



**FDA Grants Qualified Infectious Disease Product Designation and Fast Track Status for MerLion Pharma's Lead Antibacterial Candidate Finafloxacin**

**Singapore, 22nd August 2013** - MerLion Pharmaceuticals (MerLion) announced today that the U.S. Food and Drug Administration (FDA) has designated **finafloxacin** for oral and intravenous (iv) use as a Qualified Infectious Disease Product (QIDP) and for Fast Track development for the treatment of complicated urinary tract infections (cUTI) including pyelonephritis, complicated intra-abdominal infections (cIAI) and acute bacterial skin and skin structure infections (ABSSSI).

A QIDP is defined as an antibacterial or antifungal drug for human use intended to treat serious or life threatening infections, including those caused by antibiotic or antifungal resistant pathogens, new or emerging pathogens, or “qualifying pathogens” with the potential to pose a serious threat to public health.

The QIDP designation for finafloxacin will enable MerLion to benefit from a number of incentives, including priority review with New Drug Application submissions to the FDA and eligibility for an additional five-year extension of market exclusivity under the Hatch-Waxman Act.

Finafloxacin is a highly differentiated antibacterial candidate that is being developed as a potential first-line treatment for serious bacterial infections primarily in hospital settings. Following successful Phase IIa studies, a Phase II trial is currently underway in Europe to evaluate the safety and efficacy of iv and oral formulations of finafloxacin for the treatment of patients suffering from cUTI, including pyelonephritis. In addition, the safety and efficacy of finafloxacin to treat ear infections has been evaluated in two Phase III studies with a topical formulation.

Dr. Tony Buss, CEO of MerLion, commented; “The QIDP designation is provided under the Generating Antibiotic Incentives Now (“GAIN”) Act, established last year in the US and intended to provide incentives to encourage the development of new treatments for serious or life-threatening infections. We are pleased that our lead antibacterial candidate, finafloxacin, has been granted QIDP and Fast Track status for three important therapeutic indications; cUTI/pyelonephritis, cIAI and ABSSSI. We believe that the candidate, with both iv and oral formulations available, has significant potential as a first-line therapy to treat a broad spectrum of serious drug-resistant Gram-positive and Gram-negative infections.”

## **More About Finafloxacin**

Finafloxacin has an outstanding safety profile and exhibits an all-inclusive spectrum of activity that covers Gram-positive, Gram-negative, anaerobic and atypical pathogens. The compound 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 acidified environments found at most infection sites e.g. urine, abscesses, deep seated wounds, chronically infected tissues and stomach mucosa.

To date, finafloxacin has been studied in 980 human subjects; in addition to successful Phase IIa studies (treatment of uncomplicated UTI 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 have been successfully completed.

A Phase II cUTI trial is currently underway in Europe and is expected to be completed in early 2014. The trial 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 cUTI.

## **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 and mid-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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