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MerLion completes phase I of finafloxacin study

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Singapore: Following successful first-in-man phase I and two phase IIa clinical studies with the oral formulation of finafloxacin, Singapore-based MerLion Pharmaceuticals has completed 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 seven days with up to 1,000 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, 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."