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Shionogi receives FDA approval for cUTI drug

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FETROJA® (cefiderocol) Approved by the FDA for Treatment of Complicated Urinary Tract Infections

Japan based Shionogi & Co., Ltd. has announced the U.S. Food and Drug Administration (FDA) has approved FETROJA® (cefiderocol) for patients 18 years of age or older who have limited or no alternative treatment options, for the treatment of complicated urinary tract infections (cUTI), including pyelonephritis, caused by the following: susceptible Gram-negative microorganisms: *Escherichia coli*, *Klebsiella pneumoniae*, *Proteus mirabilis*, *Pseudomonas aeruginosa*, and *Enterobacter cloacae* complex. Approval of this indication is based on limited clinical safety and efficacy data for FETROJA.

“FETROJA will fill a very important unmet medical need because of its unique method of penetrating the cell wall of Gram-negative bacteria and its ability to overcome many of the resistance mechanisms that bacteria employ against antibiotics. Today’s approval represents Shionogi’s ongoing commitment to develop medicines that help fight these life-threatening infections in patients for whom limited or no alternative treatment options exist,” said Isao Teshirogi, Ph.D., president and CEO at Shionogi.

FETROJA was designated a Qualified Infectious Disease Product (QIDP) by the FDA, providing Fast Track designation and Priority Review. Shionogi anticipates making FETROJA commercially available in early 2020.