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MerLion Pharmaceuticals Announces Successful FDA Type C Meeting for the Systemic Application of the Antibiotic Finafloxacin Against Infections caused by *Burkholderia pseudomallei* (Meliodiosis)

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News on the development of finafloxacin

Berlin, Germany (31/08/2022) - MerLion Pharmaceuticals GmbH (MerLion), a pharmaceutical company focused on the development of novel antibiotics, reported the receipt of the final meeting minutes from the U.S. Food and Drug Administration (FDA) following a successful Type C meeting with the Agency on the development of the antibiotic finafloxacin for the treatment of melioidosis, in a naturally occurring as well as a biodefense context.

"FDA provided clear guidance and considered the program outlined by MerLion for the development of finafloxacin towards potential licensure for the treatment of infections caused by *Burkholderia pseudomallei* - for both a naturally occurring and biodefense-related melioidosis indication - feasible," said Dr. Andreas Vente, Managing Director of MerLion Pharmaceuticals GmbH. "The melioidosis market authorizations would be based on an NDA for the treatment of a further, though more common, infectious disease of unmet medical need requiring hospitalization," Dr. Vente stated further.

"MerLion Pharmaceuticals is in particular looking forward to continuing the collaboration with its partners from the UK's Defence Science and Technology Laboratory (Dstl). The success of this collaboration has been and will continue to be instrumental in establishing finafloxacin as a treatment against *B. pseudomallei* infections, and wouldn't have been possible so far without key funding by the U.S. Defense Threat Reduction Agency (DTRA) under project HDTRA1-12D-0003-0019," Dr. Vente expressed.

Melioidosis ("Whitmore's disease") is a serious, often lethal infection caused by the Gram-negative bacterium *B. pseudomallei*, which is found in subtropical and tropical areas of the world. In 2022 the U.S. Centers of Disease Control and Prevention (CDC) announced melioidosis was endemic in parts of the southern, continental United States. Four unrelated melioidosis cases reported in the United States in 2021, caused by contaminated, imported aromatherapy sprays, further highlight the danger of *B. pseudomallei* as a potential bioterror pathogen.

About Finafloxacin

Finafloxacin is a novel fluoroquinolone antibiotic with best-in-class features, developed by MerLion Pharmaceuticals GmbH. Finafloxacin combines well-known, significant efficacy and resistance-breaking capabilities with an outstanding safety profile. In clinical and pre-clinical settings, the compound has shown broad utility in treating different severe infections (including those caused by resistant Gram-negative pathogens) and a substantially improved therapeutic profile in comparison to existing gold standard therapies.

The superior antibacterial profile of finafloxacin is due to a unique mode of action, being equally active at physiological pH conditions and in acidic environments, which occur at most bacterial infection sites. Most other antibiotics, including other fluoroquinolones, show reduced activity and subsequently reduced efficacy under acidic conditions.

Finafloxacin formulations for intravenous, oral and topical administration are available.

About Dstl

Dstl – The science inside UK defence and security

The Defence Science and Technology Laboratory (Dstl) delivers high-impact science and technology (S&T) for the UK's defence, security and prosperity.

Dstl is an Executive Agency of the MOD with around 4,500 staff working across four sites; Porton Down, near Salisbury, Portsmouth West, near Portsmouth, Fort Halstead, near Sevenoaks, and Alverstoke, near Gosport.

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About DTRA

DTRA enables Department of Defense (DoD), the U.S. Government, and International Partners to counter and deter weapons of mass destruction (WMD) and emerging threats. Under the auspice of the Chemical and Biological Defense Program, DTRA has the responsibility to manage and integrate the DoD chemical and biological defense science and technology programs. DTRA's continued effort to enhance the combat support mission also advances public health services by developing innovative technologies that protect against biological threats.

For more information, visit <http://www.dtra.mil/>

About MerLion Pharmaceuticals

MerLion Pharmaceuticals GmbH is a privately held biopharmaceutical company headquartered in Berlin, Germany. The company focuses on the advanced clinical development of its antibacterial lead program, finafloxacin. MerLion is supported by a group of leading global investors.

For more information, please visit us at merlionpharma.com

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