MerLion Announces Successful Completion of a Phase I Clinical Study with Intravenously Administered Finafloxacin

Singapore, 7th November, 2012 – Following successful first-in-man Phase I and two Phase IIa clinical studies with the oral formulation of finafloxacin, MerLion Pharmaceuticals Pte Ltd (MerLion) announces the completion of the first Phase I study using an intravenous (iv) formulation of this highly differentiated antibacterial candidate.

The Phase I trial was a blinded, placebo-controlled, randomised, ascending single and multiple dose crossover study of finafloxacin administered to 58 healthy volunteers in the United Kingdom. The study results showed that single and multiple iv doses given once daily for 7 days with up to 1000 mg of finafloxacin were safe and well tolerated. There were no dose-related trends in clinical laboratory findings, vital signs, ECG, or treatment emergent adverse events for the different finafloxacin cohorts or compared to the placebo dose groups. This outstanding safety profile is in line with the results obtained previously with the oral formulation of finafloxacin in Phase I and Phase IIa (treatment of urinary tract infections and eradication of *Helicobacter pylori*) clinical trials. The study also showed a very favorable pharmacokinetic profile for the drug candidate.

Dr. Tony Buss, CEO of MerLion, commented "Results from the Phase I study with the intravenous formulation of finafloxacin underline the outstanding safety profile of this highly differentiated antibacterial candidate. Both safety and pharmacokinetic data suggest that finafloxacin will be able to be used in high-dose, short-course regimens. We are now commencing additional clinical studies to show the efficacy of finafloxacin in severe, hospital-treated bacterial infections."

About Finafloxacin

Finafloxacin is a novel, fluoroquinolone antibiotic with a unique pH activation profile. The antibacterial activity of finafloxacin increases significantly at pH values below neutral i.e. under infection relevant conditions. The compound exhibits an all inclusive spectrum of activity that covers Gram positive, Gram negative, anaerobic and atypical pathogens. Finafloxacin, which has already shown potential for the treatment of urinary tract infections and eradication of *Helicobacter pylori* in several Phase IIa studies, is being evaluated in critical care and hospital based infection settings.

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 lead antibacterial candidate, finafloxacin, through early stage clinical trials.

MerLion is supported by a group of leading global investors including Aravis, 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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