

## **(4th Nov 2009) MerLion Pharmaceuticals Pte Ltd receives IND Approval from the FDA for Finafloxacin; a Novel 'pH Activated' Antibiotic.**

MerLion Pharmaceuticals (MerLion) announced today that the U.S. Food and Drug Administration (FDA) has approved the Investigational New Drug (IND) application for the clinical testing of finafloxacin. MerLion will initiate the Phase I clinical trial in the US to evaluate the pharmacokinetic profile, safety and tolerability of finafloxacin in groups of healthy volunteers stratified by age and gender.

Finafloxacin is a novel fluoroquinolone antibiotic which exhibits significantly increased antibacterial activity at low pH (pH <7), whereas other marketed fluoroquinolones lose activity under such acidic conditions. Finafloxacin also displays better activity against adherent and slowly growing bacteria than a range of fluoroquinolones currently on the market. In addition, the compound has shown a remarkable safety, tolerability and efficacy profile in all clinical Phase I and Phase II studies completed so far. MerLion plans to extend its development programme for finafloxacin into critical care and hospital infection indications.

Dr Tony Buss, CEO of MerLion, commented “We are very pleased that the FDA has accepted our IND application and protocol for the planned US study with finafloxacin. We believe that the compound has significant potential for treating a wide range of serious bacterial infections. With this IND authorisation we are able to proceed with the age and gender study as part of the overall clinical development plan for finafloxacin.”

Dr Harald Labischinski, CSO of MerLion, added “The approval of our IND application by the FDA is a valuable step forward for our company. We are pleased that the clinical development of finafloxacin is progressing rapidly and are now planning to expand the scope of use, especially in critical care and hospital indications.”

[MerLion Pharmaceuticals Pte Ltd \(www.merlionpharma.com\)](http://www.merlionpharma.com)

MerLion Pharmaceuticals Pte Ltd is a privately-held company headquartered in Singapore, with clinical development operations based in Berlin, Germany. The company is organised into two key business units; MerLion Research and MerLion Development.

MerLion Development is progressing finafloxacin, a novel, highly differentiated antibacterial candidate, through early stage clinical trials. The compound, which has already shown potential for the eradication of *Helicobacter pylori* and treatment of urinary tract infections in several Phase IIa studies, is being evaluated in critical care and hospital based infection settings.

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