



## **MerLion Announces a Significant Milestone in the Development of Finafloxacin for Treatment of Acute Otitis Externa**

**Singapore, 26 May 2014** - MerLion Pharmaceuticals (MerLion) announced today that its North American partner has achieved a significant regulatory milestone in the development of finafloxacin for the treatment of acute otitis externa (bacterial infection of the outer ear).

Two phase three trials with a topical form of finafloxacin involving over 1,000 patients at 120 study sites in the United States and Canada have been completed successfully.

Mr. David Dally, CEO of MerLion, commented, “Today’s announcement represents the next important step in the development of finafloxacin and demonstrates its utility as a safe and fast acting broad spectrum anti-bacterial agent”.

He added, “We anticipate announcing further news in the near future on the clinical progress of the systemic formulations of finafloxacin (both intravenous and oral) in treating patients hospitalized with very serious, hard to treat, infections; also news of additional clinical developments using the topical formulation in treating other ear infections”.

### **About Finafloxacin**

Finafloxacin is a next generation, highly differentiated, fast acting fluoroquinolone antibiotic with an excellent safety profile. The antibacterial activity of finafloxacin increases significantly under infection relevant conditions (i.e. at pH values below neutral). The compound exhibits a very broad spectrum of activity that covers Gram positive, Gram negative, anaerobic and atypical pathogens.

In addition to otic indications, finafloxacin has already shown in phase IIa clinical studies its potential for treating a number of infections and is currently being evaluated in a phase II study of over 220 patients hospitalized with complicated urinary tract infections (“cUTI”) (including pyelonephritis).

In August 2013 the FDA designated finafloxacin as a Qualified Infectious Disease Product (“QIDP”) and also granted Fast Track approval status for the drug’s use in treatment of cUTI (including pyelonephritis), complicated intra-abdominal infections and acute bacterial skin and skin structure infections.

### **About Ear Infections**

Outer ear infections, referred to as otitis externa, are common bacterial infections. Although the presence of bacteria in the outer ear canal is normal and healthy, it can develop in to infection when the right conditions are present for it to thrive. Such conditions include when skin in the ear canal is damaged, often from objects like cotton swabs or when water gets trapped in the ear from activities such as swimming. The infection creates swelling, which is often painful.

## **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 antibacterial candidate, finafloxacin, through early and mid-stage clinical trials.

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