



## **MerLion completes recruitment in Finafloxacin phase II cUTI trial**

**Singapore, 18 June 2014** - MerLion Pharmaceuticals (MerLion) announced today that it has completed the planned recruitment into its Phase II trial in patients hospitalized with Complicated Urinary Tract Infection, including pyelonephritis (“cUTI”) in Germany and Poland.

The trial is a multi-dose, double-blind, double-dummy, active-control, randomised 3-arm study to evaluate the safety, tolerability, efficacy and pharmacokinetics of finafloxacin.

MerLion expects to report top-line results from the study by the end of Q3 2014.

Mr. David Dally, CEO of MerLion, commented, “The study is designed to test the safety and efficacy of different finafloxacin dose regimens with an “intravenous (“iv”) to oral step-down” option for the treatment of cUTI and pyelonephritis. We believe that finafloxacin will offer the real possibility of reduced treatment durations and concomitant shorter stays in hospital, thus improving patient convenience and significantly lowering the costs of hospitalisation and treatment. Reduced hospitalisation periods should also reduce the risk of nosocomial infections and of generating drug-resistant strains through extended therapy.”

Florian Wagenlehner, M.D., Ph.D., Clinic for Urology, Pediatric Urology and Andrology, Justus-Liebig University Giessen, Germany, lead investigator of the study stated; “We very much look forward to the results of this exciting study and anticipate that they will allow us to determine the optimum dosing regimen for Finafloxacin and to confirm the drug’s potential for use as a short course - high dose treatment of patients with cUTI and pyelonephritis.”

### **About Finafloxacin**

Finafloxacin is a next generation, highly differentiated, fast acting fluoroquinolone antibiotic with an excellent safety profile. The antibacterial activity of finafloxacin increases significantly under infection relevant conditions (i.e. at pH values below neutral). The compound exhibits a very broad spectrum of activity that covers Gram positive, Gram negative, anaerobic and atypical pathogens.

In August 2013 the FDA designated finafloxacin as a Qualified Infectious Disease Product (“QIDP”) and also granted Fast Track approval status for the drug’s use in treatment of cUTI (including pyelonephritis), complicated intra-abdominal infections and acute bacterial skin and skin structure infections.

Whilst MerLion retains the global rights to the use of iv. and oral formulations of finafloxacin for treating serious hospital infections, the compound has been partnered in North America with a major company for the treatment of otic (ear) infections, where development of a topical formulation has been successfully completed.

## **About UTI**

UTIs are the most common bacterial infections, accounting annually in USA for nearly seven million office visits and over one million emergency department visits resulting in more than 100,000 hospital admissions. Almost half of all women will experience a UTI at least once during their lifetime and a significant number of them will have recurrences. Specific subpopulations at increased risk of UTI include infants, pregnant women, the elderly, patients with spinal cord injuries, patients with urinary indwelling catheters, patients with diabetes or multiple sclerosis, patients with acquired immunodeficiency disease syndrome/human immunodeficiency virus, and patients with underlying urologic abnormalities. In the hospital and nursing home setting UTIs remains amongst the most common bacterial infections worldwide, with catheter-associated infections accounting for more than one million cases annually in USA.

*E.coli* is the most common pathogen isolated in complicated UTIs although infection with two or more organisms frequently occur, including more resistant strains of the *Proteus* and *Klebsiella* species, as well as enterococci and *Pseudomonas aeruginosa*.

## **About MerLion Pharmaceuticals**

MerLion Pharmaceuticals Pte Ltd is a privately held company headquartered in Singapore with clinical development operations based in Berlin, Germany. The company is focused on developing its antibacterial candidate, finafloxacin, through early and mid-stage clinical trials.

MerLion is supported by a group of leading global investors including Aravis Venture Partners, Bio\*One Capital (a subsidiary of EDBI), HeidelbergCapital and Nomura Research & Advisory.

For more information visit MerLion's website <http://www.merlionpharma.com>

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