased with the FDA's acceptance of our NDA filing with Priority Review," said Dr. Igor Gonda, Chief Executive Officer, Aradigm Corporation. "We look forward to working with the FDA during the review process to support approval of Linhaliq and provide a much needed treatment for NCFBE patients with chronic lung infection with *P. aeruginosa*."

Aradigm received Orphan Drug Designation for liposomal ciprofloxacin for inhalation for the management of bronchiectasis and for Linhaliq for the management of bronchiectasis. Additionally, for Linhaliq, Aradigm was granted Qualified Infectious Disease Product (QIDP) Designation for the treatment of NCFBE patients with chronic lung infections with *P. aeruginosa* followed by Fast Track Designation.

### About Non-Cystic Fibrosis Bronchiectasis

Non-cystic fibrosis bronchiectasis (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 *P. aeruginosa* have a 6.5-fold increase in hospitalization, 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 a New Drug Application to the FDA for this indication. 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](http://www.aradigm.com).

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

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