MerLion and Dstl Awarded DTRA Grant to Explore the Use of Finafloxacin against Biological Threat Agents

Singapore, 28 June 2017 - MerLion Pharmaceuticals ("MerLion") today announced that a joint project with the Defence Science and Technology Laboratory, UK (Dstl) titled "'Efficacy of Finafloxacin against Biological Threat Agents" has been awarded a grant from the United States' Defense Threat Reduction Agency (DTRA) Chemical and Biological Defense Program.

The multi-year, multi-phase project will study the impact of MerLion's novel fluoroquinolone finafloxacin for the treatment of infections caused by the biological threat agent *Burkholderia pseudomallei (B. pseudomallei)*. In addition, the broad spectrum efficacy of finafloxacin against other intracellular bio-threat agents such as *Francisella tularensis (F. tularensis)* and *Yersinia pestis (Y. pestis*), and other multi-drug resistant (MDR) pathogens of clinical significance will be investigated in further detail.

During the initial period of the project MerLion and Dstl will work towards gaining U.S. Food and Drug Administration (FDA) agreement about the next steps for the development of finafloxacin as an approved antibiotic.

This project will build on data generated both *in vitro* and *in vivo* in an existing long-standing collaboration between Dstl and MerLion which has shown that, in addition to activity against MDR pathogens, finafloxacin has significant potential for the treatment of bio-threat agents. Finafloxacin has already demonstrated strong and rapid-onset activity against *B. pseudomallei, F. tularensis* and other intracellular bio-threat pathogens.

Finafloxacin acts powerfully against two bacterial molecular targets and its rapid bactericidal effect is further enhanced by its activity in the acidic environment found at most sites of bacterial infection.

In addition, finafloxacin has been shown to be a poor substrate of the major multidrug efflux transporters which affect other fluoroquinolones and is thus able to maintain its efficacy against fluoroquinolone-resistant *B. pseudomallei* where resistance caused by efflux pumps is predominant.

MerLion has previously reported positive results for finafloxacin from a Phase 2 study in patients hospitalized with complicated urinary tract infections (cUTI) and pyelonephritis which showed that a five day course, starting with IV and switching to oral dosing, was more effective that treatment with the current standard of care (ciprofloxacin).

"We already have compelling pre-clinical results generated in the collaboration with our partners from Dstl for finafloxacin's activity against various bio-threat pathogens, as well as data from our positive clinical studies treating patients with cUTI infections", said David Dally, CEO of MerLion.

He added that "The new project will enable us to investigate the activity of finafloxacin against a variety of very difficult-to-treat pathogens in more detail and will help to position finafloxacin as an effective therapy against multiple bioterrorism threats, as well as a treatment for other life-threatening infections."

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About MerLion Pharmaceuticals

MerLion Pharmaceuticals Pte Ltd is a biopharmaceutical company, headquartered in Singapore with R&D operations in Berlin, Germany which is focused on the advanced clinical development of its antibacterial lead program, finafloxacin. MerLion is a privately held company supported by a group of leading global investors including Aravis Venture Partners, Singapore based EDBI, Heidelberg Capital and Nomura Research & Advisory. For more information please visit www.merlionpharma.com

About Dstl

The Defence Science and Technology Laboratory (Dstl) is an executive agency of UK's Ministry of Defence and is one of the principal government organisations dedicated to science and technology in the defence and security field. Dstl ensures that innovative science and technology contribute to the defence and security of the UK.

About DTRA

DTRA is the US Government Agency responsible for combating weapons of mass destruction. DTRA develops and delivers cutting-edge technologies to assist with these endeavours.

About Finafloxacin

Finafloxacin is a novel fluoroquinolone antibiotic with many "best in class" features. In clinical and pre-clinical settings the compound has shown a substantially improved therapeutic profile as compared to the existing gold standard and a broad utility in treating many severe infections, including those caused by resistant Gram-negative pathogens.

Finafloxacin's superior profile arises from the compound's unique mode of action, being equally active at physiological pH conditions and in the acidic environments which occur at the most sites of bacterial infections. Most other antibiotics, including other fluoroquinolones, show decreased activity under acidic tissue conditions, which result in significantly reducing their overall efficacy.

Results from a double-blind controlled clinical Phase 2 trial revealed a higher, more rapid and sustained level of microbiological eradication and improved clinical outcomes for patients treated with finafloxacin compared to those treated with ciprofloxacin. The trial's primary and secondary endpoints were all successfully achieved. Finafloxacin was found to be both safe and well tolerated.

MerLion has developed IV and oral formulations of finafloxacin with equivalent bioavailability, offering physicians various options for in-hospital and out-patient treatment regimens.

MerLion has licensed Finafloxacin to a major pharmaceutical partner for use in North America for ear infections. In 2014 Xtoro™, an otic suspension of finafloxacin, was approved by the FDA for treatment of acute otitis externa, commonly known as "swimmer's ear", caused by *Pseudomonas aeruginosa* and *Staphylococcus aureus*.

About *Burkholderia pseudomallei*

Burkholderia pseudomallei is a Gram-negative, bipolar, aerobic, motile rod-shaped, soil-dwelling bacterium, endemic in tropical and subtropical regions worldwide. It infects humans and animals and causes the disease melioidosis.