



## **MerLion announces FDA approval of finafloxacin otic suspension** ***First novel drug from a Singapore company to achieve FDA approval***

**Singapore, 11 February 2015** - MerLion Pharmaceuticals (MerLion), a biopharmaceutical company headquartered in Singapore with clinical development operations in Berlin, Germany, today announced that an otic suspension of finafloxacin has been approved by the FDA to treat acute otitis externa, commonly known as "swimmer's ear", caused by *Pseudomonas aeruginosa* and *Staphylococcus aureus*. Finafloxacin was licensed by MerLion to a major North American partner in 2010 for use in North America for otic (ear) infections.

MerLion retains the rights to intravenous and oral formulations of finafloxacin for all other indications and recently announced positive results from a phase 2 trial conducted in Europe treating around 200 patients hospitalized with complicated urinary tract infections. The results from this study demonstrated positive outcomes at all primary and all secondary endpoints; with patients treated once daily for five days with finafloxacin seeing higher, more rapid and sustained level of microbiological eradication and improved clinical outcomes compared to those treated with the current standard of care (ciprofloxacin taken twice daily for 10 days).

Mr. David Dally, CEO of MerLion, commented, "We are delighted to see that, following several years of the MerLion team working with our partner, the FDA has approved what we believe to be an excellent treatment for ear infections. This is especially pleasing since finafloxacin is the first novel drug from a Singapore company to achieve FDA approval."

Ms. Chu Swee Yeok, CEO and President of EDBI said, "We are heartened to have played a pivotal role in MerLion's journey since it was spun off from A\*STAR's Institute of Molecular and Cell Biology (IMCB) over a decade ago. The company's success with finafloxacin is a notable milestone in the development of Singapore's biomedical sciences industry."

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### **About MerLion Pharmaceuticals**

MerLion Pharmaceuticals Pte Ltd is a biopharmaceutical company focused on developing its antibacterial candidate, finafloxacin.

MerLion is a privately held company spun off by EDBI's Bio\*One Capital in 2002 from the former Centre for Natural Product Research (CNPR), originally a division of Singapore's A\*STAR (Agency for Science Technology and Research)'s Institute of Molecular and Cell Biology (IMCB). Along with EDBI, the company is supported by a group of leading global investors including Aravis Venture, Heidelberg Capital and Nomura Research & Advisory. For more information, please visit [www.merlionpharma.com](http://www.merlionpharma.com)

### **Notes for editors**

#### **About finafloxacin**

Finafloxacin is a fluoroquinolone antibiotic that demonstrates a substantially improved therapeutic profile over the existing gold standard and greater utility in treating many severe infections, including those caused by a number of resistant Gram-negative pathogens. This superior profile is a result of finafloxacin's unique chemical structure: in the hostile acidic conditions found at the sites of nearly all infections there is a substantially higher take-up and accumulation of finafloxacin in bacterial cells, as well as superior binding of the molecule to the two fluoroquinolone targets. Most other antibiotics,

including other fluoroquinolones, have decreased activity in these acidic conditions where their effectiveness is most needed. MerLion has developed IV and oral formulations of flaxloxacil with equivalent bioavailability, offering physicians the choice of initially treating infections in hospital or at out-patient infusion centres for one to three days with the IV regimen, then allowing patients to complete their treatment at home; reducing the risk of complications and/or secondary infections.

### **About Acute Otitis Externa**

Acute otitis externa is an infection in the outer ear and ear canal, usually caused by bacteria in the ear canal. Activities in which the ear is underwater can create a moist environment where bacteria may sometimes grow. The infection causes inflammation of the ear canal leading to pain, swelling, redness of the ear and discharge from the ear.