MerLion's finafloxacin shows positive phase 2 results in complicated urinary tract infections

Singapore, 8 January 2015 - MerLion Pharmaceuticals ("MerLion"), a biopharmaceutical company based in Singapore and Berlin, today announced positive results from a phase 2 trial with finafloxacin, conducted in Europe, treating patients hospitalized with complicated urinary tract infections (cUTI), including a high proportion with pyelonephritis.

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.

The results from this phase 2 study indicate that patients treated with a five day course of finafloxacin had a higher, more rapid and more sustained level of microbiological eradication and improved clinical outcomes than those treated with the current standard of care (ciprofloxacin taken twice daily for 10 days). The trial's primary and secondary endpoints were all successfully achieved. Finafloxacin was found to be both safe and tolerable, with only a small number of class-typical adverse events observed.

MerLion has developed IV and oral formulations of finafloxacin 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.

Mr. David Dally, CEO of MerLion, commented, "The data from this trial support the clear differentiation of finafloxacin from existing fluoroquinolones and from other antibiotics (including those in development): The safety and tolerability profile allows high once-daily dosing that, when added to the drug's excellent PK profile and bioavailability, results in finafloxacin's very rapid and sustained bactericidal effects, as well as having a low propensity for development of resistance. These results are in line with those found by our major industry partner, which has successfully developed a topical formulation of finafloxacin for treating ear infections."

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; "The rise of difficult to treat and resistant bacterial infections, particularly those caused by Gram-negative pathogens, represents a major and growing public health crisis. I believe that the need for more powerful and rapid treatments has the potential to be met by finafloxacin!"

Representatives from MerLion will be in San Francisco from January 11th to 15th, 2015 and would be interested in talking to anyone attending one of the conferences taking place there who would like to find out more about finafloxacin and this trial.

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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 supported by a group of leading global investors including Aravis Venture Partners, Bio*One Capital (a subsidiary of EDBI), Heidelberg Capital and Nomura Research & Advisory. MerLion Pharmaceuticals Pte Ltd is headquartered in Singapore with clinical development operations in Berlin, Germany. For more information please visit www.merlionpharma.com