



MerLion Pharmaceuticals Announces Initiation of first Phase II Clinical Study with Finafloxacin in Patients with Complicated Urinary Tract Infections

Singapore, 11th December 2012 - MerLion Pharmaceuticals (MerLion) announced today that it has initiated the first Phase II clinical trial using intravenous (iv) and oral formulations of finafloxacin to treat patients requiring hospitalisation with complicated urinary tract infections and pyelonephritis. Finafloxacin is a novel antibiotic that demonstrates unique acid activated activity and an outstanding safety profile, which differentiates it from existing antibiotic therapies and opens up exciting new treatment opportunities.

The Phase II trial, based on newly updated guidance from the US Food and Drug Administration, will enroll up to 258 patients across multiple centres in Germany and Poland. The trial is a multi-dose, double-blind, double-dummy, active-control, randomised 3-arm clinical study of two dosing regimens of finafloxacin. It will evaluate the safety, tolerability, efficacy and pharmacokinetics of finafloxacin in initially hospitalised patients suffering from complicated urinary tract infections.

Dr. Tony Buss, CEO of MerLion, commented; "The Phase II clinical study is designed to test the efficacy of finafloxacin as a short iv course, high dose regimen with an oral step-down option for the treatment of cUTIs. We believe that finafloxacin could 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 equate to reduced risk of nosocomial infections and also reduced risk of generating drug-resistant strains through extended therapy."

Prof. Dr. Kurt Naber, past-President of the International Society of Chemotherapy for Infection and Cancer and past-Chairman of the European Section for Infection in Urology affiliated to the European Association of Urology, stated; "Finafloxacin displays remarkable and unique antibacterial properties. It displays rapid bactericidal activity against slowly growing and surface attached bacteria in biofilms and in contrast to classical fluoroquinolones, its antibacterial activity is enhanced in the acid urinary milieu as demonstrated by increased urinary bactericidal titers. These properties may well help to overcome the treatment failures and relapses which we often face in clinical practice."

Urinary tract infections (UTIs) are among the most prevalent infectious diseases in ambulatory and hospitalised populations and account for 40% of all nosocomial infections. Up to 40% of women will develop a UTI at least once in their lifetime and a significant number of them will have recurrences. In the USA the treatment of UTI accounts for around 15% of all community-prescribed antibiotics and every year UTIs result in more than 100,000 hospital admissions.

About Finafloxacin

Finafloxacin is a novel, fluoroquinolone antibiotic with a unique pH activation profile. The antibacterial activity of the compound is enhanced in the acidified environments found at most infection sites e.g. urine, abscesses, deep seated wounds, chronically infected tissues and stomach mucosa.

Finafloxacin has an outstanding safety profile and exhibits an all-inclusive spectrum of activity that covers Gram positive, Gram negative, anaerobic and atypical pathogens.

Finafloxacin has been studied in over 740 human subjects; in addition to successful Phase IIa studies (treatment of uncomplicated UTIs and eradication of *Helicobacter pylori*) and Phase I studies with oral and iv formulations of finafloxacin, two Phase III trials with a topical formulation of the compound are nearing completion.

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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